HRS Clinical Document
Development Methodology Manual and Policies

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Table of Contents

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Abstract

The Heart Rhythm Society (HRS) has been developing clinical practice documents in collaboration and partnership with other professional medical societies since 1996. The HRS formed a Scientific and Clinical Documents Committee (SCDC) with the sole purpose of managing the development of these documents from conception through publication. The SCDC oversees the process for developing clinical practice documents, with input from the HRS Executive Committee and the Board of Trustees. As of September 2017, the HRS has produced more than 100 publications with other professional organizations. This process manual is produced to publicly and transparently declare the standards by which the HRS develops clinical practice documents, which include clinical practice guidelines, expert consensus statements, scientific statements, clinical competency statements, task force policy statements, and proceedings statements. The foundation for this process is informed by the National Academy of Medicine's (formerly Institute of Medicine's) standards for developing trustworthy clinical practice guidelines; the new criteria from the National Guidelines Clearinghouse, effective June 2014; SCDC member discussions; and a review of guideline policies and methodologies used by other professional organizations.

1.1 Introduction

The Heart Rhythm Society (HRS) is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients and the primary information resource on heart rhythm disorders. The HRS mission is to improve the care of patients by advancing research, education, and optimal health care policies and standards. In support of this mission, the HRS has developed and published numerous scientific and clinical documents. The purpose of HRS clinical documents is to provide recommendations to our membership, as well as other entities (e.g., the U.S. Food and Drug Administration [FDA], industry, health care providers), on timely issues in need of new or updated guidance. This document outlines the current policies for the development of clinical practice guidelines and expert consensus statements, as evaluated by the Scientific and Clinical Documents Committee (SCDC).

1.2 Purpose and Scope of the Manual

The purpose of this manual is to describe the processes for guideline and consensus statement development (clinical practice documents) and to produce recommendations that will influence care. **It is intended to be a practical resource for the following individuals**:

- Writing group Chairs and authors
- Staff directly and indirectly involved in the document development process
- Licensed health care providers and other stakeholders interested in the HRS clinical documents methodology

Subsequent sections of the manual describe each step in more detail.

1.3 Overview of the Clinical Document Development Process

Figure 1 illustrates the entire document development process. After a topic is identified and approved, partner/collaborating organizations are invited to join the HRS in the document development process. This includes the formation of the writing committee and definition of the scope, outline, timeline, and responsibilities. A timeline is established in collaboration with an HRS staff liaison and an SCDC committee liaison and is discussed as part of an orientation meeting or conference call with the writing group Chair/Cochair and/or Vice-Chairs.

Next, the Chair/Vice-Chair(s) refine the scope, formulate an outline (see Chapter 3), and set the minimum level of consensus. The writing group Chair will assign members to work on each section and direct the scheduling of conference calls during the first month of document development. Writing group members perform evidence reviews (see Chapter 4) and draft recommendations. Preliminary surveys for consensus performed immediately after the evidence review can help determine areas of consensus and identify areas requiring further discussion (see Chapters 5 and 6). A face-to-face meeting may be held by the writing committee to discuss remaining areas of controversy after initial votes for consensus on recommendations. Once a slate of recommendations has been agreed upon by the writing committee, feedback will be obtained in an open (public) comment from the HRS membership and/or external stakeholders. A final draft of the completed document, including recommendations, text, tables, and figures, is then submitted to the SCDC for internal peer review.

1 month
- Topic identification
- Establishment of writing committee Chair, Cochairs, and members

1 month
- Scope refinement
- Minimum consensus
- Document outline
- Committee member assignments
- Refinement of timeline for first draft
- Conference call scheduling

6 months
- Evidence review
- Recommendation development and consensus
- Text development
- Tables and figures
- Public comment on recommendations

1–2 months
- Writing committee review
- SCDC review
- Document revision

2–3 months
- External review
- Document revision
- Writing committee final review and sign-off

2–3 months
- HRS endorsement
- External endorsement

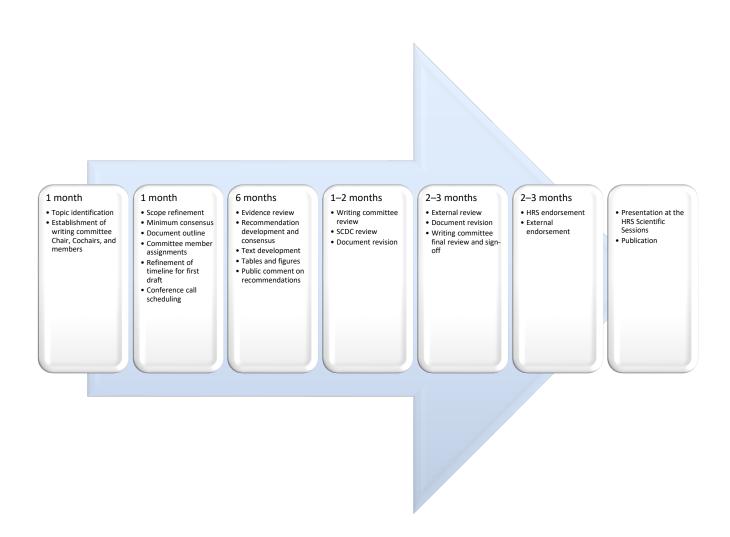- Presentation at the HRS Scientific Sessions
- Publication

Figure 1   Clinical Document Development Process.

1.4 Peer Review and Endorsement

The peer review and endorsement procedure are discussed in detail in Chapter 7. The initial draft is internally reviewed by the SCDC and the HRS member peer reviewers, who help determine its readiness for external peer review. If any relevant concerns become apparent during the document review and approval stages, the SCDC will communicate with the HRS President in a timely fashion.

The internal review process is expected to take 1–2 months. Once the internal review process is completed, the document proceeds to external peer review and is sent to partner and collaborating societies. Throughout the review process, itemized comments are provided to the Chair for revisions and itemized responses. The document is then returned to the SCDC for review for endorsement. If the document is not ready for endorsement, one or more additional rounds of revision may be necessary. The external review and further SCDC review process are expected to take 2–3 months.

Once approved by the SCDC, the document is submitted to external endorsing organizations for final endorsement. The SCDC Chair and the HRS staff will communicate the SCDC's final decision to the Executive Committee and the Board of Trustees. The endorsement process is expected to take 2–3 months.

1.5 Publication, Presentation, and Postpublication Updates

HRS clinical practice documents are published online in the *Heart Rhythm* journal (see Chapter 8). Documents are also presented at the annual HRS Scientific Sessions. Implementation and maintenance of clinical practice documents are discussed in Chapters 9 and 10.

1.6 Definitions

Clinical practice documents provide assistance with clinical decision making by describing a range of acceptable approaches for the diagnosis, management, or prevention of various arrhythmic conditions, based on an expert review of the scientific literature or expert consensus opinion in areas where evidence is unavailable, yet guidance is desirable. Clinical practice documents include clinical practice guidelines, expert consensus statements, scientific statements, clinical competency statements, task force policy statements, clinical decision pathways, and proceedings statements.

For the **technology category of clinical documents**, see Chapter 12.

For **clinical decision pathways**, see Chapter 14.

Clinical practice guidelines are defined by the Institute of Medicine as follows: "Clinical practice guidelines are 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." Clinical practice guidelines are developed through a rigorous methodological approach that mandates the review and consideration of the available medical literature. The HRS has determined that a systematic review must be performed to support at least one recommendation to achieve status of a guideline for the document.

Expert consensus statements provide recommendations that are informed by a review of evidence, but do not necessarily meet the standard of a guideline. However, similar to a guideline statement, an expert consensus statement provides recommendations supported by evidence. Recommendations

supported only by expert opinion are permitted but should be limited. Expert consensus statements are intended to inform practitioners, payers, and other interested parties of the opinion of the HRS concerning areas of evolving clinical practice, technologies, and/or competencies that are widely available or new to the practice community.

Scientific statements promote greater awareness about cardiovascular diseases and represent a consensus of leading experts, undergo peer review, and require SCDC approval.

Clinical competency statements define the minimum education, training, experience, ongoing practice, and cognitive and technical skills that the Society defines as necessary for competent performance of cardiovascular procedures. These statements are based on published data linking these factors with competency in certain procedures or, in the absence of such data, on the consensus of expert opinion. As with all documents, a survey tool should be used to detail consensus among the writing group.

Task force policy statements are reports made in collaboration or consultation with other stakeholders. They address the need for changes to current policies and will usually be presented to the Health Policy Committee for congressional and regulatory action. As with all documents, a survey tool should be used to detail consensus among the writing group.

Proceedings statements are derived from HRS-developed and/or -sponsored conferences that explore issues, procedures, or technologies in depth, without necessarily arriving at specific policies or recommendations. These proceedings may be divided into two subgroups depending on the decision of the Board of Trustees:

- These proceedings are approved by the HRS as reflecting current opinion on this topic.

- The following disclaimer should be added: These proceedings do not necessarily reflect the views of the HRS on this topic.

The appropriate annotation should be prominently placed in the document text.

Clinical practice documents are expected to reflect a consensus of the writing group. Official recommendations require a minimum consensus of 67% or greater. The level of consensus for a particular document should be determined at the onset of the document development process by the document Chair/Cochairs in collaboration with the writing group and the SCDC.

The determined level of consensus may be greater than the minimum level specified here. A survey tool should be used to determine consensus for each recommendation. The preamble to the document should describe how consensus was reached and the minimum percentage. As further detailed in Chapter 5, the HRS uses the American College of Cardiology (ACC)/American Heart Association (AHA) Class of Recommendations (COR) and Level of Evidence (LOE) system for all recommendations.

2.1 Document Topic Identification

2.1.1 Practice Guidelines and Consensus Documents

Potential document topics originate from the SCDC, the HRS members, and the HRS committees. The HRS membership may be invited to suggest document topics via a web-based survey, e-mail solicitation, and/or the HRS Clinical Guidelines & Documents webpage. The SCDC Chair and staff liaison solicit topics and communicate potential topics to other HRS committees (e.g., the Health Policy Committee) and members of the Executive Committee, as applicable.

The SCDC reviews proposed topics at the face-to-face meeting during the annual HRS Scientific Sessions in May. Factors affecting topic priority include alignment with the HRS Strategic Plan, partnership opportunities, potential for international collaboration, impact on membership, relevance of the topic, predicted LOE, policy implications, other HRS committee priorities, overlap with existing guidelines, suitability for the HRS, and suggested scope. These considerations culminate in an initial prioritization survey, typically prior to the HRS Scientific Sessions. A final SCDC vote on the highest-priority topics occurs after the face-to-face meeting, by June or July.

The SCDC prepares a proposal outlining the justification for the highest-priority topic choices, including a recommendation for document type. Proposals are submitted to the Executive Committee for discussion and approval. The proposal is then advanced to the Board of Trustees for approval. All document topics are commissioned by the Board of Trustees. The number of documents produced is based on the available annual operating budget.

For additional details on document identification see **Appendix A** "Guidance for HRS Document Topic Selection."

2.2 Involvement of Partnering, Collaborating, or Endorsing Organizations

The HRS collaborates with other societies on the development of scientific and clinical documents principally to further our mission. Scientific documents that are authoritative and widely representative of international consensus will be the most effective in influencing clinical care, resulting in better care and better outcomes worldwide.

When collaborating with other organizations, the Society has a strong preference for working with societies that are regional (multinational) in representation, as opposed to representing single countries. However, exceptions may be made depending on the specific expertise needed. With few exceptions, the societies with which the HRS collaborates should have a strong independent track record in writing and approving documents and must have adequate infrastructure to support this enterprise.

The Society values collaboration with other organizations whenever possible to develop a credible and trustworthy clinical document. As such, other medical associations or societies may be asked to join the effort at various levels of participation. As a preliminary step in document development, the SCDC Chair, the HRS SCDC staff liaison, the President, and the document Chair determine the desired partnering, collaborating, and/or endorsing

organizations. If partnership requests have financial implications, such partnerships require approval by the Board of Trustees. Each society/organization has its own set of policies associated with partnership, collaboration, and endorsement and should be consulted at the onset of the document development process to ensure that requirements for the desired level of participation are met. The HRS SCDC staff liaison assists with the development of all partnership, collaboration, and endorsement requests/invitations. All requests are addressed from the current President of the HRS to the President of the other society/organization.

2.2.1 Criteria for Involvement

The Society considers the following criteria when determining partnering, collaborating, and/or endorsing organizations for an HRS document:

- Cross-membership representation in the HRS (e.g., many members of the HRS are also members of other societies)

- Origin of body of evidence from certain regions or countries

- Writing group Chair and/or writing group member suggestions (e.g., expert writing group members may be members of specialty societies related to the document topic)

2.2.2 Levels of Involvement

Multicountry international organizations may be invited to participate in a partnership or on a collaborative level. Organizational resources associated with jointly developed documents are governed by letters of agreement between the HRS and any partnering organizations.

There are three levels of clinical document development involvement:

Partnership is a joint agreement between two or more societies to develop a document, often with equal representation in the writing group. Partnership agreements typically include some financial responsibilities for each partner; financial responsibility is negotiated by the Presidents of the partner organizations. All partner societies have equal approval weight at the time of final document approval and endorsement. Partners are listed in the title of the document (e.g., "HRS/EHRA" [Heart Rhythm Society/European Heart Rhythm Association]) and are also noted in a separate statement on the title page (e.g., "Developed in partnership with …"). The final document is simultaneously published in each of the organizations' journals, where applicable.

Collaboration is an agreement between two or more societies, where the final approval of the document is granted by the lead society or partner societies and not by a collaborating society. Collaboration agreements do not include financial responsibilities for each collaborator. In general, collaborating organizations appoint a member of their society to the writing group and review the document for final endorsement by the society. The names of collaborating organizations are not listed in the title but are noted in a separate statement on the title page (e.g., "Developed in collaboration with …"). This statement must be approved by each participating organization before the publication of the document.

Endorsement is an agreement between societies that have neither joined in a partnership nor collaborated on the development of the document. These organizations may be asked to review and endorse the document after the final approval, but do not conduct peer review or suggest changes. When endorsement is

requested of a society, the invitation specifies that a response be received within a finite period of time. Endorsing societies without writing group representation are typically acknowledged in a separate statement on the title page (e.g., "Endorsed by …").

2.3 Formation of the Writing Group

The SCDC nominates the writing group Chair, Cochairs, or Vice-Chairs and suggested writing group members for all HRS documents.

2.3.1 Selection of the Document Chair

The document Chair and Cochair(s) or Vice-Chair(s) are proposed by the SCDC and sent to the Executive Committee/Board for approval. **The Chair(s), and one of the Vice-Chairs, must be free of any relevant relationships with industry (RWIs).**

2.3.2 Members of the Writing Group

Once the Chair and Cochair(s) or Vice-Chair(s) are approved, writing group members are proposed by the Chair(s), the SCDC, the Executive Committee, and any other relevant committees within the HRS. This list is then submitted by the SCDC to the Executive Committee for final approval. If electrophysiologists who are not HRS members are proposed to the writing committee, they either must be proposed by a partner or collaborating society or should join the HRS as a member for the duration of the project. Any issues with member selection are resolved by the HRS President and the SCDC Chair.

In coordination with the appointed Chair, the SCDC puts forth a roster of potential writing group members. Contributors may be chosen from other specialties as necessary (e.g., it may be appropriate on some documents to include nonelectrophysiologists or experts in related fields). In the event that these nonelectrophysiologists express an interest to serve as a writing committee member and are not proposed by a partner or collaborating society (see Section 2.3.5), the HRS will not require that they join the HRS as a member. The writing group should be comprised of a diverse group of men and women from different geographical regions, with experts from both academic and nonacademic settings, ideally avoiding multiple members from the same institution, and including nonphysician clinicians when relevant. The preponderance of evidence suggests that heterogeneity of thought in a decision-making group leads to better performance. The HRS is committed to improving the quality of clinical documents by increasing the diversity of writing group constituents. Writing group members must be dedicated to building consensus and be comfortable with a collaborative writing process. Attendance at scheduled face-to-face meetings and group conference calls is essential, as is the ability to work independently. A literature search to help identify potential writing group members is recommended. Nonclinical writing group members may include epidemiologists, statisticians, informatics specialists, patients, or consumer advocates. The suggested roster will also include a brief justification for recommended individuals.

Writing committee members should be chosen based on one or more of the following:

- Individual's known contribution to the field on the document's topic or issue
- Individual's ability to meet deadlines and remain committed to a project
- Individual's expertise in developing clinical practice guidelines or evidence review methodology

- An appropriate balance of authors for a broad perspective on the topic and its issues

- Representation, when appropriate, from a specific society (e.g., Society of Thoracic Surgeons [STS], American Stroke Association [ASA], Heart Failure Society of America [HFSA], European Heart Rhythm Association [EHRA])

- Individual representing a stakeholder important to the specific clinical practice document (e.g., patient, ancillary health care provider, policy expert)

2.3.3 Size of the Writing Group

The number of authors for each document is decided by the SCDC Chair and the document Chair. There is no preset limit to the number of authors, but a minimum of 10 is suggested for consensus documents and practice guidelines. For certain documents, it may be necessary to include a larger number of authors (e.g., 16+) to ensure that the document reflects expertise in the field and related disciplines.

2.3.4 Management of Relationships with Industry

The SCDC monitors writing group composition for RWI, as well as other potential areas of bias, such as intellectual bias/perspectives or organizational relationships potentially competitive with the HRS. Participation on the writing committee is dependent upon a review of all relevant RWIs. A majority of the writing committee members must be free of relevant RWIs (exception is made for the Technology Category [see Chapter 12]). At the discretion of the SCDC, certain disclosed relationships, such as participation in government-sponsored or university-managed Data Safety Monitoring Boards or research, as well as certain institutional, organizational, government, or nonprofit relationships, may be considered NOT

relevant to the writing of the document. The SCDC may request review by the Ethics Committee when potential writing committee member's disclosures may suggest a conflict that would preclude participation. The receipt of royalties from or ownership of stock in relevant industries is not permitted. See the HRS Code of Ethics on management of RWIs for scientific and clinical documents and its Appendix C "Guidance for Writing Committees/Groups." See also Section 2.3.8 in this process manual.

Section 2.5 details the evaluation of RWIs.

2.3.5 Representation from External Societies

At the outset of document development, the SCDC Chair, the HRS SCDC staff liaison, the HRS President, and the document Chair determine the invited partnering, collaborating, and/or endorsing organizations. See Section 2.2 for further details. Organizations are allotted a set number of writing group members depending on their level of involvement. Representatives for external societies are also subject to the writing group vetting process described in Section 2.5. Formal invitations are then extended to representative writing committee members, with a copy to the appropriate staff contact for the society/organization.

2.3.6 SCDC Liaison to the Writing Group

The SCDC assigns a current member of the committee as a representative to each HRS-led document. The SCDC representative will have full writing responsibilities and act as a mentor regarding the processes and procedures of the SCDC. See **Appendix B** "SCDC Methodologist/Liaison Responsibilities."

2.3.7 Confidentiality/Nondisclosure Agreement

All potential writing group members, the SCDC liaison(s), the HRS staff, and peer reviewers must sign a Confidentiality/Nondisclosure Agreement to be eligible to participate in the development of an HRS-led document. Confidentiality also applies to the SCDC members and staff.

Members of a document in progress may have access to confidential and/or proprietary materials or data related to the subject matter. This information must be kept strictly confidential to ensure the integrity of the development process. All document content is embargoed until approved by the governing bodies of the HRS and officially released. Document content (including recommendations, algorithms, figures, tables, and text) cannot be disclosed to anyone under any circumstances.

Writing group members may be approached by colleagues, industry, or media to provide their expert opinion on an issue relevant to the document content. It is permitted to discuss the publicly available evidence and the issues under consideration in the document. However, disclosure of any document content or indication of agreement or disagreement on any topic is prohibited. Writing group members may share content from any previously published document, but they may not indicate that the content will or will not change.

All document materials are the property of the HRS. Reproduction of document material in any form prior to publication is strictly prohibited. Document materials may be reproduced after publication with the permission of the HRS.

Breaches of confidentiality may result in removal from the writing group.

2.3.8 Code of Ethics

All writing group members must adhere to the current HRS Code of Ethics and Professionalism (https://www.hrsonline.org/sites/default/files/2020-06/HRS_Code-of-Ethics.pdf), including policies on conduct, disclosure of RWIs, conflict of interest, and guidance for writing groups.

2.4 HRS Staff Support

The HRS provides project management support for the development of clinical and scientific documents. See **Appendix C** "HRS Staff Responsibilities."

2.5 Evaluation of Relationships with Industry

The HRS has developed policies to minimize the influence of intellectual and financial biases during document development. The HRS recognizes the necessity of involving experts among the members of a writing committee, including those who in some cases have RWI. Once a document topic has been approved by the Board of Trustees, the SCDC Chair and the HRS SCDC staff liaison identify relevant financial RWIs. A relationship may be considered relevant when it involves the same or similar subject matter, intellectual property, assets, topics, or issues addressed in the document. Relevant RWI also may exist when the entity makes a drug, drug class, device, or device class addressed in the document, or when the writing committee member or household member may reasonably be affected positively or adversely by the document content. Regarding the development of clinical

practice guidelines, relevant RWI may include industry-funded or -sponsored research. Final determinations regarding the relevance of specific RWI may be made in collaboration with the HRS leadership and/or the Ethics Committee. Once selected, authors are asked to avoid forming any new relevant RWIs during the writing effort until publication to maintain the balance of the writing group. The SCDC monitors writing group composition for RWI, as well as other potential areas of bias or conflicts of interest.

Consistent with the HRS Disclosure of Relationships Policy, all writing group members are required to fully disclose all RWIs, including intellectual property and royalty income. A full disclosure of RWIs for each writing committee member will be published in the document (see **Appendix D**).

Specific RWI policies for the clinical document writing group are as follows:

- The Chair(s), and one Vice-Chair, is prohibited from having relevant RWIs as determined by the Society.

- Chairs and Vice-Chairs (and their immediate family members) should not own equity interests, stocks, or stock options or have ownership, partnership, or principal interests in a financially interested enterprise, excluding mutual funds that may hold such stock in its portfolio, or have the potential to profit financially from the recommendations of the document.

- No authors should own equity interests, stocks, or stock options or have ownership, partnership, or principal interests in a financially interested enterprise, excluding mutual funds that may hold such stock in its portfolio, or have the potential to profit financially from the recommendations of the

document. Authors are permitted to have such financial interests if these interests are not relevant to the document.

- A majority of the writing committee members must be free of relevant RWIs (exception is made for the Technology Category [see **Chapter 12**]).

Writing group RWIs are governed by the HRS Code of Ethics.

Document Chairs are expected to manage discussions during meetings or conference calls to avoid one or more individuals from unduly influencing the outcome of the discussion, whether they have a relevant RWI related to the topic under discussion, a relevant relationship with another (nonindustry) entity related to the topic, or other bias related to the discussion.

2.6 Participation by Industry, Regulatory Bodies, or Other Stakeholders

The HRS policy states that industry and regulatory bodies may be involved with clinical documents in an advisory capacity. They cannot participate in document authorship.

The Chair(s) and members from the writing group may choose stakeholder Resource Groups. These Resource Groups may include representatives from industry, government agencies, educational institutions, or from other clinical or nonclinical groups. Representatives are chosen to provide additional information or insight, which can strengthen the document during the course of its development. Writing group Chairs may elect to have Resource Groups review content for accuracy, but Resource Group members are not authors on the document and do not vote on recommendations. Resource Groups

are reviewed by the SCDC and may be reported to the Executive Committee.

2.7 Copyright and Ownership of Documents Including Illustrations

The HRS must acquire full copyright or an exclusive and unlimited license to use any artwork, diagram, picture, or figures (herein referred to as Illustrations) for inclusion into scientific documents.

A budget must be established at the initial stage of any document development effort with sufficient funds budgeted to cover any work-for-hire associated with Illustrations. Only designated HRS staff can make procurement or acquisition arrangements on behalf of the Society. Society members cannot obligate HRS funds for the purposes of Illustrations. Final authority to obligate funds lies with the Director of Clinical Documents and the Chief Learning Officer (CLO).

Ideally, the committee and the HRS should seek full copyright and ownership of Illustrations. Model language as part of overall Consulting Agreement (available via the Director of Clinical Documents) is as follows:

> The parties agree that all original reports, analyses, data, programming, graphic images, designs, drawings, or other works of authorship (the "Work Products") created by the Consultant for the HRS under this Agreement shall be owned by the HRS. The HRS maintains, without limitations, all rights to use, reproduce, print, publish, modify, license, and display the Work Product. The HRS further maintains, without limitations, all rights to copy and use the Work Product in print or any medium now or hereafter developed.

If full copyright cannot be acquired, at a minimum, a full license to use the Illustrations as outlined in the model language must be acquired. Only the Director of Clinical Documents and the CLO are authorized to negotiate licensing language. If contract/licensing negotiations must occur, sufficient funds must have been budgeted to allow for possible full legal review of the license language.

3.1 Determining the Scope

After the HRS Board approves a document topic, the SCDC will provide the Chair(s) with a general scope of the document based on discussions among the SCDC and the HRS leadership. The Chair will confirm the scope based on his or her expertise, available evidence, and rationale for the document. In defining the scope of the document, the Chair should clearly state what the document will and will not address. If there are multiple Chairs represented by different organizations, those Chairs should also have input on the scope. During their first teleconference, the writing group members will review the scope to ensure that it is clear and acceptable to all. Major changes to the scope will be communicated to the SCDC document liaison and the SCDC Chair. **The scope of the document will do the following:**

- Define the target condition or procedure: any diseases or procedures should be explicitly defined within the document; this is especially useful when existing definitions are controversial or unclear.

- Define the target patient or clinical presentations: the target patient can be specified in terms of demographics, presenting signs and symptoms, and past health history. It may be useful to include the types of patients or clinical presentations that are beyond the scope of the document.

- Specify the intended audience and practice settings.

- Identify interventions to consider.

- Identify outcomes to consider.

Many of the HRS documents are developed in partnership or in collaboration with international organizations. If applicable, the document should state when there are global differences in disease management and practice patterns. Recommendations that are only applicable within the United States should be clearly defined as such. **Checklist 1** provides a guide for determining the document scope.

3.2 Determining the Clinical Objectives of the Document

Recommendations that allow users to understand the evidence and apply it to clinical practice are an essential product of clinical documents. As such, writers should progress with specific clinical objectives in mind and consider what kind of guidance the readers will expect in the completed document. The clinical objectives can be revised and updated as the document is developed. A comprehensive set of objectives should be created within each main concept addressed by the document outline. These clinical objectives are the basis for future literature searches and recommendations. **Checklist 1** provides a guide for determining the clinical objectives.

3.3 Determining the Document Outline

The document Chair develops a preliminary outline based on the scope. Prior to the first writing group meeting, the HRS staff lead circulates the draft outline to the writing group for review and feedback. Additional feedback may be provided during the first group meeting. Writers are encouraged to precisely define the outline during the early stages of development. The draft outline is submitted to the SCDC for review.

Checklist 1   Determining the Clinical Document Scope and Clinical Objectives

General questions

☐ What are the target health condition(s), diagnostic test(s), or interventional procedure(s)?

☐ What is within the scope?

☐ What is beyond the scope?

☐ What is the literature inclusion date range?

☐ What is the epidemiology of the topic?

☐ Who is the intended audience?

☐ What is the public health impact?

☐ What is the target patient population?

☐ How does the document relate to any existing HRS clinical documents?

Questions related to the clinical objectives

☐ What are the important clinical objectives?

☐ What subtopics and related topics must be included? What comorbidities should be covered?

☐ What are the potential benefits and risks for individual patients associated with an intervention or procedure?

☐ What clinical options are available?

☐ What topics and subtopics have already been covered in any existing HRS or other society clinical documents?

3.4 Determining Writing Assignments

Writing assignments are made by the Chair with input from the writing group members who may be surveyed for their section preferences. Typically, sections or subsections will be assigned a primary author who is responsible for drafting the original content of the section and secondary author/reviewers who will provide edits and additional content. A separate Section Chair may also be assigned. The Chair is encouraged, if feasible, to select writing group members who are free of relevant RWIs as primary authors, particularly for subsections that present recommendations.

3.5 Timelines and Responsibilities

Documents that do not meet deadlines will be delayed until a high-quality document can be produced. **It is the responsibility of the Chair(s) to ensure timely completion and integration of sections.** If difficulties are encountered with meeting document deadlines, adjustments in writing responsibilities might be needed. The SCDC liaison will report to the SCDC Chair and assist with the mediation of any difficulties. The SCDC Chair will notify the Executive Committee of any significant delays.

The Chair works closely with the HRS SCDC staff to determine the most appropriate timeline for each document. The draft timeline is reviewed during the group's first meeting to ensure everyone is aware of major deadlines. Each section will have a deadline for completion. The HRS staff lead will assist the Section Chairs with adhering to the deadlines.

4.1 Preparing the Literature Search

Once the outline, scope, clinical objectives, and writing assignments of the document have been determined, a comprehensive evidence search occurs. The Institute of Medicine stipulates that guideline formation be based on a systematic review of the medical literature. It is unreasonable to expect systematic reviews of the evidence to address every key question. Nevertheless, at least several of the core questions addressed in a practice guideline should be based on a high-quality systematic review of the literature. When high-quality systematic reviews either can be performed or already exist that address several key components of a document, the production of a guideline as opposed to a consensus statement is appropriate.

When a relevant systematic review is either unavailable or is too costly to produce, the document is termed "Expert Consensus Statement." Nevertheless, consensus statements will still seek to employ many of the principles of systematic review as outlined below in order to evaluate the current evidence base effectively.

4.2 Literature Search Methodology

Current resources for evidence identification include MEDLINE (via PubMed), Embase, and the Cochrane Library. The HRS staff assigned to the document can assist in compiling requested searches and citations relevant to the topic from the above-mentioned databases and forward them to the writers. Literature searches should focus on evidence that can support a recommendation. Highest-quality evidence includes well-performed, randomized controlled trials and meta-analyses, whereas lower-quality evidence includes observational studies. Case studies and opinion documents may be helpful to support the text but cannot be used to support recommendations. (See Chapter 5 for the classification of LOEs for recommendations.) All studies used to support recommendations should be summarized using a standardized template that includes type of study, inclusion and exclusion criteria, and findings including statistical results, limitations, or other comments (**Table 1**).

4.3 Documentation of Literature Search

All literature searches for document development (terms used, date of search, and database used) should be recorded and stated within the introduction of the document.

4.4 Use of Other Guidelines/Authorities

Consensus statements or guidelines either developed by the HRS or other societies can be cited in the text, but may not be used to specifically support a recommendation.

4.5 Use of Unpublished Data

The results from unpublished data should not be considered except in the case of unpublished data in trials presented at a major national or international scientific meeting that is no older than 2 years. Unpublished data may not be used to support a recommendation.

Table 1   HRS Clinical Evidence Table

Study name or acronym; Author; Year published; PMID	Aim of study; Endpoints; Study type (RCT, observational—multicenter or single center; case series or other [if RCT include intervention and comparator]); Study size (N)	Patient population with inclusion and exclusion criteria	Results (absolute event rates, *P* values; OR or RR; 95% CI)	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Study Title or Acronym: • Year published • PMID	**Aim:** **Endpoints:** **Study type:** **Size:**	**Inclusion criteria:** **Exclusion criteria:**			

CI = confidence interval; OR = odds ratio; RCT = randomized controlled trial; and RR = relative risk.

4.6 Sorting the Evidence

4.6.1 Reviewing the Evidence

Literature search results are maintained by each individual section writer who reviews identified abstracts and removes nonrelevant citations. A full-text review of relevant manuscripts is then performed, and relevant studies are identified.

4.6.2 Synthesizing and Interpreting the Evidence

1. For each clinical objective within the document: a literature search is performed to create a list of references.

2. Evidence tables are created (see **Table 1**) that summarize each study, including the type of study (such as randomized controlled trial, observational study, or meta-analysis of randomized trials).

The table includes the full citation and PubMed ID.

3. All studies that are used to support a specific recommendation must be summarized in an evidence table.

4. Separate evidence tables are created for each subsection of the document that provides recommendations. A concise narrative in the text of the document to summarize what is contained in the evidence tables can be helpful to interpret the evidence in the context of the subsection of the document.

4.7 Expert Interpretation of the Evidence

Expert interpretation of the evidence is necessary. Often, medical evidence may conflict, be of varying quality, and/or address patient populations other than those under consideration.

5.1 Recommendation Development

The writers are challenged with considering a vast array of evidence, or lack of evidence, to formulate applicable and clear recommendations. Recommendations are likely to be the most-read section of a consensus statement or guideline and should be written in simple and persuasive language, in a direct writing style, with an active voice, and bullet points. The patient population for which the recommendation applies should be clearly identifiable. If possible, recommendations should be written in a patient-centered statement. The clinical message should be clinically relevant, convincing, and framed in terms of potential gains and unambiguous measurable outcomes. Writers should be aware that recommendations are often taken out of the context of textual support and should format recommendations with this in mind.

It is imperative that the recommendations accurately reflect the evidence; recommendations stem from the review of the evidence, and not vice versa. In other words, writing committee members should avoid conclusion-motivated thinking, the temptation to formulate recommendations, and then search for supportive evidence for those ideas. **Evidence review comes first.**

The recommendations are the core content, whereas text enhances these recommendations by summarizing the evidence, judging the benefits and harms, and highlighting exceptions and clinical alternatives. For this reason, it is encouraged that recommendations be paired with a brief paragraph that includes the evidence used to support that recommendation, making clear why the recommendation was formulated. An example of this format is provided (**Table 2**).

Recommendations should be incorporated into flow diagrams and checklists that illustrate how to utilize the recommendations in patient care. Health care providers often rely upon these figures and tables for point-of-care decisions. As consensus statements and guidelines may also be the basis for other HRS activities such as performance measures and appropriate use criteria, recommendations should be stand-alone text written in complete sentences with appropriate detail (**Table 2**).

5.2 Classification of Recommendations with Corresponding Recommendation Terminology and Level of Evidence

The COR is an assessment of the relative benefit to risk. Class 1 recommendations have the highest benefit to risk, whereas Class 2a and Class 2b have intermediate benefit to risk. Class 3 recommendations are subdivided into two other categories: benefit equal to risk or a risk that exceeds benefit (**Figure 2**).

Once the recommendation idea has been formulated, it must be written with specific language that corresponds to the COR to which it will be assigned. For example, a Class 1 recommendation can use words such as "is recommended" or "is indicated." A Class 2a recommendation can use the words "is reasonable" or "can be useful." Class 2b recommendations incorporate the word "may," such as "may be reasonable" or "may be considered." Finally, Class 3 recommendations use the words "not recommended" or "potentially harmful."

A standardized color scheme should be used, with green for Class 1, yellow for Class 2a, orange for Class 2b, and red for Class 3.

Only Class 1 and 2a recommendations with an LOE A or B can incorporate statements regarding the comparative effectiveness of one treatment with respect to another. The construct of these recommendations may include words or phrases accompanied by the additional terms "in preference to" or "to choose" to indicate the favored intervention. For example, "Treatment A is recommended in preference to treatment B for ..." or "It is reasonable to choose Treatment A over Treatment B for ...." Studies that support the use of comparator verbs should involve direct comparisons of the treatment or strategy being evaluated. These direct comparison studies can be randomized controlled trials, longitudinal registries, and/or observational studies. Furthermore, recommendations are solely based on the merit of available clinical evidence; therefore, even though a new, recently approved drug may not have postmarketing surveillance data on population-based effects, the drug may be mentioned in guidelines and consensus statements and recommended as an option for treatment.

The LOE based on the quality of individual studies with respect to design and execution is assigned to each recommendation.

The SCDC has adopted the use of the ACC/AHA COR/LOE (**Figure 2**), which provides a transparent and explicit mechanism for classifying recommendations and their associated LOE. Level A evidence is high-quality evidence from more than one randomized controlled trial or in conjunction with high-quality registries. Mega-trials should *not* be considered sufficient sole justification for assigning such a high LOE. Level B evidence is lower-quality randomized (B-R) or nonrandomized (B-NR) studies. Level C-LD data are comprised of studies that have significant limitations in design, such as observational studies of small cohorts. Assigning an LOE B-R, B-NR, or C-LD should not be construed as implying that the recommendation is weak. Many important clinical questions addressed in the guidelines and consensus statements either do not lend themselves to experimentation or have not yet been addressed by high-quality investigations. Even though randomized controlled trials may not be available, the clinical question may be so relevant that it would be delinquent to not include it in the consensus statement or guideline. **Abstracts and case reports should not be used to support a recommendation.** Any **prior HRS or other society consensus statements or guidelines cannot be used to support a recommendation, and the original evidence should be referenced instead. All recommendations with LOE A, B-R, B-NR, or C-LD require at least one supporting reference.** Finally, Level C-EO is a consensus of expert opinion based on clinical experience, standard of care, or when evidence is insufficient, vague, or conflicting.

The classification of recommendations and LOE are considered by many to be the core of the guideline or consensus statement. As such, they are among the most debated aspects of the document within the writing group.

Any combination of classification of recommendation and LOE is possible. For example, a recommendation can be a Class 1,

even if it is based entirely on expert opinion and no research studies have ever been conducted on the recommendation (Level C-EO). Similarly, a Class 2a or 2b can be assigned a Level A if there are multiple randomized controlled trials coming to divergent conclusions.

5.3 Patient-Centered Care

To promote and facilitate shared decision making between clinicians and patients, writing committees should consider the role of patient preferences when the recommendation involves decisions with substantial personal choice or values. Patient-specific values, modifiers, comorbidities, and issues of patient preference may influence the choice of particular tests, therapy, or frequency of follow-up. The recommendation should incorporate language related to patient preference, especially when two or more treatment therapies are recommended at the same COR.

5.4 Pharmacotherapy

Investigational treatments or drugs that are not available for general use may be mentioned but should be clearly described as such and not given Class 1, 2a, or 2b recommendations. The presence or absence of FDA approval of a drug or device for a specific purpose should generally not be mentioned.

5.5 Reconciling Recommendations

Vetting and reconciling recommendations to ensure consistency with prior HRS-led documents is essential. Newly crafted recommendations that overlap with and are directly related to existing recommendations or that address the exact same disease states, patient populations, or treatments should be consistent and concordant with the "older" recommendations unless there is a compelling reason not to do so. The only instances where a recommendation is allowed to be discordant from that in a prior HRS-led document should be when there is a special consideration such as new evidence, an orphan drug/population, or a very specific subset of the general patient population. In these circumstances, the referring document text should clearly detail the reasoning behind the change in the consensus recommendation from the prior HRS-led document.

Table 2   Example of a Recommendation with Associated Class of Recommendation, Level of Evidence, Synopsis, Recommendation-Specific Supportive Text with References to the Evidence That Supports the Recommendation

COR	LOE	Recommendation	References
2b	**C-LD**	**1.** In adult patients with suspected HCM, cardiac CT may be considered for diagnosis if the echocardiogram is not diagnostic and CMR imaging is unavailable.	1–3

Synopsis
Cardiac CT provides excellent spatial resolution allowing for clear definition of LV structure (including hypertrophy pattern, wall thickness measurement, detection of subaortic membrane and intracardiac thrombus) and function. Small studies have demonstrated ability of CT to assess myocardial fibrosis, although this adds further radiation exposure and needs further validation. In addition to myocardial structure, CT can provide an assessment of coronary anatomy, including stenosis and anomalous origin of coronary arteries. Disadvantages of CT are the use of radiation and radioiodine contrast and inferior temporal resolution compared with echocardiography.

Recommendation-Specific Supportive Text
1. Although not used commonly, CT can provide important insights when echocardiography is technically limited and CMR imaging is contraindicated or unavailable and is one of the tools that can be used to define coronary anatomy.[1–3]

CLASS (STRENGTH) OF RECOMMENDATION

CLASS 1 (STRONG)   **Benefit >>> Risk**

Suggested phrases for writing recommendations:
- Is recommended
- Is indicated/useful/effective/beneficial
- Should be performed/administered/other
- Comparative-Effectiveness Phrases†:
  – Treatment/strategy A is recommended/indicated in preference to treatment B
  – Treatment A should be chosen over treatment B

CLASS 2a (MODERATE)   **Benefit >> Risk**

Suggested phrases for writing recommendations:
- Is reasonable
- Can be useful/effective/beneficial
- Comparative-Effectiveness Phrases†:
  – Treatment/strategy A is probably recommended/indicated in preference to treatment B
  – It is reasonable to choose treatment A over treatment B

CLASS 2b (WEAK)   **Benefit ≥ Risk**

Suggested phrases for writing recommendations:
- May/might be reasonable
- May/might be considered
- Usefulness/effectiveness is unknown/unclear/uncertain or not well-established

CLASS 3: No Benefit (MODERATE)   **Benefit = Risk**
(Generally, LOE A or B use only)

Suggested phrases for writing recommendations:
- Is not recommended
- Is not indicated/useful/effective/beneficial
- Should not be performed/administered/other

Class 3: Harm (STRONG)   **Risk > Benefit**

Suggested phrases for writing recommendations:
- Potentially harmful
- Causes harm
- Associated with excess morbidity/mortality
- Should not be performed/administered/other

LEVEL (QUALITY) OF EVIDENCE‡

LEVEL A

- High-quality evidence‡ from more than 1 RCT
- Meta-analyses of high-quality RCTs
- One or more RCTs corroborated by high-quality registry studies

LEVEL B-R   **(Randomized)**

- Moderate-quality evidence‡ from 1 or more RCTs
- Meta-analyses of moderate-quality RCTs

LEVEL B-NR   **(Nonrandomized)**

- Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

LEVEL C-LD   **(Limited Data)**

- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies
- Physiological or mechanistic studies in human subjects

LEVEL C-EO   **(Expert Opinion)**

- Consensus of expert opinion based on clinical experience

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

* The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

† For comparative-effectiveness recommendations (COR 1 and 2a; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

‡ The method of assessing quality is evolving, including the application of standardized, widely-used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; EO, expert opinion; LD, limited data; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.
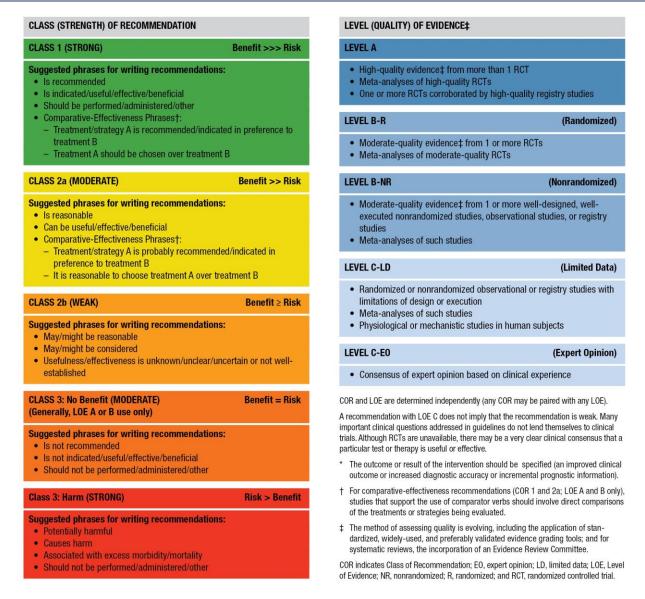
Figure 2   Applying Class of Recommendations and Level of Evidence to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care. The recommendations are formulated using the COR and LOE system developed by the ACC and AHA (Halperin et al. J Am Coll Cardiol 2016;67:1572–1574).

6.1 Group Decision Making

Writing committee discussions and consensus development continue throughout all stages of document development. HRS clinical practice documents are team-written documents; coming to consensus on the scope, clinical objectives, evidence tables, text, recommendations, and visual summaries occurs throughout document development. Subsection writers often come to consensus through conference calls or e-mail exchanges of information, while the entire writing committee comes to consensus during face-to-face meetings, whole-committee conference calls, and consensus surveys. **The preamble to the document should describe how consensus was reached, including the pre-defined threshold for consensus.** The document should also clarify how controversial areas that fail to meet consensus are handled. Important clinical questions that either lack sufficient data to formulate a recommendation or fail to achieve a consensus-approved recommendation can be discussed in the text.

Clinical practice document recommendations are voted on during pre-peer review writing committee sign-off, and then the writing committee votes again on recommendations that changed as a result of peer review. Confidential balloting is required for all recommendations, and voting is based on the context of quorum. A quorum is achieved with 2/3 of the votes cast by the members entitled to vote, whether in person or by permitted electronic means.

Abstaining from a vote should be only an exceptional circumstance, one that should require discussion with the SCDC liaison and/or the writing committee Chair. In the event that an abstention did occur during this process, the number of abstaining votes would not count in the denominator when calculating the percentage of consensus achieved.

6.2 Maintaining Consistency with Other Documents on the Same or Related Topics

Clinical practice documents in development often cover the same or related material as other HRS or other collaborative society scientific documents. Whenever possible, guidelines and consensus statements should refer to, rather than repeat, already-published information. The Chair, along with staff and the SCDC liaison, will help the writing committee identify related material in other guidelines and statements.

The SCDC liaison to the writing committee and the HRS staff should monitor consistency across clinical practice documents as appropriate to identify potential areas of disagreement. The writing Chair is encouraged to confer with the SCDC as needed to resolve areas of apparent disagreement with any other HRS-led or other society-led documents.

The policy for addressing instances of nonconcordance in recommendations is covered in Chapter 5.

6.3 Writing Group Sign-off

At the final stages of clinical practice document development, writers should re-examine the original goals regarding the scope of the guideline as identified in Chapter 3. Any identified gaps should be filled or explained before the document is sent for peer review. **The writing committee will be asked to give a formal approval of the document before peer review and provide a formal sign-off on the post-peer review version of the document prior to the SCDC review. The writing committee approval is achieved with a 2/3 or higher vote from the writing group members.**

7.1 Review Stages

Clinical practice document peer reviewers are relied upon for critical and unbiased scientific and literary appraisal. All clinical practice documents include review by the SCDC, the official HRS-appointed peer reviewers, and external review by collaborating societies. The **stages of peer review** include internal review within the HRS, external review, responses to these reviews, and the endorsement/approval process, both within the HRS and with external societies. Each stage is described below.

7.1.1 Internal Review

Internal peer review involves review by the SCDC and the official HRS peer reviewers. The SCDC assigns two of its members to review the document and assigns three non-SCDC members as additional peer reviewers. These non-SCDC members are typically recommended by the SCDC members, document Chair(s), or Executive Committee members. The SCDC makes the final determination of peer reviewers.

HRS staff will collect information regarding reviewers' RWI pertaining to the topics covered in the clinical practice document for SCDC consideration. All reviewers are required to provide this information and sign a confidentiality agreement to participate in the review process. Peer reviewers who have RWIs are not excluded from participating in the peer review process. However, the RWI information provided by the potential reviewer will be assessed by the SCDC to determine whether the reviewer is suitable for the specific clinical practice document. If the SCDC determines that there are significant conflicts that could compromise

an objective review, an alternate reviewer may be considered. As with clinical document writing committee members, RWI information for reviewers is included in an appendix of the published document. Peer reviewers with diverse and competing viewpoints are likely to enhance the clinical practice document review process.

7.1.2 External Review: Collaborating Societies and Other Organizations

Invitations to review a clinical practice document in development may be sent to organizational representatives and other stakeholders based on the topic of the document. These stakeholders may include industry, the FDA, or Centers for Medicare and Medicaid Services (CMS) representatives. Collaborating organizations also participate in peer review. After peer review is complete, clinical practice documents will be routed for an HRS internal peer review.

7.1.3 Response to Peer Review

HRS staff will collect all reviewer comments, send them to the document Chair who is required to officially respond to all peer review comments, and obtain the writing committee's sign-off on the post-peer review version of the document. The response to the comments is not a dialogue between the document Chair and the individual(s) providing comment; the goal is, rather, to provide the SCDC and the partner/collaborating organizations (*the peer review responses are sent to the appropriate organizations during the document endorsement process*) with information on how the document evolved during each stage of the review and endorsement process. Any

recommendations that changed as a result of peer review should be approved by the writing group through a consensus survey. Depending on the extent of changes made to the document, the document often needs to be re-reviewed by the full SCDC committee. Once the SCDC approves the clinical practice document (by a majority vote via electronic communication or on an SCDC call), it is sent to the partner/collaborator societies for a request for endorsement.

7.2 Endorsement

The document is sent for external endorsement following endorsement/approval by the SCDC. If any relevant concerns become apparent during the document review and approval stages, the SCDC will communicate with the HRS President in a timely fashion. The SCDC Chair and the HRS staff will communicate the SCDC's final decision to the Executive Committee and the Board of Trustees. The document manager will send a letter from the current President (after the President's approval) to the requesting organization's President with an official request for endorsement. Included in the endorsement request should be the final document and a copy of the reviewer comments with the Chair(s)' responses. The external endorsement process typically takes 4–6 weeks. The masthead of the document should appropriately reflect the sponsoring organization as well as partnering/joint organizations; additionally, endorsing organizations should be clearly noted in the introduction of the document. If an organization declines to endorse the document, then the name of that organization will be removed from the masthead and introductory text.

External endorsement of HRS documents by other organizations, while desired, is not necessary prior to presentation of the document. If external endorsement is not achieved prior to presentation, it should be appropriately noted in the press release. The HRS document project manager will coordinate preparation of a press release with the appropriate HRS Communications and Marketing staff (see Section 8.2).

8.1 Publication of HRS-Led Clinical Practice Documents

All clinical practice documents initiated by the HRS will be published in *Heart Rhythm*. If a document is to be published in more than one journal, the HRS staff will coordinate with the publisher for a simultaneous publication. Chairs will be asked to respond to author queries from the publisher during the proofreading stage.

8.1.1 Publication of Endorsed Documents

HRS endorsement of documents developed by external societies does not guarantee publication of the document in *Heart Rhythm*. Publication *will be considered* by the HRS and/or the Editor-in-Chief of *Heart Rhythm* on a case-by-case basis. If publication is desired, it should be advised at the time the endorsement request is submitted to the HRS. Upon endorsement and subsequent publication of the document, the HRS requests a courtesy notification of final publications.

8.1.2 Copyright Assignment and License Agreement

The HRS owns all rights, title, interest, and copyright of HRS-led documents and owns joint copyright of partner documents led by other organizations. Duplication, modification, alteration, enhancement, and distribution of documents are not permitted without permission from the HRS. It is important for writing group members to go through the proper channels to obtain permission to reprint/modify document content.

8.1.3 Editorial Response Policy

In accordance with the *Heart Rhythm* journal policy, the document Chair may choose to issue a response to any accepted Letters to the Editor pertaining to the document. Document Chairs are encouraged to make the HRS staff and the SCDC leadership aware of these letters and provide copies of drafted responses, prior to the submission to *Heart Rhythm*. Letters that are accepted for publication may be published with or without a response per journal policy.

8.2 Presentation of Clinical Practice Documents

The document Chairs are encouraged to present the scope, methodology, conclusions, recommendations, call for future research, and other content from the clinical document during the HRS Scientific Sessions and other professional society meetings.

HRS-led documents should be presented at the HRS Scientific Sessions first, unless previous arrangements have been made. The document Chair is responsible for developing the objectives and an outline for formal presentations. The HRS document project manager will coordinate preparation of a press release with the appropriate HRS Communications and Marketing staff.

9.1 Guideline Dissemination and Implementation as a Core Focus during the Document Development Process

It is increasingly evident that evidence from essential research and recommendations from well-constructed guidelines do not easily translate into improvements in public health. Despite investment in health research of billions of dollars a year, a consistent finding is the abysmal failure to translate the results of this research investment into practice or policy. Implementation failure can occur due to structural barriers, but also due to intrinsic factors such as ambiguity and inconsistency in how recommendations are constructed and written.

9.2 GuideLine Implementability Appraisal Tool

A validated instrument to provide feedback to document writers about how recommendations are developed is the GuideLine Implementability Appraisal (GLIA) tool. The GLIA instrument (http://gem.med.yale.edu/glia/login.htm) analyzes the following domains:

- **decidability** (precisely under which conditions to do something)
- **executability** (what to do under which circumstances)
- **validity** (degree to which the recommendation reflects the intent of the developer and the strength of the evidence)
- **flexibility** (degree to which the recommendation permits for interpretation and alternatives)
- **effect on process of care** (degree to which the recommendation impacts a usual workflow)

- **measurability** (degree to which the recommendation identifies markers or endpoints to track the effects of implementation)
- **novelty/innovation** (degree to which the recommendation proposes behaviors considered unconventional by clinicians and patients)
- **computability** (ease with which a recommendation can be operationalized within an electronic information system)

GLIA can be used to create and modify recommendations that are easier to implement, and it allows for the development of strategies that address identified barriers.

9.3 Implementation Planning

A synthesized checklist for implementation planning is found at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4329197/table/Tab1/. Fundamental to this framework is the concept that guideline implementation would be more successful if planning for dissemination and implementation occurs throughout the development of recommendations and if recommendations are written in a user-friendly and clear way with unambiguous measurable outcomes (**Figure 3**).

Consideration should be given to various dissemination formats (research version, analytical tool, short version for point-of-care, lay-language version) and the overall visualization of information. Recommendations should be written to be actionable and, when possible, to include discrete measurable outcomes.

Guideline development
- Evaluate clinical trial data
- Assess the need for guideline development in area of clinical practice
- Consider guideline implementation issues and strategies during guideline development stage; develop plan for dissemination and implementation
- Consider incorporating appropriate stakeholders (patients, policymakers) into writing process
- Write recommendations in clear, usable format
- Consider including measurable outcomes or goals

Guideline dissemination
- Assess potential strategies for guideline dissemination (Scientific Sessions, media, publication, website)
- Develop electronic, print, social media formats

Guideline implementation
- Consider factors affecting implementation
- Identify implementability domains
- Implement strategies and tools, assess milestones and measures
- Support measurement of outcomes of adherence and nonadherence to guidelines

Guideline implementation tools
- Review tools developed to promote implementation (versions, format, point-of-care tools, novel tools)
- Facilitate continuous quality improvement

Figure 3   Process Flowchart of Guideline Development and Implementation.

The SCDC reviews topics for new documents annually, and this includes the need to update and revise a prior document. **The need to revise a prior document may occur for any of the following reasons:** 1) policy changes from federal regulatory bodies in emerging areas of cardiovascular disease assessment and treatment; 2) new published evidence; or 3) the document is more than 5 years old and requires review and assessment for currency.[1]

New studies must be published in peer-reviewed journals. Large randomized placebo-controlled trials are desired; however, important nonrandomized studies may be considered, especially in the realm of patient safety. In addition, methodological strengths/weaknesses, degree of impact on current practice, number and results of previous trials on the topic, and the likelihood of additional studies influencing current findings are taken into consideration.

Once the document has reached 5 years post-publication, a minimum of two blinded individuals should independently review and make a recommendation to the SCDC at an upcoming meeting or teleconference. The three recommendations available to the SCDC are 1) the document is still current and should be reassessed in 5 years; 2) the document should be retired; or 3) the document should be updated. Revisions are managed in the same way as a new guideline or consensus statement.

The authority to retire a published clinical document will reside with the SCDC. The SCDC decision on document retirement will be communicated to the HRS President prior to a formal motion by the SCDC and will not require ratification from the Executive Committee or the Board of Trustees.

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[1]Shekelle PG. Updating practice guidelines. JAMA 2014;311:2072–2073

The HRS acknowledges that many organizations are producing high-quality clinical practice documents that would benefit the HRS membership. When documents are submitted to the HRS for consideration of endorsement, the SCDC will evaluate these documents and make a decision regarding endorsement. If any relevant concerns become apparent during the document review and endorsement stages, the SCDC will communicate with the HRS President prior to formulating a final recommendation. In cases of affirmation of value or no endorsement, the external society will not be notified until after the decision has been discussed with the HRS President and the Board of Trustees. External clinical practice documents include partner, collaborator, and endorsement-requested documents.

The HRS has adopted **two categories of endorsement for clinical practice documents from external societies**: full endorsement and affirmation of value. For either category of endorsement, the document must include disclosure information on RWIs for all authors, and there can be no industry participation in the document development.

Full endorsement is reserved for clinical practice documents the major recommendations of which are approved by the HRS and clinical practice documents that were developed with a methodology equivalent to that used by the HRS for its own clinical practice documents.

Affirmation of value is a category of endorsement for clinical practice documents that the HRS recognizes as having educational and clinical value for its members, but either

a) the document methodology is not sufficiently concordant with the HRS document methodology or

b) the document recommends or suggests significant practices or standards of care that are substantially discordant with recommendations of any existing HRS clinical practice documents or generally accepted practice in the United States.

Clinical practice documents are submitted to the HRS for endorsement by related specialty society organizations or through other channels of communication (e.g., members and the HRS staff). The HRS encourages these organizations to inform the HRS of any documents that are in development and may be considered for endorsement. Although HRS endorsement does not require HRS input into the document, the likelihood of endorsement is greatly increased by the HRS's involvement in the development of the document. **Table 3** indicates how the HRS may promote and disseminate these documents to the HRS membership.

For endorsement of external documents, the HRS may not be included in the document title. The HRS endorsement or affirmation of value may be included on the cover page of the document or in the text according to the conventions of each organization. The HRS must approve how the Society's name appears in the final document.

Table 3 Promotion and Dissemination of Clinical Documents to the HRS Membership

	Publish in *Heart Rhythm*?	**Post on the HRS website?**	**Promote* to HRS membership?**
Endorsement	Optional	Yes	Yes
Affirmation of value	No	Optional	Optional
No endorsement	No	No	No

* Promotion can be as focused as posting the document on the HRS website or as wide as an all-member e-mail.

It has been recognized that there is a need for documents that look to the future for the direction of health care and technology development. Such documents by their nature may need input from members of industry, third-party organizations such as the U.S. Food and Drug Administration (FDA) or patient advocacy groups, or the HRS members with particular subject matter expertise who may have RWI that would exceed the currently accepted parameters detailed in the HRS Code of Ethics and Professionalism. Examples of such document types include the following:

1) Proceedings: a group of individuals convene to have a summit or "think tank" and then report on their ideas.

2) Market research white papers: a group of individuals discuss outcomes of market research or surveys. Such studies may be directly funded by industry.

A new category of clinical documents was created with the following parameters:

1) The purpose of the document is to delineate a future direction of research, development of technology, or health care policy.

2) The document will not provide clinical practice recommendations or use the words "recommendation" or "recommend" to avoid any confusion with clinical practice documents. Agreed upon ideas can be referred to as "key points" or "action steps."

3) The Chair, and one Vice-Chair, of the document will be free of RWI.

4) The remainder of the writing committee may have RWI, with no specific dollar limit, but may not have stock, stock options, equity, or royalties that are relevant or be directly employed by industry (see **Table 4** for further information).

5) It is encouraged that the writing committee utilize industry forums to engage representatives of industry, the FDA, or other third-party organizations in a dialogue to provide an exchange of information.

6) It is encouraged that the writing committee utilize, in an advisory role to provide information based on their expertise, physicians or health care providers who are content experts yet have relevant stock options, royalties, or other relationships that may be determined to create conflict of interest. These physician advisors or health care advisors may not be employed by industry. These advisors may be indicated as such on the masthead of the document. These advisors will not participate in writing of the document but may be invited to review the document after it has passed review by the SCDC.

7) The document will have a full disclosure of RWI for each writing committee member and for each advisor.

8) The introduction section of the document will clearly state the purpose of the document and the parameters as delineated above, specifically including the role of advisors versus writing committee members. This language must be approved by the SCDC to ensure it correctly captures these parameters.

In order to ensure that these documents are generally understood to be distinct and separate from HRS clinical practice documents, a new type has been adopted. Possibilities for such a type include "HRS Needs Assessment Document," "HRS Directed Action Document," or "HRS White Paper" to convey that the purpose of the document is to delineate a future direction for research, technology, or health care policy.

Consistent with the Disclosure of Relationships Policy defined in the [HRS Code of Ethics and Professionalism](), all writing group members and advisors are required to fully disclose all RWIs, including intellectual property, royalty, and royalty income. **The following definitions are used to outline categories for reporting RWI.**

Table 4   Definitions Used to Outline Categories for Reporting RWI

Category	Description
Honoraria/ Speaking/ Consulting	Honoraria from a third party, gifts or in-kind compensation for consulting, lecturing, speaking engagements, advisory board, or membership, legal testimony or consultation (e.g., expert witness), or other purpose. Disclosure of travel, entertainment, food, beverage, and education expenses for industry-sponsored meetings is required.
Speakers' Bureau	When a company has the right to dictate or control the content of the presentation or talk, and/or the company creates the presentation material and has final approval of the content and edits, and/or when one is expected to act as a company's agent or spokesperson for the purpose of disseminating company or product information.
Research (PIs and Named Investigators Only)	For principle investigator and named investigators only, grants received from industry, foundations, or government sources granted to the institution.
Fellowship Support	Fellowship support
Stock Options/ Partnership	Includes any equity interests and any stock or stock options for a publicly traded and financially relevant company and for a nonpublicly traded company. Includes status or position of ownership/partnership/principal in an entity excluding mutual diversified funds.
Board Mbs/Other	Other relationships not described above must be disclosed: royalty income; Officer, Trustee, Director, Committee Chair, or Any Other Fiduciary Role of a relevant for-profit or nonprofit organization, whether or not remuneration is received for service; intellectual property rights, including patent or other intellectual property in a for-profit corporation, manifested in a tangible form that can be legally protected whether or not such rights are currently commercialized via a license agreement or other means (e.g., patent, trademark, or copyright).

Focused Clinical Decision Pathways or Focused Clinical Practice Pathways provide guidance on a focused clinical management area that is not covered in another clinical practice document and in a format that is easily accessed at the point of care. This can include topics where published evidence may be limited but should not rely solely upon expert opinion.

Focused Clinical Decision Pathway/Focused Clinical Practice Pathway Development Criteria:

- **Focused scope:** The writing group will be provided a list of questions to answer in a structure that will include flow charts and tables to summarize key concepts.

- **Page count:** Text will be limited to 20 pages or less.

- The document will be accompanied by **multimedia** such as a PowerPoint presentation and a brief video.

- The document will not include any collaborating societies.

- The document will not provide any formal (namely, Class-oriented) recommendations and will not use "recommendation" type language.

- **Timeline:** The document draft should be completed within 6 months.

- **Currency:** The document will be reviewed no more than 2 years after publication to ensure that it is current.

- **Writing group composition and RWIs:** The document category will adhere to the RWI policy in place for HRS-led clinical practice documents. This includes the requirement that the Chair and at least one Vice-Chair be free of relevant RWIs. No members may have relevant stock or stock options, royalty income, licensing or principle interests in a financially interested enterprise (including a start-up company) excluding mutual funds that may hold stocks in its portfolio or be directly employed by industry. In addition, the SCDC, in consultation with the Ethics Committee, can determine that a relationship may create conflict of interest and exclude the individual from participation in the writing group.

- A full **disclosure table** of all document participants will be published with the document.

- The **introduction section** of the document will clearly state the purpose of the document and parameters as delineated above, specifically with regard to RWI.

- In order to ensure that these documents are generally understood to be distinct and separate from HRS expert consensus statements, the title of "HRS Focused Clinical Decision Pathway" or "HRS Focused Clinical Practice Pathway" will be used.

Considerations for Topic Selection

- Content should be unique (minimal overlap with previous or current clinical documents published by the HRS or other organizations).
- A timely full or focused update of any previous HRS clinical practice guidelines can be considered.
- Guidelines or consensus statements covered by other international organizations (such as the European Society of Cardiology [ESC]) may be acceptable topics.

Considerations for Topic Prioritization

- The proposed topic addresses a condition that is associated with a significant morbidity or mortality.
- The proposed topic addresses an issue that is important to the population as a whole or to a particular subgroup.
- Document recommendations are the best mechanism for improving and reducing inequalities in patient care. Examples include improving quality of life and reducing avoidable morbidity or premature mortality.
- Widespread variation in practice such that in the absence of recommendations, there might be inappropriate clinical practice and/or treatments.
- The proposed topic is timely.
- Recommendations from the document could lead to a performance measure.

For all documents proposed by the SCDC to the Board of Trustees for approval, the SCDC will present a summary and/or table with the following proposal justification:

- Title of proposed document
- Proposed scope
- Type of document (e.g., guideline, consensus)
- Rationale for prioritization
- Impact on primary audience (e.g., intended users)
- Possible collaborations
- International impact
- Alignment with strategic plan (or priority of another committee)
- Prevalence, if known
- Summary of relevant data to consider (potential LOE)
- If a document update, a brief summary of recent science justifying the need for an update
- Health policy objectives, if applicable
- Potential overlap with other current guidelines, consensus statements, or HRS documents
- Whether and/or why the HRS is best suited or uniquely positioned to develop the document

Responsibilities of the SCDC Methodologist/Liaison to Writing Committees

The SCDC assigns a current member of the Committee as a representative to each HRS-led document as a liaison with methodological expertise. Depending on the availability of EBM methodology experts among the Committee members, a methodologist may be chosen from outside the SCDC, with an additional appointment of an SCDC member as a liaison.

1. **General**

   a. Participate as a full writing and voting member of the writing group (WG).

   b. Report progress to the SCDC during SCDC teleconferences and meetings. Update to the SCDC should include, when applicable, the document outline, draft recommendations, and controversies that may impact progress of document development. The SCDC methodologist/liaison should be aware of the document timelines, provide reminders to the writing group and Chairs as needed, and alert the SCDC and the SCDC Chair of deviations.

2. **Recommendations**

   a. Ensure that recommendations are patient centered, clearly written, and user-friendly, and if applicable, provide unambiguous measurable outcomes. Recommendations should be written in simple and persuasive language, using a direct writing style, the active voice, and bullet points.

   b. Ensure correct language for the assigned Class of Evidence, according to the ACC/AHA Applying Class of Recommendations and Level of Evidence to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care (Figure 2).

   c. Ensure that correct level of evidence is assigned based on the references cited to support the recommendation.

   d. Ensure that evidence used to support a recommendation is in accordance with the HRS Process Manual (may not include case reports or editorials).

   e. Ensure that knowledge byte written for each recommendation; this text is meant to explain the recommendation but not have any "recommendation" type language that would suggest other recommendations.

   f. If PICO format is used, ensure that this is adequately described in the document.

   g. Ensure reconciliation with other clinical documents: determine whether there are prior or ongoing clinical documents and guidelines that may have overlapping recommendations.

3. **Evidence Tables**

   a. Ensure that evidence tables are created by the primary writers to include all references that will support recommendations, using the SCDC-approved template.

   b. Review the key references to ensure that they are sound and reasonably support the level of evidence of recommendations [see item 2 c)].

   c. If a systematic review or a meta-analysis is included, scrutinize this paper in particular.

4. **Working with the Chair and Vice-Chair**

    a. Ensure, with the HRS staff, that primary writers for sections that will develop recommendations are free of RWI.

    b. Assist in the creation of a document table of contents.

        i.   Identify sections that will have recommendations.

        ii. Identify primary and secondary writers.

        iii. Indicate anticipated paragraph limits for text that is not in knowledge bytes (up front, will help keep the document from bloating).

    c. Ensure that the document remains concise; review: text should be brief, focus should be on recommendations and knowledge bytes [see above item 4 b) iii)].

    d. Ensure that every key section has tables, figures, and flowcharts as appropriate to present the material; the goal is to create a document for which the basic ideas are understood just from the tables and figures alone (without having to read the text).

5. **Completing the First Draft**

    a. Write the introduction that identifies the HRS document development processes.

        i.   Include the threshold for consensus and the mean consensus of recommendations in the introduction.

        ii. Describe PICO format if used to motivate any of the recommendations and evidence review.

    b. Assist Chair and Vice-Chair in assembling the chapters and ensuring that redundancy is limited; this often involves further rewrites by the Chair and Vice-Chair. Volunteer to help in these rewrites as the HRS methodologist understands the processes best and knows the HRS clinical practice document format.

Step 1: Topic Selection and Approval

- Request topic submissions from the HRS membership, the SCDC, the Health Policy Committee, and the Executive Committee for consideration.
- Compile topic submissions according to the SCDC prioritization format.
- Facilitate formal voting by the SCDC and send recommendations to the Executive Committee and the Board of Trustees for approval.
- Work with the SCDC Chair to determine partnering, collaborating, and endorsing societies.

Step 2: Writing Group Selection and Approval

- Facilitate Chair selection and approval through the SCDC and the Executive Committee.
- Send official letters of invitation and requests for writing group representatives to partnering and collaborating organizations.
- Provide a list of members expressing interest in participating in writing groups and consider leaders in the specific content area.
- Provide the Executive Committee with suggested list of Chairs and authors for approval.
- Send nomination letters to selected candidates.
- Collect RWI information from all nominated members and vet RWI for each member based on relevance to the topic.
- Confirm participation of partnering and collaborating societies: agreements signed by all applicable parties, representatives are requested from partnering and collaborating societies, contacted for participation, and vetted for RWI.
- Update RWI in the HRS database.
- Compile a writing group roster with detailed contact information.
- Create document charge and timeline.
- Educate document Chairs/writing group on the HRS writing process.

Step 3: Document Writing Phase

- Coordinate writing group teleconferences; assemble and distribute document drafts; track document versions.
- Assist with construction of flowcharts and tables.
- Provide technical support to members and chairs.
- Monitor status of document process with frequent updates to Chair and/or writing group.
- Provide update of document progress to the SCDC liaison.
- Assist with reference management.
- Assist with permission requests.
- Construct surveys for voting on recommendations; tally recommendation votes to ensure consensus is achieved.
- Ensure adherence to process and timeline and coordinate the SCDC review of the document for approval and preparation for external review.

- Update partnering, collaborating, and endorsing societies on document development progress in preparation for peer review.

Step 4: Peer Review Phase

- Request peer reviewers from partners and collaborators.
- Send official letters of invitation to peer reviewers; request and file confidentiality agreement form and RWI information.
- Coordinate open comment period.
- Collate all peer reviewer comments for Chair response.
- Send revised document and Chair responses to partners and collaborators.
- Facilitate SCDC review of revised document.
- Send final draft to external societies for final endorsement.

Step 5: Publication and Presentation Phase

- Coordinate with *Heart Rhythm* on production timelines; coordinate copublication with partner societies, if applicable.
- Send document to medical editor for review.
- Verify proper HRS formatting of document.
- Submit document to *Heart Rhythm* for review and approval; assist the Chair with author queries from the journal.
- Coordinate press release.
- Promote the document, ensuring press coverage and communication of the document objectives.
- Assist the Chair in developing a slide set of document recommendations.

Author disclosure table

(*for Expert Consensus Statements*)

Writing group member	Employment	Honoraria/ Speaking/ Consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/ Partnership/ Principal/ Majority stockholder	Stock or stock options	Intellectual property/ Royalties	Other

Number value: 0 = $0; 1 = ≤ $10,000; 2 = > $10,000 to ≤ $25,000; 3 = > $25,000 to ≤ $50,000; 4 = > $50,000 to ≤ $100,000; 5 = > $100,000. *Research and fellowship support are classed as programmatic support. Sources of programmatic support are disclosed but are not regarded as a relevant relationship with industry for writing group members or reviewers.

Disclosure table

(*for Technology Document Category*)

Name	Employment	Honoraria/ Speaking/ Consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/ Partnership/ Principal/ Majority stockholder	Stock or stock options	Intellectual property/ Royalties	Other
Writing group members									
Advisors									

Number value: 0 = $0; 1 = ≤ $10,000; 2 = > $10,000 to ≤ $25,000; 3 = > $25,000 to ≤ $50,000; 4 = > $50,000 to ≤ $100,000; 5 = > $100,000 to ≤ $200,000; 6 = > $200,000 to ≤ $300,000; 7 = > $300,000 to ≤ $400,000; 8 = > $400,000.

*Research and fellowship support are classed as programmatic support. Sources of programmatic support are disclosed but are not regarded as a relevant relationship with industry for writing group members, advisors, or reviewers.

Reviewer disclosure table

Peer reviewer	Employment	Honoraria/ Speaking/ Consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/ Partnership/ Principal/ Majority stockholder	Stock or stock options	Intellectual property/ Royalties	Other

Number value: 0 = $0; 1 = ≤ $10,000; 2 = > $10,000 to ≤ $25,000; 3 = > $25,000 to ≤ $50,000; 4 = > $50,000 to ≤ $100,000; 5 = > $100,000. *Research and fellowship support are classed as programmatic support. Sources of programmatic support are disclosed but are not regarded as a relevant relationship with industry for writing group members or reviewers.

Author Relationships with Industry and Other Entities (Relevant)

Committee member	Consultant/ Advisory board/ Honoraria	Speakers' bureau	Research grant	Fellowship support	Stock options/Partner	Board Mbs/Other
Julia H. Indik, MD, PhD, FHRS	None	None	None	None	None	None
Kristen K. Patton, MD, FHRS	None	None	None	None	None	None
Marianne Beardsall, MN, FHRS, CCDS	None	None	None	None	None	None
Carol A. Chen-Scarabelli, ARNP, MSN, PhD	None	None	None	None	None	None
Mitchell I. Cohen, MD, CCDS, CEPS, FHRS	None	None	None	None	None	None
Timm-Michael L. Dickfeld, MD, PhD, FHRS	None	None	None	None	None	None
David E. Haines, MD, FHRS	None	None	None	None	None	None
Robert H. Helm, MD, FHRS	None	None	None	None	None	None
Kousik Krishnan, MD, FHRS	None	None	None	None	None	None
Jens Cosedis Nielsen, MD	None	None	None	None	None	None
John Rickard, MD	None	None	None	None	None	None
John L. Sapp, Jr., MD, FHRS	None	None	None	None	None	None
Mina Chung, MD, FHRS	None	None	None	None	None	None

1.4 Peer Review and Endorsement, 1st paragraph, *add*

If any relevant concerns become apparent during the document review and approval stages, the SCDC will communicate with the HRS President in a timely fashion.

1.4 Peer Review and Endorsement, 3rd paragraph, *replace*

Once approved by the SCDC for recommendation for endorsement, the document is submitted to the Executive Committee for review and subsequently to the Board of Trustees for final endorsement. The document is also submitted to external endorsing organizations for final endorsement.

with

Once endorsed by the SCDC, the document is submitted to external endorsing organizations for final endorsement. The SCDC Chair and HRS staff will communicate the SCDC's final decision to the Executive Committee and the Board of Trustees.

1.6 Definitions, 4th paragraph, *replace*

Scientific statements promote greater awareness about cardiovascular diseases and represent a consensus of leading experts, undergo peer review, and require SCDC approval with final approval by the HRS Executive Committee and the Board of Trustees.

with

Scientific statements promote greater awareness about cardiovascular diseases and represent a consensus of leading experts, undergo peer review, and require SCDC approval.

2.3.2 Members of the Writing Group, 1st paragraph, *add*

If electrophysiologists who are not HRS members are proposed to the writing committee, they either must be proposed by a partner or collaborating society or should join the HRS as a member for the duration of the project.

2.3.2 Members of the Writing Group, 2nd paragraph, *add*

In the event that these nonelectrophysiologists express an interest to serve as a writing committee member and are not proposed by a partner or collaborating society (see Section 2.3.5), the HRS will not require that they join the HRS as a member.

6.3 Writing Group Sign-off, 1st paragraph, *replace*

The writing committee will be asked to give a formal approval of the document before peer review and provide a formal sign-off on the post-peer review version of the document prior to the SCDC/Executive Committee/Board of Trustees review.

with

The writing committee will be asked to give a formal approval of the document before peer review and provide a formal sign-off on the post-peer review version of the document prior to the SCDC review.

7.1.3 Response to Peer Review, 1st paragraph, *replace*

The response to the comments is not a dialogue between the document Chair and the individual(s) providing comment; the goal is, rather, to provide the SCDC/partner/collaborating

organizations (the peer review responses are sent to the appropriate organizations during the document endorsement process), the Executive Committee, and the Board of Trustees with information on how the document evolved during each stage of the review and endorsement process.

with

The response to the comments is not a dialogue between the document Chair and the individual(s) providing comment; the goal is, rather, to provide the SCDC and the partner/collaborating organizations (the peer review responses are sent to the appropriate organizations during the document endorsement process) with information on how the document evolved during each stage of the review and endorsement process.

7.1.3 Response to Peer Review, 1st paragraph, *replace*

Once the SCDC approves the clinical practice document (by a majority vote via e-mail or on an SCDC call), it is sent to the Executive Committee with a recommendation for endorsement.

with

Once the SCDC approves the clinical practice document (by a majority vote via electronic communication or on an SCDC call), it is sent to the partner/collaborator societies for a request for endorsement.

7.2 Endorsement, *delete Figure 3 "HRS Endorsement Process" and replace*

Upon completion of the internal and external peer review and incorporation/response to all peer review comments, the document is ready to begin the HRS endorsement process. See Figure 3 for an overview of the process.

Step 1: *Send the document to the Scientific and Clinical Documents Committee.* The SCDC reviews the manuscript, recommendations, evidence tables, any additional supporting documentation, and all comments throughout the peer review process, internal and external.

Step 2: *Send the document to the Executive Committee.* After approval from the SCDC, the document manager will send the document to the Executive Committee, whose members review the document and recommend endorsement and/or send the document back to SCDC with comments. This process is typically done via e-mail.

Step 3: *Send the document to the Board of Trustees.* After the Executive Committee members confirm their recommendation for endorsement, the document manager will send the document to the Board of Trustees with a recommendation for endorsement from the Executive Committee and the SCDC. A 2/3 vote of approval, typically done via e-mail, is necessary for the document to be endorsed by the Society. Board of Trustees approval is needed in order for the document to be published or presented at a scientific meeting. Documents not receiving a 2/3 consensus will be further discussed by the SCDC Chair, the President, and the document Chair(s) and handled on a case-by-case basis.

Step 4: *Send the document to partner/collaborator societies.* The document cannot be sent for external endorsement until after the Board has endorsed the document.

with

The document is sent for external endorsement following endorsement/approval by the SCDC. If any relevant concerns become apparent during the document review and approval stages, the SCDC will communicate with the HRS President in a timely fashion. The SCDC Chair and HRS staff will communicate the SCDC's final decision to the Executive Committee and the Board of Trustees.

Chapter 10 Focused Updates or Revisions to Clinical Practice Documents, 1st paragraph, *replace*

The need to revise a prior document may occur for a variety of reasons, including policy changes from federal regulatory bodies in emerging areas of cardiovascular disease assessment and treatment, and new published evidence.

with

The need to revise a prior document may occur for any of the following reasons: 1) policy changes from federal regulatory bodies in emerging areas of cardiovascular disease assessment and treatment; 2) new published evidence; or 3) the document is more than 5 years old and requires review and assessment for currency.[1] ([1]Shekelle PG. Updating practice guidelines. JAMA 2014;311:2072–2073)

Chapter 10 Focused Updates or Revisions to Clinical Practice Documents, 3rd paragraph, *add*

Once the document has reached 5 years post-publication, a minimum of two blinded individuals should independently review and make a recommendation to the SCDC at an upcoming meeting or teleconference. The three recommendations available to the SCDC are 1) the document is still current and should be reassessed in 5 years; 2) the document should be retired; or 3) the document should be updated. Revisions are managed in the same way as a new guideline or consensus statement.

Chapter 10 Focused Updates or Revisions to Clinical Practice Documents, 4th paragraph, *replace*

A full document revision occurs if the SCDC determines that there is enough new evidence that a significant number of the recommendations need to be revised, or when there is a compelling reason to change the scope or focus of an existing document. Revisions are managed in the same way as a new guideline or consensus statement.

with

The authority to retire a published clinical document will reside with the SCDC. The SCDC decision on document retirement will be communicated to the HRS President prior to a formal motion by the SCDC and will not require ratification from the Executive Committee or the Board of Trustees.

Chapter 11 HRS Endorsement Policy of Externally Developed Clinical Practice Documents, 1st paragraph, *add*

If any relevant concerns become apparent during the document review and endorsement stages, the SCDC will communicate with the HRS President prior to formulating a final recommendation. In cases of affirmation of value or no endorsement, the external society will not be notified until after the decision has been discussed with the HRS President and the Board of Trustees.

1.6 Definitions, 1st paragraph, *add*

For technology category of clinical documents, see Chapter 12.

2.5 Evaluation of Relationships with Industry, *replace*

A full disclosure of RWIs for each writing committee member will be published in the document.

with

A full disclosure of RWIs for each writing committee member will be published in the document (see Appendix D).

6.1 Group Decision Making, 3rd paragraph, *add*

Abstaining from a vote should be only an exceptional circumstance, one that should require discussion with the SCDC liaison and/or the writing committee Chair. In the event that an abstention did occur during this process, the number of abstaining votes would not count in the denominator when calculating the percentage of consensus achieved.

6.1 Group Decision Making, 3rd paragraph, *replace*

Confidential balloting is required for all recommendations.

with

Confidential balloting is required for all recommendations, and voting is based on the context of quorum. A quorum is achieved with 2/3 of the votes cast by the members entitled to vote, whether in person or by permitted electronic means.

6.3 Writing Group Sign-off, 1st paragraph, *add*

The writing committee approval is achieved with a 2/3 or higher vote from the writing group members.

Chapter 12 Technology Category of Clinical Documents and Associated RWI Policy, *new Chapter 12 was added*

Appendix B Scientific and Clinical Documents Committee Liaison Responsibilities, *replace*

The Scientific and Clinical Documents Committee (SCDC) liaison:

1. Participates as a full writing and voting member of the writing group (WG).

2. Educates the WG, including the Chairs, about document processes, including a determination of consensus levels, literature review, recommendation classification, and determination of LOE.

3. Helps ensure that appropriate document processes are followed, such as voting on each final recommendation, performing appropriate literature reviews, and reporting to the SCDC any concerns of previously unknown or new relevant COI/RWI of a WG member. The SCDC liaison and HRS document staff liaison provide guidance for voting processes and development of recommendations throughout the writing process. All final document recommendations must achieve the minimum threshold for consensus, prespecified by the Chair.

4. Provides guidance on the overall structure of the document, in accordance with this process manual, including the following:

   a. Evidence tables

   b. Association of recommendations with its supportive evidence to result in an appropriate designation of LOE

   c. Reconciliation with other clinical documents: determine whether there are prior or ongoing clinical documents and guidelines that may have overlapping recommendations

5. Encourages the development of tools that facilitate implementation of the document recommendations. These may include algorithms, figures, tables, and web-based tools that can be readily utilized by HRS membership. The SCDC liaison and HRS document staff liaison facilitate interaction with the Education Committee as appropriate.

6. Reports progress to the SCDC during SCDC teleconferences and meetings. Updates to the SCDC should include, when applicable, the document outline, draft recommendations, and controversies that may impact progress of document development. The SCDC liaison should be aware of the document timelines, provide reminders to the writing group and Chairs as needed, and alert the SCDC and SCDC Chair of deviations.

with

Appendix B Scientific and Clinical Documents Committee Methodologist/Liaison Responsibilities

Responsibilities of the SCDC Methodologist/Liaison to Writing Committees

The SCDC assigns a current member of the Committee as a representative to each HRS-led document as a liaison with methodological expertise. Depending on the availability of EBM methodology experts among the Committee members, a methodologist may be chosen from outside the SCDC, with an additional appointment of an SCDC member as a liaison.

1. **General**

   a. Participate as a full writing and voting member of the writing group (WG).

   b. Report progress to the SCDC during SCDC teleconferences and meetings. Update to the SCDC should include, when applicable, the document outline, draft recommendations, and controversies that may impact progress of document development. The SCDC methodologist/liaison should be aware of the document timelines, provide reminders to the writing group, and Chairs as needed, and alert the SCDC and SCDC Chair of deviations.

2. **Recommendations**

   a. Ensure that recommendations are patient centered, clearly written, and user-friendly, and if applicable, provide unambiguous measurable outcomes. Recommendations should be written in simple and persuasive language, using a direct writing style, the active voice, and bullet points.

   b. Ensure correct language for the assigned Class of Evidence, according to the ACC/AHA Applying Class of Recommendations and Level of Evidence to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care (Figure 2).

    c.   Ensure that correct level of evidence is assigned based on the references cited to support the recommendation.

    d.   Ensure that evidence used to support a recommendation is in accordance with the HRS Process Manual (may not include case reports or editorials).

    e.   Ensure that knowledge byte written for each recommendation; this text is meant to explain the recommendation but not have any "recommendation" type language that would suggest other recommendations.

    f.   If PICO format is used, ensure that this is adequately described in the document.

    g.   Ensure reconciliation with other clinical documents: determine whether there are prior or ongoing clinical documents and guidelines that may have overlapping recommendations.

3. **Evidence Tables**

    a.   Ensure that evidence tables are created by the primary writers to include all references that will support recommendations, using the SCDC-approved template.

    b.   Review the key references to ensure that they are sound and reasonably support the level of evidence of recommendations [see item 2 c)].

    c.   If a systematic review or a meta-analysis is included, scrutinize this paper in particular.

4. **Working with the Chair and Vice-Chair**

    a.   Ensure, with HRS staff, that primary writers for sections that will develop recommendations are free of RWI.

    b.   Assist in the creation of a document table of contents.

        i.   Identify sections that will have recommendations.

        ii.   Identify primary and secondary writers.

        iii.   Indicate anticipated paragraph limits for text that is not in knowledge bytes (up front, will help keep the document from bloating).

    c.   Ensure that the document remains concise; review: text should be brief, focus should be on recommendations and knowledge bytes [see above item 4 b) iii)].

    d.   Ensure that every key section has tables, figures, and flowcharts as appropriate to present the material; the goal is to create a document for which the basic ideas are understood just from the tables and figures alone (without having to read the text).

5. **Completing the First Draft**

    a.   Write the introduction that identifies the HRS document development processes.

        i.   Include the threshold for consensus and the mean consensus of recommendations in the introduction.

        ii.   Describe PICO format if used to motivate any of the recommendations and evidence review.

    b.   Assist Chair and Vice-Chair in assembling the chapters and ensuring that redundancy is limited; this often involves further rewrites by the Chair and Vice-Chair. Volunteer to help in these rewrites as the HRS methodologist understands the processes best and knows the HRS clinical practice document format.

Appendix D Disclosure Tables, *new Appendix D was added*

Author disclosure table

(*for Expert Consensus Statements*)

Writing group member	Employment	Honoraria/ Speaking/ Consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/ Partnership/ Principal/ Majority stockholder	Stock or stock options	Intellectual property/ Royalties	Other

Number value: 0 = $0; 1 = ≤ $10,000; 2 = > $10,000 to ≤ $25,000; 3 = > $25,000 to ≤ $50,000; 4 = > $50,000 to ≤ $100,000; 5 = > $100,000. *Research and fellowship support are classed as programmatic support. Sources of programmatic support are disclosed but are not regarded as a relevant relationship with industry for writing group members or reviewers.

Disclosure table

(*for Technology Document Category*)

Name	Employment	Honoraria/ Speaking/ Consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/ Partnership/ Principal/ Majority stockholder	Stock or stock options	Intellectual property/ Royalties	Other
Writing group members									
Advisors									

Number value: 0 = $0; 1 = ≤ $10,000; 2 = > $10,000 to ≤ $25,000; 3 = > $25,000 to ≤ $50,000; 4 = > $50,000 to ≤ $100,000; 5 = > $100,000 to ≤ $200,000; 6 = > $200,000 to ≤ $300,000; 7 = > $300,000 to ≤ $400,000; 8 = > $400,000. *Research and fellowship support are classed as programmatic support. Sources of programmatic support are disclosed but are not regarded as a relevant relationship with industry for writing group members, advisors, or reviewers.

Reviewer disclosure table

Peer reviewer	Employment	Honoraria/ Speaking/ Consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/ Partnership/ Principal/ Majority stockholder	Stock or stock options	Intellectual property/ Royalties	Other

Number value: 0 = $0; 1 = ≤ $10,000; 2 = > $10,000 to ≤ $25,000; 3 = > $25,000 to ≤ $50,000; 4 = > $50,000 to ≤ $100,000; 5 = > $100,000. *Research and fellowship support are classed as programmatic support. Sources of programmatic support are disclosed but are not regarded as a relevant relationship with industry for writing group members or reviewers.

2.1.2 Documents Originating in Other HRS Committees, subsection, *delete*

Any potential statements, surveys, or documents published by the HRS must undergo peer review and approval through the SCDC. Suggestions for documents arising from other committees must be advanced to the SCDC. In situations where documents or reports arise as part of other initiatives, early communication with the SCDC is required. The initiating committee must also obtain approval from the Executive Committee and the Board of Trustees prior to developing the document.

2.3.2 Members of the Writing Group, 2nd paragraph, *add*

The preponderance of evidence suggests that heterogeneity of thought in a decision-making group leads to better performance. The HRS is committed to improving the quality of clinical documents by increasing the diversity of writing group constituents.

Nonclinical writing group members may include epidemiologists, statisticians, informatics specialists, patients, or consumer advocates.

2.3.4 Management of Relationships with Industry, 1st paragraph, *add*

Participation on the writing committee is dependent upon a review of all relevant RWIs. A majority of the writing committee members must be free of relevant RWIs (exception is made for the Technology Category [see Chapter 12]).

2.5 Evaluation of Relationships with Industry, 1st paragraph, *replace*

Once a document topic and writing group have been approved by the Board of Trustees, the SCDC Chair and HRS SCDC staff liaison identify relevant financial RWIs. A relevant relationship involves subject matter, intellectual property, assets, topics, or issues addressed in the document. The SCDC monitors writing group composition for RWIs, as well as other potential areas of bias or conflicts of interest. Once selected, authors are asked to avoid forming any new relevant RWIs during the writing effort until publication to maintain the balance of the writing group.

with

The HRS has developed policies to minimize the influence of intellectual and financial biases during document development. The HRS recognizes the necessity of involving experts among the members of a writing committee, including those who in some cases have RWI. Once a document topic has been approved by the Board of Trustees, the SCDC Chair and the HRS SCDC staff liaison identify relevant financial RWIs. A relationship may be considered relevant when it involves the same or similar subject matter, intellectual property, assets, topics, or issues addressed in the document. Relevant RWI also may exist when the entity makes a drug, drug class, device, or device class addressed in the document, or when the writing committee member or household member may reasonably be affected positively or adversely by the document content. Regarding the development of clinical practice guidelines, relevant RWI may include industry-funded or -sponsored research. **Final determinations regarding the relevance of**

specific RWI may be made in collaboration with the HRS leadership and/or the Ethics Committee.

Once selected, writing committee members are asked to avoid forming any new relevant RWIs during the writing effort until publication to maintain the balance of the writing group.

The SCDC monitors writing group composition for RWI, as well as other potential areas of bias or conflicts of interest.

2.5   Evaluation of Relationships with Industry, 5th paragraph, *add*

- A majority of the writing committee members must be free of relevant RWIs (exception is made for the Technology Category [see Chapter 12]).

Chapter 13 Focused Clinical Decision Pathways, *new Chapter 13 was added*.

HRS Clinical Document
Development Methodology Manual and Policies

Access the HRS Clinical Document Development Methodology Manual and Policies:
Executive Summary

Access Clinical Resources website