# ARTICLE IN PRESS

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## Practice guidelines

# Scientific document development standards for the society of cardiovascular computed tomography (SCCT): A statement from the SCCT Guidelines Committee

Lauren A. Baldassarre <sup>a,\*</sup>, Lynne Koweek <sup>b</sup>, Daniele Andreini <sup>c</sup>, Kelley Branch <sup>d</sup>, Dawn Brennaman <sup>e</sup>, Ricardo P.J. Budde <sup>f</sup>, Stacy De La O <sup>g</sup>, Timothy Fairbairn <sup>h</sup>, Sandeep S. Hedgire <sup>i</sup>, Jonathan R. Weir-McCall <sup>j,k</sup>, Pam K. Woodard <sup>l</sup>, Dennis Wong <sup>m</sup>, Marcus Y. Chen <sup>n</sup>, Working Group on behalf of the SCCT Guidelines Committee

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#### ABSTRACT

The Society of Cardiovascular Computed Tomography (SCCT) is an international community of physicians, scientists and technologists advocating for research, education, and clinical excellence in the use of cardiovascular computed tomography (CCT). SCCT members are committed to improving health outcomes through effective use of CCT. The SCCT routinely authors, endorses, and jointly collaborates on scientific documents that reflect the best available evidence and expert consensus supported in practice of CCT. This paper outlines SCCT's methodology for developing scientific documents. It was formulated by members of the SCCT Guidelines Committee and approved by the SCCT Board of Directors.

### 1. Introduction and overview

The Society of Cardiovascular Computed Tomography (SCCT) is an international community of physicians, scientists and technologists advocating for research, education, and clinical excellence in the use of cardiovascular computed tomography (CCT). SCCT members are committed to improving health outcomes through effective use of CCT.

The SCCT routinely authors, endorses, and jointly collaborates on scientific documents that reflect the best available evidence and expert consensus supported in practice of CCT including:

- Evidence-based guidelines
- · Appropriate use criteria
- Expert consensus documents
- White papers
- Position statements
- SCCT endorsed scientific documents

This paper outlines SCCT's methodology for developing scientific documents. It was formulated by members of the SCCT Guidelines Committee and approved by the SCCT Board of Directors. The document

E-mail address: lauren.baldassarre@yale.edu (L.A. Baldassarre).

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a Section of Cardiovascular Medicine and Department of Radiology and Biomedical Imaging, Yale School of Medicine, 789 Howard Ave, New Haven, CT, 06519, USA

<sup>&</sup>lt;sup>b</sup> Department of Radiology, Duke University Medical Center, Durham, NC, USA

<sup>&</sup>lt;sup>c</sup> Division of Cardiology and Cardiac Imaging, IRCCS Ospedale Galeazzi Sant'Ambrogio, University of Milan, Italy

<sup>&</sup>lt;sup>d</sup> University of Washington Heart Institute, Seattle, WA, USA

e Heart Failure Society of America, USA

<sup>&</sup>lt;sup>f</sup> Department of Radiology and Nuclear Medicine, Erasmus Medical Center, Rotterdam, the Netherlands

g Sage & Rosemary Consulting, Burlington, WA, USA

<sup>&</sup>lt;sup>h</sup> Liverpool Heart and Chest Hospital, USA

<sup>&</sup>lt;sup>1</sup> Massachusetts General Hospital- Harvard Medical School, USA

<sup>&</sup>lt;sup>j</sup> School of Clinical Medicine, University of Cambridge, Cambridge, UK

k Department of Radiology, Royal Papworth Hospital, Cambridge, UK

<sup>&</sup>lt;sup>1</sup> Mallinckrodt Institute of Radiology, Washington University School of Medicine in St. Louis, USA

m Monash University, USA

<sup>&</sup>lt;sup>n</sup> National Institutes of Health, USA

<sup>\*</sup> Corresponding author.

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is intended primarily for the Guidelines Committee, writing groups, collaborating organizations, and staff involved in the development of scientific documents.

SCCT develops scientific documents using methodology informed by best practices, such as standards developed by the National Academy of Medicine (formerly the Institute of Medicine [IOM]). It posts published scientific documents, which are open access on the SCCT website. <sup>2</sup>

The purpose of these scientific documents is to provide information to health care professionals and patients that may assist in clinical decisionmaking and research endeavors. As new evidence emerges quite rapidly, published scientific documents may not always include the most recent evidence available, although they will be updated at certain intervals as deemed appropriate. And, importantly, there is great variation amongst individual patients, which cannot be fully accounted for within these documents but must be taken into account when interpreting these documents and any recommendations within them. Furthermore, these documents cannot be fully inclusive of all available methods of care for all varieties of patients nor are they exclusive of other treatments. And, therefore, published scientific documents from SCCT are to act as a guide to good practice, and ultimately the responsibility of determining the best course of care for a patient is with the treating health care provider, who applies their own knowledge and experience as well as the specifics of the patient to their treatment decisions. Regarding these scientific documents, the SCCT makes no warranty and assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of these documents.

#### 2. Types of scientific documents

- Clinical practice guidelines: Evidence-based, incorporating a critical review of the literature including evidence statements and class of recommendations. Guidelines are reserved for areas in which there is a sufficient level of clinical evidence that can be graded and used to generate clear recommendations.<sup>3-5</sup>
- Expert consensus documents: Evidence-based, incorporating a critical review of the literature and is used in conjunction with expert opinion. Documents in this category often do not have extensive literature to permit development of clinical practice guidelines. Grading of evidence for recommendation statements is expected.
- Appropriate use criteria: Specification of when it is appropriate to
  perform a medical procedure or service. An "appropriate" procedure
  is one for which the expected health benefits exceed the expected
  health risks by a wide margin. Appropriate use criteria documents
  facilitate physician decision-making by combining the best available
  scientific evidence with the collective judgment of physicians, to
  determine the appropriateness of performing a specific test or other
  procedure.<sup>6,7</sup>
- White papers: Authoritative reports intended to inform audiences regarding a complex issue and presents SCCT's philosophy on the topic to advance understanding of an issue, promote further discussion, address a problem, or make conclusions based on the best available evidence. SCCT white papers may focus on clinical issues, policy matters, or both. Although SCCT white papers can originate from (and be prepared by) committees other than the Guidelines Committee, the Guidelines Committee is responsible for ensuring that white papers follow the same preparation and approval procedures as for SCCT clinical documents.
- Position statements: Address an important clinical, technical, safety,
  or policy issue. The goal is often to provide appropriate background
  information as well as rationale behind the position adopted. The
  document can convey recommendations by SCCT based on limited
  evidence on an important evolving topic. The position statement may
  result from a specific task force designed to review that issue.
- SCCT endorsed documents: SCCT endorsements of another society's scientific documents require approval by the Executive Committee.
   This commonly involves an SCCT representative serving on the

scientific document's writing group and involvement in nominating peer reviewers for the manuscript. These documents, therefore, are considered "co-authored" documents, with the option of either having the SCCT named in the subtitle or listed after the subtitle as "endorsed by the SCCT." The Executive Committee has the opportunity to evaluate the peer reviews, writing group's responses and final manuscript prior to making a final endorsement decision.

#### 3. Development stages for SCCT scientific documents

The process of proposal submission, evaluation, manuscript development, adoption and ultimate publication in the *Journal of Cardiovas-cular Computed Tomography* (JCCT) is summarized in Fig. 1.

# 4. Submit and select topic

There are several ways in which a scientific document topic can be initiated, including through SCCT leadership (Executive Committee or Board of Directors), the Guidelines Committee, SCCT members, and allied external organizations. Topic ideas may be submitted at any time via the SCCT website. The Guidelines Committee reviews submissions and recommends projects to the Executive Committee.

In their consideration, the Guidelines Committee will consider whether the topic:

- Reduces/mitigates patient risk, and/or improves patient safety and quality outcomes
- Addresses standards of care for CCT practice and aims to decrease ambiguity/increase clarity about diagnostic algorithms or testing methodology
- Includes evidence that emerging technologies and/or diagnostic testing will impact the practice of CCT at large and the patients served
- Improves/clarifies public perception of CCT's role in medicine
- Has the potential for collaboration with allied organization(s) to facilitate dissemination and adoption and improve outcomes

### 5. Develop proposal

The scope of the topic is defined by the Guidelines Committee and may be refined in collaboration with the individual(s) submitting the topic.

# 6. Proposal essentials

- Topic statement
- Statement of purpose
- Outline
- Document type
  - o Clinical guideline\*
  - o Appropriate use criteria\*
  - o Expert consensus document
  - o White paper
  - o Position statement
- Proposed collaborations with external organizations (optional)
  - o Co-authoring
  - o Endorsing
  - o Co-publishing
- Estimated timeline
- Proposed writing group chair/co-chair and members

\* On clinical guidelines and appropriate use criteria, SCCT typically participates under the lead of larger external organizations and follows their research and review of evidence methodology.<sup>3</sup>

As part of the proposal development process, the Guidelines Committee identifies stakeholders and determines the types of expertise and diversity balance needed for the proposed writing group (including

# **Development Stages for SCCT Scientific Documents**

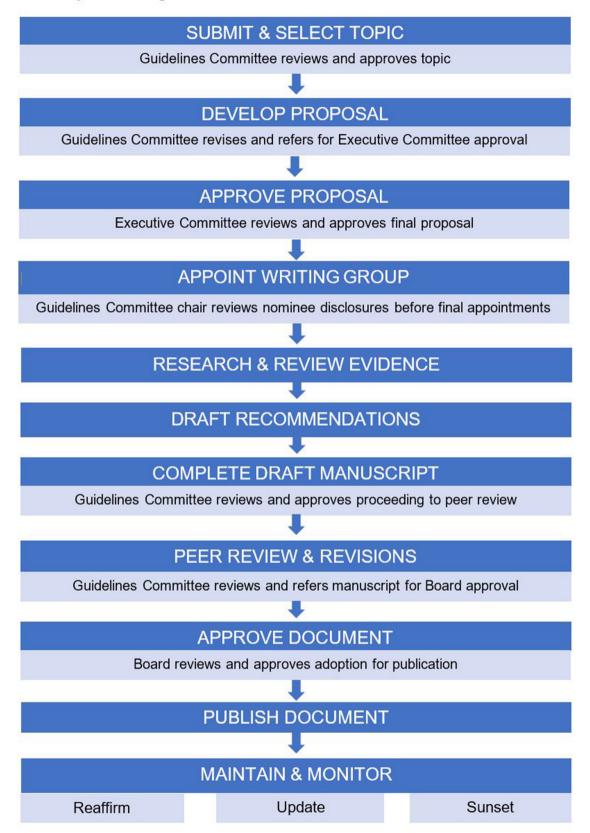


Fig. 1. Overview of development stages for SCCT scientific documents.

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factors such as specialty, gender, career level, practice setting and geographical location). When reviewing the proposed writing group, including the chair, and often a co-chair, the Guidelines Committee will provide oversight to ensure diversity and balance in the group, which typically is 10–12 members based on the complexity of the topic. The Committee also proposes possible collaborations with external organizations.

#### 7. Approve proposal

Once the Guidelines Committee approves the proposal, the Guidelines Committee refers the proposal to the Executive Committee for consideration and final approval. The Executive Committee will consider the scope and value of the proposal in the context of SCCT's mission and strategic goals in making its determination.

# 8. Establish writing group

Once a scientific document proposal is approved by the Executive Committee, the Guidelines Committee invites the writing group chair nominee(s) to lead the project. The writing group chair and member appointments are contingent upon disclosure and review of relationships with industry for relevant conflicts of interest. Writing group members may not be employed by industry.

If external organizations are approved as potential co-authors, the organizations will be asked to nominate representatives to serve on the writing group. The Guidelines Committee will make final decisions on writing group appointments representing co-authoring external organizations based on overall diversity balance.

#### 8.1. Review of conflict of interest

Before the commencement of a manuscript, writing group members are required to declare in writing any relationships with industry relevant to the topic. SCCT policy requires disclosure 12 months prior through the time of publication, of material financial interest in, or potential for benefit of significant value from, the scientific document's development or its recommendations. Any relationships that could be interpreted as constituting an actual, potential, or apparent conflict are required disclosures. When in doubt, writing group members should disclose activities; the Guidelines Committee chair in consultation with the SCCT Continuing Medical Education Committee chair determine if relationships are deemed a conflict.

SCCT's policy requires that a majority of writing group members are free of relevant conflicts of interest. If members are identified as having a relevant conflict of interest, it could be decided to put conflict of interest precautions or strategies in place. As a result, a person with a significant conflict of interest may be excluded from authorship or may be required to abstain from participation in the writing, vote, or discussion of those topic areas that present a conflict.

If a scientific document is published, writing group members' names and disclosures are published with the scientific document.

## 8.2. Collaboration with other societies

There are three ways in which SCCT collaborates with external organizations on scientific documents:

o **Co-authoring:** External organization is invited to nominate 1–2 representatives to participate on the writing group. The representative(s) must be approved by the Guidelines Committee. While the work of the writing group is confidential, organization representatives on writing groups are expected to keep their organization's leadership apprised of the progress and to share any feedback or concerns with the writing group to address during the development process. Co-authoring organizations are also invited to recommend

peer reviewers. Co-authoring organizations may be invited to copublish the scientific document.

- o Endorsing: External organization is invited to formally endorse the final scientific document after Board of Directors approval. Endorsers may not provide edits. Endorsing organizations names are listed in a subtitle of the published scientific document and may be invited to copublish the scientific document.
- o Co-publishing: External journal is invited to co-publish the final scientific document simultaneously with JCCT without peer review or revision and with attribution to SCCT in the title of the article. SCCT copyright must be acknowledged. Co-authorship or endorsement is preferred for co-publication.

#### 9. Research and review evidence

For scientific documents that SCCT leads on authoring — primarily expert consensus documents, white papers and position statements — SCCT establishes a writing group, which is charged with developing a manuscript and revising it as appropriate following a peer review process. For development of clinical guidelines and appropriate use criteria, SCCT typically collaborates under the lead of larger external organizations and follows their research and review of evidence methodology.

For SCCT led documents, best practices for evidence review of the literature should be followed and the methodology should be described in the document. PubMed search terms for the supporting evidence should be included, and a description of more detailed search methods may be included as an online supplement as well. Expert consensus documents, white papers and position statements that include clinical recommendations should include the level of evidence used to support the recommendation (Fig. 2); those without recommendation statements should provide a table describing the level of evidence of the studies supporting that document.

#### 10. Draft recommendations

The writing group considers patient-centered factors such as.

- 1. Patient Safety and Quality Outcomes
  - Will a significant gap remain in knowledge if the problem is not addressed?
  - Is a recommendation needed to address it?
  - Are the benefits of addressing the need larger than any potential undesirable effects?
- 2. Values of stakeholders:
  - Is there knowledge of how clinicians and patients value the need for the problem to be addressed?
  - Is this value uniform amongst all stakeholders?
  - Will this lead to variability in different decisions from key stakeholders?
- 3. Resources:
  - Will this recommendation affect resource requirements and on what size scale?
  - What will be the downstream effects of increase in resource need?
- 4. Health Equity
  - Will the recommendation widen or lead to disparities amongst certain groups or within certain settings?
  - Will the recommendation have variable importance and effectiveness amongst certain disadvantaged groups or settings?
  - When implementing the recommendation, what should be considered in order to decrease inequities?
- 5. Feasibility
  - Is the recommendation feasible to implement?
  - Is the recommendation sustainable?
  - What barriers exist to limit implementation and how will these be considered in the recommendation?
- 6. Acceptability



Fig. 2. Categories of Levels of Evidence. 3-7

- Will all stakeholders accept the recommendation?
- If the recommendation will not be widely accepted, what are the reasons for this and how will this be considered in the recommendation?

# 11. Complete draft manuscript

Once the writing group has completed the manuscript, the Guidelines Committee determines if the manuscript is ready to proceed to peer review. The writing group chair addresses any concerns of the Guidelines Committee and then submits the manuscript to the JCCT system for peer review. The draft manuscript adheres to JCCT's Guide for Authors: https://www.elsevier.com/journals/journal-of-cardiovascular-computed-tomography/1934-5925/guide-for-authors.

#### 12. Peer review and revisions

The manuscript peer review process is facilitated through JCCT. The Guidelines Committee recommends a slate of potential peer reviewers based on subject matter expertise and diversity factors. Peer review candidates are then vetted through the COI process and shared with the JCCT editorial team. Three to five peer reviewers are charged with assessing the quality of the scientific document, its scientific validity, its support for the SCCT mission to advance patient care, and the overall excellence of the scientific document (Fig. 3).

Peer reviewers are anonymized during the review and revision process. All comments from peer reviewers are seriously considered and incorporated. If a scientific document is published, peer reviewer names and disclosures are published with the scientific document.

# 13. Approve document

Following completion of the peer review and revision process, the Guidelines Committee considers a referral to the Board of Directors to adopt the scientific document. If partner organizations are co-authoring the guideline, their respective boards are also asked to consider adoption approval.

The Board of Directors (and any co-authoring organization boards) considers the peer reviewer recommendations, the writing group's responses to the reviews, the revised manuscript, and any additional feedback from the Guidelines Committee, in making its decision. By this time, there should be no substantive issues that arise. If any substantive

# Peer Review Considerations

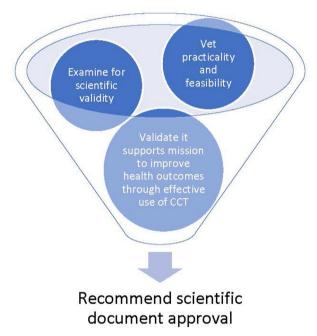


Fig. 3. Peer reviewers provide feedback and recommend a decision.

issues arise, the issues and the document will go back to the full writing group for vote and then back to the collaborating organizations.

After a scientific document has been approved to be adopted, it may then be sent to any other collaborating organizations for an up/down endorsement decision prior to publication.

#### 14. Publish document

The Board of Directors is the final authority on whether or not to publish a manuscript. All scientific documents that are approved by the Board of Directors are published in the JCCT, whether developed solely or in partnership. Prior to publication, any organizations approved by the Board of Directors to be invited to endorse the final scientific document

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are contacted. Scientific documents are published with the disclosures of the writing group members and the peer reviewers.

All scientific documents are published with a disclaimer to outline the intended use of the document and are freely available via JCCT and on the SCCT website<sup>2</sup> at https://scct.org/page/Guidelines.

#### 15. Maintain and monitor

The Guidelines Committee reviews scientific documents for currency and validity on a regular basis. Scientific documents are reviewed between 2 and 5 years after publication, or sooner if deemed necessary, at which point they are affirmed as current or recommended for updating or archiving, for the SCCT Board's consideration. These assessments are intended to evaluate the impact of a document on clinical practice and, ultimately, on patient-important outcomes. The Guidelines Committee will base these decisions on the opinions of the Committee members as well as the presence of new evidence that would affect the recommendation. As new data and evidence may emerge rapidly in some areas, the Guidelines Committee will determine if a more frequent review is needed for any of these documents.

#### **Declaration of competing interest**

There are no conflicts of interest for this document.

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