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Standards and Guidelines

SCAI Publications Committee Manual of Standard Operating Procedures: 2022 Update

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Abbreviations: AGREE, Appraisal of Guidelines for Research and Evaluation; COI, conflicts of interest; CPG, clinical practice guideline; GRADE, Grading of Recommendations Assessment, Development, and Evaluation.

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A B S T R A C T

Evidence-based recommendations for clinical practice are intended to help health care providers and patients make decisions, minimize inappropriate practice variation, promote effective resource use, improve clinical outcomes, and direct future research. SCAI has been engaged in the creation and dissemination of clinical guidance documents since the 1990s. These documents are a cornerstone of the Society's education, advocacy, and quality improvement initiatives. The Publications Committee is charged with the oversight of SCAI's clinical documents program and has published the first iteration of this manual of standard operating procedures in 2019 to ensure consistency, methodological rigor, and transparency in the development and endorsement of the Society's documents. The manual has been updated based on feedback from the implementation of the original version to add specificity and expand the breadth of available document formats. The manual is intended for reference by the Publications Committee, document writing groups, external collaborators, SCAI representatives, peer reviewers, and anyone seeking information about the SCAI documents program.

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1. Publications Committee

Committee charge

Mission statement

To promote optimal patient care through educational, policy, and clinical/scientific documents that reflect the current state-of-the-science in interventional cardiology.

Charges

- Direct the initiation and development of SCAI statements and guidelines to provide evidence-based guidance for clinical practice
- Appoint diverse writing groups and representatives with expertise and recognition in the specialty according to Society policies governing relationships with industry
- Coordinate with the Scientific Outcomes Committee to strategically prioritize and promote Society guidelines, position statements, and scientific/policy statements
- Provide a timely review of topic proposals according to Society policies and methodology

Committee member roles and responsibilities

Voting members of the SCAI Publications Committee are expected to fulfill all of the following responsibilities for this role:

- **Engagement:** Member participation is measured by meeting attendance, completed peer reviews, participation in voting on matters before the committee, and participation in ad hoc committee projects and working groups. Members should aim to attend a majority of committee calls in each term year.
- **Confidentiality:** Unless otherwise stated, all materials and discussions are confidential and should not be shared outside the Publications Committee.
- **Stewardship:** Members should adhere to organizational and committee-specific policies/procedures and oversee the adherence of subordinate working groups, including writing groups.
- **Disclosure:** Members are required to complete an annual disclosure of their financial and professional relationships and recuse themselves from any discussions or decisions on issues related to their relevant disclosures.

The chair of the Publications Committee is expected to fulfill all of the above, with additional responsibility for leadership of the committee to include facilitation of group discussions, building consensus around committee decisions, and providing timely updates to Society leadership on committee activities.

Voting process and policies

The Publications Committee requires a majority of unconflicted voting members to constitute a quorum. The decisions are made by a majority vote of the quorum.

2. Terms and definitions

Glossary

- **Conflict of interest (COI):** Any financial or intellectual relationship with the potential to introduce actual or perceived bias to the process of creating a clinical guidance document.
- **Industry:** Any for-profit entities that develop, produce, market, or distribute drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions.
- **Relevant relationship:** A nonfinancial or financial relationship of any amount with an organization or individual that could be positively or negatively impacted by the recommendations of a clinical guidance document.
- **Recommendation:** The answer to a clinical question posed by an expert writing group, typically involving a comparison of 1 or more health care interventions. Recommendations are supported by scientific literature published in peer-reviewed journals and are formed through a rigorous process using established methods for evidence collection, synthesis, and extrapolation. Recommendations are intended to provide guidance to relevant stakeholders but may be sensitive to clinical judgment, patient values and preferences, local culture and health care infrastructure, cost, and other special considerations. Recommendations should be phrased according to a uniform, predetermined structure that expresses the direction (for or against the intervention), strength, and certainty/level of the evidence.
- **Sponsor:** The organization providing funding, resources, and oversight to support the development of a guidance document.
- **Systematic review:** A research process to answer a specific question comparing 2 or more health care interventions. Systematic reviews follow a predefined protocol to "identify, select, assess, and synthesize the findings of similar but separate studies."[1]
- **Writing group:** A multidisciplinary and diverse panel of experts approved by the Publications Committee to carry out the development of a clinical guidance document.

Types of SCAI guidance documents

The Society produces and endorses guidance documents as a service to the field of interventional cardiology. All SCAI-sponsored documents are developed under the oversight of the Publications Committee and must be approved for initiation by the committee. The document types defined below describe the various methods used to formulate Society guidance (Table 1):

- **Clinical practice guidelines:** According to the National Academy of Medicine (formerly the Institute of Medicine), clinical practice guidelines (CPGs) "are statements that include recommendations intended to optimize patient care. They are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."[2] SCAI-sponsored CPGs are developed according to standards set forth in the Institute of Medicine publication "Clinical Practice Guidelines We Can Trust."[2]
- **Expert consensus statement:** An expert consensus statement is developed by a multidisciplinary, independent writing group utilizing a systematic process for achieving consensus on evidence-based recommendations intended to provide guidance on a controversial clinical topic, particularly in the absence of published data.
- **Position statement:** An expert writing group is convened to formulate an official Society position or opinion. This type of document includes clinical competence and training standards, best practices, institutional and operator requirements, practice bulletins, and advisories.
- **Policy statement:** Provides information to members on legislative, regulatory, or economic issues; describes and directs related advocacy efforts.
- **Scientific statement:** Reviews the state-of-the-science for a specific disease condition or procedure, including summarizing the relevant literature and identifying future research priorities.
- **Rapid communication:** An alert to members on an urgent, time-sensitive, or quickly evolving clinical issue, such as a warning from a regulatory agency or other emergency situation.

3. Topic identification and prioritization

The policies and processes in this section are intended to ensure that resources (human, technological, institutional, and financial) are allocated to topical areas where recommendations can provide the greatest benefit to interventionalists and their patients. Topic prioritization involves both strategic planning for the future and responding to new circumstances as they develop.

Topic identification

The Publications Committee conducts an annual assessment to identify high priority topics for SCAI clinical guidance documents and considers ad hoc proposals from SCAI committees, councils, or individual members on a monthly basis. Any combination of the following activities may serve as the basis for a proposal to update an existing SCAI-sponsored guidance document or initiate a new document:

- **Review of new evidence:** Clinical guidance documents are an important tool for integrating new data about health care interventions into practice. If new, practice-changing evidence is available on a topic, recommendations may be warranted to inform clinical decision making.
- **Review of existing guidance (SCAI sponsored and other):** It may or may not be appropriate to initiate a new guidance document depending on whether existing guidance is available and current. Redundant documents often create more confusion than they resolve.
- **Review of practice trends:** Any area of clinical practice where there is significant uncertainty or variation may be a candidate for a clinical guidance document. Practice trends may be observed via survey, published research, or qualitative observations from members and their colleagues.

Proposal review

Any topic proposal, regardless of origin, must be submitted for consideration by the Publications Committee using the proposal template. This form captures requisite information in a standard format to ensure efficiency and objectivity in the prioritization process.

- **Proposal form:** See Supplement 1.
- **Proposal review:** The Publications Committee conducts an annual prioritization process to conduct forward planning of the Society documents portfolio. The annual process begins in March and culminates with the May meeting of the Board of Trustees. Proposals received outside the annual window for prioritization are discussed on a monthly basis during regularly scheduled meetings of the Publications Committee. Following the discussion, committee members independently complete a survey to rank the proposal according to the prioritization criteria described below. A proposal must receive support from a majority of the committee members to be prioritized. Proposals that do not meet the threshold for prioritization are deferred and may be resubmitted for consideration after a minimum period of 6 months.

Criteria for prioritization

The criteria by which topics are ranked for initiation are transparent and available to all internal and external stakeholders. Potential topics are assessed in each of the following domains:

- **Disease burden:** incidence/prevalence, impact on health care system, frequency of risk factors, avoidable morbidity/mortality, impact on individual patient quality of life
- **Variation in clinical practice:** uncertainty or controversy resulting in disparities in patient care
- **Practice evolution:** rapidly changing data or technology may impact the decision about if/when to initiate a document
- **Availability of evidence:** although it is important to estimate whether data are available to inform recommendations, it may also be desirable to undertake document development with the purpose of guiding research priorities and helping clinicians make the best use of limited evidence
- **Redundancy/overlap:** availability/currency of guidance from SCAI or another organization

Table 1. Comparison of types of SCAI guidance documents

Document type	Publications Committee oversight	Expert writing group	Systematic evidence review	Systematic consensus process	Endorsed by SCAI leadership
Clinical practice guidelines	X	X	X	X	X
Expert consensus statement	X	X		X	X
Position statement	X	X			X

- **Feasibility:** capacity of the Society to undertake development and dissemination of the recommendations
- **Rapid communications only:** urgency (major clinical or policy significance, high burden on patients or health systems); time sensitivity (response is only relevant/useful if provided within a certain time frame)

Stakeholder identification

Stakeholders are individuals or constituencies who are expected to be affected by the document recommendations. They are identified in conjunction with each topic so that they can be placed into appropriate roles to capture their perspective (writing group membership, official collaboration, public comment/peer review, etc.) and establish buy-in to facilitate adoption. Stakeholders may include the following:

- SCAI Clinical Interest Councils
- Clinicians (multidisciplinary)
- Professional societies
- Policymakers
- Payers
- Industry
- Patients/caregivers/consumers

4. Collaboration with other organizations

Based on the stakeholder analysis conducted during topic prioritization, SCAI may engage other organizations in document development through any of the following models of collaboration (Table 2). When participating in a collaboration that is sponsored by another organization, SCAI will adhere to the policies and processes of the project sponsor. Invitations to collaborate using a model not described herein will be assessed on a case-by-case basis. Any collaboration (SCAI-sponsored or sponsored by another organization) and terms thereof are approved through the Publications Committee before the project is initiated.

Partnership

All organizations are equal partners in the development and dissemination of the document, including all of the following criteria:

- Terms of partnership and development methodology agreed to by all partners
- All organizations listed as sponsors in the document title
- Representative(s) on the writing group
- Participation in peer review
- Organizational approval of the final document
- Joint ownership and copublication of the final document

Endorsement

One organization sponsors the development and dissemination with input from other organizations as follows:

- Representative(s) on the writing group
- Participation in peer review
- Organizational approval of the final document

Affirmation of value

An organization or individual presents a document in the final form for official Society recognition. Although the Society has not participated in the document's development, affirmation of value recognizes that the content is relevant and valuable for members and their patients. The affirmation of value is attained through organizational approval of the final document.

5. COI disclosure and management

The COI disclosure and management policy for clinical guidance documents is consistent with the SCAI code of ethics.[3] It has been developed in accordance with standards set forth by the National Academies of Medicine (formerly the Institute of Medicine)[2] and based on the Council for Medical Specialty Societies Code for Interactions with Companies and Guidelines International Network: Principles for Disclosure of Interests and Management of Conflicts in Guidelines.[4,5]

Collection of relationships

Nominees to SCAI writing groups must prospectively disclose all intellectual and financial relationships of any amount from the 12 months prior to their nomination. The scope of disclosure includes any relationship with industry, relationships with other entities (including government entities and not-for-profit organizations), and intellectual interests (including published opinions and institutional affiliations). Disclosure information is collected using the SCAI Clinical Document Disclosure Form (Supplement 2). Failure to complete the disclosure process in good faith may result in exclusion or removal from a writing group and disqualification from participation in future SCAI clinical guidance document development efforts.

Management of relationships

Disclosures are assessed on a case-by-case basis for relevance to the document subject matter and significance according to the SCAI Policy for Management of relationships with industry (Supplement 3) to determine the appropriate strategy for mitigating potential COIs. Disclosure information and management strategies are reviewed and approved through the Publications Committee.

The writing group reviews all disclosure information prior to each meeting. Writing group members are required to update their disclosures as needed throughout the development process and prior to the publication of the final document. All writing group disclosure information is published as a supplement to the guidance document. SCAI policies on the collection and management of disclosures are also publicly available.

Document funding sources

SCAI-sponsored clinical guidance documents are developed independently without funding from the industry. Any outside funding used in document development (for example, from a partnering society) will be disclosed in the document text.

Table 2. Models for collaboration

Model	Agreement on terms	Listed in title	Representative(s)	Peer review	Organizational approval	Copublication
Partnership	X	X	X	X	X	X
Endorsement			X	X	X	
Affirmation of value					X	

6. Writing group formation

Recruitment of writing group members

Writing group members may be recruited or nominated through the following channels:

- Collaborating organization
- Publications Committee
- Other SCAI committees or clinical interest councils
- Self-nomination
- Identified based on content or methods expertise, including authorship of other publications or guidelines related to the topic
- Identified based on stakeholder analysis

Writing group composition

The composition of each writing group will vary based on the topic. Writing groups are organized to ensure maximum diversity and expertise in each of the following domains:

- **Perspective:** research interests, content expertise, background, experience
- **Demographic characteristics:** gender, race, age, seniority, geographic region, institutional affiliation
- **Stakeholder representation:** patients, caregivers, frontline clinicians, researchers, content experts, methodology experts
- **Financial and nonfinancial relationships:** see SCAI disclosure and management policy
- **Publications Committee liaison:** the committee will appoint 1 liaison to serve in each writing group

Writing group size

Each writing group has 10 to 12 members, including a chair and vice-chair. If multiple collaborators nominate representatives to the writing group, this number may be increased to 15. The writing group membership is limited to ensure meaningful and effective participation by all members.

Writing group member responsibilities

Writing group members are expected to be active participants in the document development process, fulfilling the following responsibilities: attend conference calls and/or in-person meetings, appraise evidence, vote on decisions and recommendations, write portions of the document manuscript, and approve the final draft. In addition, writing group members are expected to comply with all SCAI policies related to document development, disclosure, and confidentiality. Any member of the writing group representing SCAI must be an SCAI member; writing group members representing collaborating organizations are not required to be SCAI members.

Writing group members who do not fulfill the responsibilities above are subject to removal from the writing group at the discretion of the document chair and Publications Committee chair.

Writing group chair and vice-chair

The writing group chair and vice-chair are leadership roles, distinct from general writing group membership.

- **Responsibilities:** In addition to the writing group member responsibilities described above, the chair and vice-chair have additional responsibility for leadership of the writing group to include facilitation of group decisions; building consensus; providing updates on the development effort to the Publications Committee and SCAI leadership; and assisting writing group members to comply with SCAI confidentiality, disclosure, and recusal policies. The vice-chair may assume the role of chair on a temporary or permanent basis if the chair is unable to fulfill the responsibilities of the role.
- **Selection criteria:** Nominees are subject to SCAI policies for the disclosure and management of COIs and must be SCAI members. The nominees should be experienced leaders and content experts.

SCAI representatives on external writing groups

Writing group members representing SCAI on documents that are sponsored by another organization are expected to comply with all responsibilities and policies described by the sponsor. In addition, SCAI representatives should include the perspective and positions of the Society in writing group discussions whenever possible and must be SCAI members. Representatives to external documents are responsible for updating the Publications Committee on the development process.

Appointment process

Writing groups and representatives to external documents are vetted and appointed through the Publications Committee and president. The full Executive Committee may provide input, as requested by the president. Each nominee must complete a disclosure and accept his/her role and responsibilities prior to appointment.

Authorship

Each writing group member who participates according to the description of his/her role and responsibilities will be listed as an author of the published document. Any contributor who does not meet the criteria for authorship will be acknowledged in the document text. The chair determines the order of authors.

7. Methodology for document development

The framework described below ensures that the processes for collecting, synthesizing, and reporting evidence remain consistent and transparent across various projects.

Confidentiality

All aspects of the document development process are confidential until the publication of the resulting manuscript. This includes the content of writing group discussions, materials circulated among writing group members, and content of the document. Writing group members should refrain from commenting regarding the development effort in public, including to members of the media and industry.

Scoping, evidence collection, and synthesis

SCAI has selected the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach for the assessment of the quality of the evidence to inform CPGs. The subsequent sections of this manual describe guideline development processes and policies that are consistent with the GRADE approach for guideline development.

- **Search protocol:** CPGs are informed by a systematic review that is planned and executed according to the National Academy of Medicine (formerly Institute of Medicine) Standards for Systematic Reviews.[1] The Society may contract an expert methodologist to perform this work. A report of the systematic review is published in conjunction with the resulting guideline.
- **Quality of evidence:** The GRADE approach to rating the quality of evidence begins with the study design and addresses 5 additional criteria: limitations in study design or execution (risk of bias),

inconsistency of results, indirectness of evidence, imprecision, and publication bias.
- **Evidence summary:** The best evidence available to answer each prioritized clinical question is summarized in a table to facilitate interpretation.
- **Low-quality evidence:** When evidence is rated as high-quality, the writing group can be confident that the data represent the true effect of a health care intervention. However, it is common for a search to turn up only low-quality evidence. In this case, the writing group aims to make the best possible recommendation with limited data by utilizing a rigorous approach to collecting and summarizing evidence. Compiling low-quality evidence for a clinical question is also useful to direct future research on the topic. Writing groups should avoid prioritizing questions based on the expected quality of evidence and instead focus on identifying areas where recommendations will be most impactful. If the writing group agrees there is a substantial risk that their decision may be wrong, they may decline to make a recommendation and instead report on the discussion.

Formulating recommendations

Depending on the type of document, the writing group follows one of the below processes for translating evidence into recommendations. All group decision-making processes are subject to SCAI policies for the disclosure and management of COIs.

- **GRADE evidence-to-decision framework:** A CPG writing group follows a structured and explicit process to make judgments about the evidence and formulate recommendations. The writing group considers all of the following domains: quality of the evidence, balance between desirable and undesirable effects of the intervention, the magnitude of benefits and harms, patient values and preferences, feasibility, acceptability, health equity, cost, and resource use. If the writing group does not reach a consensus during discussion, decisions are made by majority vote.
- **Expert consensus:** An expert consensus statement writing group utilizes a modified Delphi method for collecting and reconciling judgments about the evidence and the recommendations.
- **Position statement/rapid communication:** A position statement or rapid communication writing group formulates recommendations through group discussion and majority vote.
- Scientific and policy statements do not make recommendations for clinical practice or training.

Format of recommendations

Recommendations are presented in a standard format across all SCAI documents to facilitate implementation and minimize confusion. Recommendations are worded to be clear and contain enough information to be actionable. Each CPG recommendation includes the following:

- **PICO values:** population, intervention, comparator, outcome
- **Direction:** for or against the intervention
- **Strength:** strong or conditional (Table 3)
- **Degree of certainty:** corresponds to the quality of evidence

Remarks

Depending on the context, the writing group may include any of the following additional considerations in a remark that accompanies the recommendation:

- Justification or explanation for judgments
- Subgroup considerations
- Implementation considerations (including strategies to address any concerns about acceptability or feasibility)

Table 3. Format of recommendations

Strength	Wording	Rationale	Implications
Strong	"The writing group recommends…" or "Clinicians should…"	The writing group is confident that the desirable effects of an intervention outweigh its undesirable effects, or vice versa.	Most patients will be best served by the recommended course of action.
Conditional	"The writing group suggests…" or "Clinicians might…"	The desirable effects of an intervention probably outweigh its undesirable effects, or vice versa.	Not all patients will be best served by the recommended course of action. This decision is sensitive to individual circumstances, values, and preferences.

- Evidence gaps
- Future research priorities

Rapid communication methodology

Rapid communications follow a streamlined development process to preserve the integrity of the statement while expediting the development process commensurate with the urgency of the issue in question.

- Topic is prioritized through an expedited process by the Publications Committee chair and cochair and SCAI president based on the criteria for rapid communications described above.
- Potential writing group members submit disclosures; the writing group must have a 50% + 1 majority of voting members without relevant financial relationships.
- Writing group members are identified and appointed through an expedited process by the Publications Committee chair and cochair and SCAI president with the consultation of additional subject matter experts as needed.
- The statement undergoes an accelerated review process by members of the Publications Committee who are available to provide comments within 1 week.
- Publications and Executive Committees provide accelerated approval and endorsement of the final manuscript.

Writing the manuscript

The document manuscript is a report by the writing group describing the process, evidence, and judgments that resulted in the recommendations. All SCAI-sponsored documents are structured according to a standard format:

- **Masthead:** title (sponsoring organization[s], a type of document, topic), author names and affiliations, description of endorsements, disclosure of funding sources
- **Abstract:** a brief summary of the document highlights
- **Introduction:** background on the topic, justification for prioritization, description of the clinical questions
- **Methods:** description of the process used to create the document (writing group formation, disclosure and management of COIs, collection and synthesis of evidence, formulation of recommendations, group decision making); detailed enough to be replicable
- **Analysis:** question-by-question description of the writing group deliberations and judgments (evidence appraisal, translation of evidence into recommendations)
- **Conclusion:** answers the clinical questions posed in the introduction with a summary of the recommendations; describes any unanswered questions that warrant further research

- Unless otherwise decided during the writing group formation, the chair and vice-chair have primary responsibility for writing the manuscript.

Figures, tables, and algorithms

The following tables are included with each document manuscript:

- Summary of recommendations
- Summary of evidence (may be an online supplement)
- Summary of writing group disclosure information (may be an online supplement)
- The writing group may also include figures or algorithms to illustrate the recommendations in accordance with the publication requirements.

Publication requirements

SCAI-sponsored guidance documents are intellectual property of the Society and submitted for publication in *JSCAI*, the Society's official journal; additional venues for distribution, if applicable, are vetted and approved through the Publications Committee based on the models for collaboration defined above.

8. Peer review and public comments

Review of the document draft is critical to capture any stakeholder perspectives that are not represented on the writing group. Based on the stakeholder analysis conducted during topic prioritization, the review process should target all members of the intended audience and any constituency that will be affected by the recommendations. The draft text is reviewed according to each of the following criteria: accuracy, practicality, clarity, organization, and usefulness.

Strategies for collection of feedback

- **Writing group review:** All members of the writing group must approve the document draft that will be circulated for external review.
- **Public comment:** Documents that are expected to have broad, practice-changing effects may have a public comment period in addition to or instead of a closed peer review. This process enables the Society to anticipate controversy and respond with an appropriate implementation strategy. It also enhances the transparency of the document development process and serves as the first step in disseminating the recommendations. This process is conducted by posting a draft of the document in the public domain for a minimum of 30 days along with a survey form to collect any resulting feedback.
- **Peer review:** This is a closed process by which specific members of the target audience are selected by the Publications Committee to review the draft document. Peer review includes at least 1 member of the Publications Committee and 2 reviewers who are not committee members. Collaborative documents will also be reviewed by 2 reviewers who are nominated by each cosponsoring or endorsing organization. Reviewers are not required to be SCAI members.

Response to feedback

The writing group chair and vice-chair are encouraged to acknowledge all comments and provide a rationale for why the document was revised or not in response to specific feedback. If substantive revisions are made, the entire writing group will be asked to approve the new text. The response to reviewer comments will be included with materials provided to the Publications Committee for endorsement consideration.

9. Endorsement

Endorsement is required for any guidance document to carry the imprimatur of SCAI. This includes both SCAI-sponsored documents and documents that are sponsored by other organizations. Endorsement is a 2-step process:

Publications committee approval

During the peer review phase of any document that is expected to be endorsed by SCAI, representative(s) from the writing group or SCAI peer reviewer(s) will present a summary of the document to the Publications Committee, including a description of any concerns that arose during the development or review effort. The representative(s) or reviewer(s) will communicate any questions or feedback from the Publications Committee to the writing group.

After a final document has been approved by the writing group, it is submitted to the Publications Committee for approval consideration. Approval votes are conducted according to the process described in the Society's bylaws.[6] A document may not be approved if the development process does not conform to the policies described in this manual. The committee will provide a rationale for any nonapproval decision and, if possible, recommend a remedy to the writing group.

Executive committee approval

Documents that are approved by the Publications Committee advance to the Executive Committee for the final approval step. When a majority of Executive Committee members vote in favor of endorsement, a document becomes official SCAI guidance and may include the Society's imprimatur in the title or in a statement within the document masthead.

Endorsement by collaborating organizations

After an SCAI-sponsored document has successfully completed the SCAI endorsement process, it may be submitted to collaborating organizations or other stakeholders for external endorsement. This process operates according to the policies of the endorsing organization.

Criteria for endorsement

Endorsement is distinct from the review phase of document development. At this point, the document is considered final and no additional feedback is expected. If the writing group has adhered to SCAI policies and responded to comprehensive feedback collected during review, the resulting document is considered to have met the criteria for endorsement.

10. Evaluation and maintenance

Evaluating documents

Documents are appraised in the following 2 domains:

- **Methodology:** This assessment is intended to evaluate the development process. The Appraisal of Guidelines for Research and Evaluation (AGREE) II Instrument provides a structured framework for evaluating the scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence.[7] This manual aims to ensure that SCAI-sponsored documents are rated as high quality according to the AGREE criteria. The Publications Committee may use the AGREE II Instrument to assess the methodological rigor of any document presented to the committee for evaluation, re-evaluation, or approval.
- **Effectiveness:** This assessment is intended to evaluate the impact of a document on clinical practice and, ultimately, on patient-important

outcomes. Documents are developed with evaluation in mind, including a description of measurable outcomes that should change with the implementation of the recommendations. The Publications Committee, Quality Improvement Committee, or other SCAI committee, clinical interest council, or individual may undertake research to evaluate practice patterns associated with document recommendations.

Evaluating process and policies

This manual and any other processes and policies related to document development and the Publications Committee are evaluated on a continuous basis. Feedback is collected from committee members, writing group members, collaborating organizations, and other document stakeholders, including end users. Changes to SCAI bylaws are approved through the board of trustees. Changes to this manual are initiated through the Publications Committee. Updates may be recommended wherever necessary to improve the methodological rigor or operational efficiency of the SCAI clinical documents program. Any updates to the manual are documented and dated as approved by the committee.

Evaluating currency

SCAI-sponsored documents are published with a dated record of when the evidence review was conducted and when the final recommendations were endorsed. Documents are considered current for up to 5 years after publication, depending on new developments in the field. At the end of 5 years, if not before, the Publications Committee commissions a literature search to evaluate the currency of the recommendations. The search may be performed by a subset of the committee, or by members of the original writing group.

Criteria for initiating an update

A document update may be initiated any time between 2 and 5 years after publication. An immediate update is triggered if any of the recommendations are discovered to be harmful for patients. Other considerations are the emergence of new evidence or new technologies and changes in practice patterns or parameters. Updates are prioritized according to the criteria described in the Topic identification and prioritization section.

If an update is warranted but not initiated after 5 years, the document is considered retired, and wherever possible, references to the document are updated to reflect that the recommendations are no longer current. In the absence of a review for currency, a document is considered retired.

If an update is not warranted based on a literature search, references to the document are modified to reflect the date of the latest assessment and the conclusion that the recommendations still represent the best guidance available on the topic.

Declaration of Competing Interest

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Supplementary material

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Peer review statement

Given her role as Editor in Chief, Alexandra Lansky had no involvement in the peer review of this article and has no access to information regarding its peer review.

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