Heart Rhythm Society℠

HRS Scientific Documents Methodology Manual

Endorsed by the HRS Executive Committee: January 2025

www.HRSonline.org

Table of Contents

David S. Frankel, MD, FHRS (Chair),[1] Jayanthi N. Koneru, MD (Vice Chair),[2] Nazem Akoum, MD, MS, FHRS,[3] Michael J. Cutler, DO, PhD, FHRS,[4] Luigi Di Biase, MD, PhD, FHRS,[5] Angela Fix, MPH, MWC,[6] Melanie A. Gunawardene, MD,[7] Roy M. John, MD, PhD, FHRS, CCDS,[8] Jacqueline E. Joza, MD, MS,[9] Ammar M. Killu, MBBS, FHRS,[10] Jeremy P. Moore, MD, MS, FHRS, CCDS, CEPS-P,[11] Naga Venkata K. Pothineni, MD,1[2] John L. Sapp, Jr., MD, FHRS,[13] Konstantinos C. Siontis, MD, FHRS,[10] Pugazhendhi Vijayaraman, MD, FHRS,[14] Xander H.T. Wehrens, MD, PhD, FHRS,[15] and Erica S. Zado, PAC, FHRS[1]

From the [1]Cardiovascular Division, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pennsylvania, [2]Division of Cardiology, Virginia Commonwealth University, Richmond, Virginia, [3]University of Washington, Seattle, Washington, [4]Intermountain Medical Center, Salt Lake City, Utah, [5]Albert Einstein College of Medicine at Montefiore Health System, New York, New York, [6]Heart Rhythm Society, Washington, District of Columbia, [7]Asklepios Hospital St. Georg, Hamburg, Germany, [8]Stanford University, Palo Alto, California, [9]McGill University Health Centre, Montreal, Quebec, Canada, [10]Department of Cardiovascular Medicine, Mayo Clinic, Rochester, Minnesota, [11]UCLA Cardiac Arrhythmia Center, University of California Los Angeles Medical Center, Los Angeles, California, [12]Kansas City Heart Rhythm Institute, Overland Park, Kansas, [13]Queen Elizabeth II Health Sciences Centre, Halifax, Nova Scotia, Canada, [14]Geisinger Heart Institute, Mountain Top, Pennsylvania, [15]Cardiovascular Research Institute, Departments of Integrative Physiology and Medicine (in Cardiology), Baylor College of Medicine, Houston, Texas

Correspondence: documents@hrsonline.org

Abstract

The Heart Rhythm Society (HRS) is committed to advancing scientific knowledge in electrophysiology through development of scientific documents. These documents support HRS's mission to provide evidence-based and timely resources for healthcare professionals involved in heart rhythm care. In conjunction with the Clinical Guidelines Committee, the Scientific Documents Committee (SDC) oversees the process of developing these documents, from topic identification to endorsement and publication, with a commitment to transparency and quality. This methodology manual outlines the structured, yet flexible approach the SDC uses to create scientifically robust documents that address the evolving needs of the field. Built upon best practices from HRS's experience and guidance from standards in evidence synthesis, this manual serves as a comprehensive resource for committee members, authors, and stakeholders engaged in the production of HRS scientific documents.

Chapter 1 Introduction and Definitions

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.

1.2 Purpose and Scope

The HRS Scientific Documents Methodology Manual outlines the processes and standards for the development of scientific documents, such as scientific statements, clinical decision pathways, white papers, and competency/training statements. The objective is to provide a structured, yet flexible, methodology that allows for the timely production of high-quality documents to maintain HRS's leadership in cardiac electrophysiology. Unlike clinical practice guidelines which are overseen by the Clinical Guidelines Committee and require a longer, more rigorous development process, scientific documents are designed to be produced efficiently while still adhering to the principles of evidence-based medicine. **This manual is intended to be a practical resource for the following individuals**:

- Writing committee chairs and members.
- Staff directly and indirectly involved in the document development process
- Health care providers, scientists, trainees, and other stakeholders.

1.3 Definition of Terms

Cardiac rhythm management (CRM) company: A company with at least a portion of its business in a heart rhythm-related field. This includes traditional CRM companies, such as manufacturers of cardiac implantable electronic devices, ablation equipment and medications, but also diversified companies that have, or are developing, a presence in the CRM field, such as software and computer companies.

Industry: A company whose primary business is producing, marketing, selling, re-selling or distributing healthcare products used by or on patients.

Recommendation: Any recommendations in HRS scientific documents that provide expert guidance based on the best available evidence and expert opinion at the time of development. Unlike clinical practice guidelines, which require a systematic review of evidence, these recommendations are formed through an agreement of experts on the writing committee and reflect current understanding, clinical experience, and emerging research. Recommendations are intended to guide healthcare professionals in specific areas where clear evidence may be limited but practical guidance is needed. While they aim to inform practice, they allow for flexibility and should be applied in the context of individual patient circumstances, clinical judgment, existing uncertainties, and evolving evidence.

Relationships with industry (RWI): Any personal, professional, financial, or nonfinancial relationship with an entity that has the potential to introduce actual or perceived bias to Society-related activities (e.g., the development of a Society-sponsored scientific document).

Relevant relationship: A nonfinancial or financial relationship of any amount with an entity involved in the same or similar subject matter, intellectual property, assets, topics, or issues addressed in the document. A relationship may also be relevant 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.

Sponsor: The organization that provides funding, resources, and oversight to support the development of a document.

Writing committee: A multidisciplinary and diverse panel of experts appointed to develop a Society document.

1.4 Types of Documents

Scientific statement: A statement that raises awareness and provides an authoritative summary of the current state of knowledge on specific arrhythmia-related diseases, methodologies, or procedures. These documents are developed by experts, synthesizing available evidence, even when high-quality data are limited. They aim to educate healthcare providers, researchers, trainees, and the public, highlighting trends, emerging science, and future research needs.

Rapid science update: A document providing timely responses to new scientific information and evidence that may not be addressed in existing HRS guidelines or expert consensus statements but could impact patient morbidity or mortality. These updates are concise and developed quickly to address urgent, time-sensitive clinical issues.

Clinical decision pathway: A document that provides focused guidance on specific clinical management areas not covered by other HRS documents, offering practical, point-of-care support. These documents facilitate quick clinical decision-making, using flow charts, tables, and multimedia tools to simplify complex concepts. They address areas where evidence is limited or evolving but do not rely solely on expert opinion.

Appropriate use criteria: A document outlining common clinical scenarios and rating when it is reasonable to perform procedures or interventions in heart rhythm care. These documents aim to guide clinical decision-making and improve patient outcomes by integrating evidence, physician expertise, and cost factors, while allowing room for individualized clinician judgment.

Competency and training statement: A statement that defines the minimum education, training, experience, and technical skills required for healthcare providers to competently provide clinical care and perform EP procedures. These documents focus solely on the training qualifications and ongoing practice standards needed for safe and effective patient care.

Operator and institutional requirements: A document outlining the minimum qualifications for healthcare providers (operators) and the necessary institutional resources required to provide different types of EP care, including procedures. These documents address both the individual operator's training and certification, as well as the institutional infrastructure, equipment, and safety protocols needed to deliver high-quality, safe care.

Data standards: A document defining standardized data elements and corresponding definitions for use in clinical, basic, or translational research, registries, and quality improvement initiatives in the heart rhythm field. These documents create a structured framework to ensure consistency and interoperability in data collection across studies, enabling cross-study comparisons and improving the generalizability of research outcomes to clinical practice.

Health policy statements: A statement outlining HRS's position on key healthcare policies and programs related to electrophysiology. These documents are developed to advocate healthcare standards and regulatory policies that promote high-quality patient care and represent the interests of heart rhythm specialists. They are not intended to define the technical aspects of EP research or provide direct clinical guidance, though they may cover topics related to both.

Chapter 2 Scientific Documents Committee

2.1 Committee Charge

The Scientific Documents Committee (SDC) oversees the development of HRS scientific documents. The committee ensures that topics reflect the needs of the heart rhythm community and align with HRS's strategic objectives.

2.2 Responsibilities

The SDC is charged with the following responsibilities:

- Identify and prioritize topics for scientific documents.
- Appoint diverse writing committees and ensure adherence to HRS methodology.
- Ensure proactive coordination with other HRS committees, such as the Clinical Guidelines Committee, to avoid overlap and maximize impact.
- Review and approve external document endorsements.
- Ensure efficient document development to allow for rapid response to emerging topics.

2.3 Decision-Making Authority

The SDC has the following decision-making authority:

- Establish committee procedures and processes for document creation.
- HRS-led documents:
    - Identify scientific document topics and submit proposals to the Executive Committee for approval.
    - Identify chairs and writing committee members for scientific documents and submit a slate of authors to the Executive Committee for approval.
- External-led documents (HRS is a collaborator):
    - Make decisions on collaborator invitations from external organizations on behalf of HRS.
    - Make decisions on the HRS nominees for writing committees of external-led scientific documents on behalf of the Society (collaborator document only).
- External-led documents (HRS is a partner)
    - Recommend action on partner invitations from external organizations to the Executive Committee.
    - Identify writing committee members for external-led scientific documents and submit a slate of authors to the Executive Committee and Board for approval.
- Review and make endorsement decisions for all external-led scientific documents and communicate the endorsement decision to the Board.

2.4 Committee member responsibilities

Members of the SDC have the following responsibilities:

- **Engagement:** Member participation is measured by meeting attendance, completed reviews, participation in voting, and participation in ad hoc projects. Members should aim to attend a majority of committee calls during the term year.
- **Confidentiality:** Unless otherwise stated, all materials and discussions are confidential and should not be shared outside the SDC.
- **Stewardship:** Members should adhere to organizational and committee-specific policies/procedures and oversee the adherence of writing committees.
- **Disclosure:** Members are required to complete an annual disclosure of their relationships with industry and occasionally to recuse themselves from discussions or decisions on issues related to their relevant disclosures.

The chair and vice chair of the SDC are expected to fulfill all the committee member responsibilities, with the additional responsibility of leading the committee, which includes facilitating discussions, building consensus around committee decisions, and providing timely updates to Society leadership on committee activities.

2.5 Voting Process

The SDC requires a response from at least two-thirds of its voting members to establish a

quorum for committee decisions. Once quorum is met, decisions are made by a simple majority of the responses received.

Chapter 3 Topic Identification and Prioritization

3.1 Topic Identification

Potential topics for scientific documents are identified through continuous input from HRS members, committee discussions, and reviews of emerging clinical, research, or technological trends. The SDC reviews new topic proposals on a continuous basis to ensure timeliness and a consistent pipeline of new projects.

3.2 Criteria for Topic Prioritization

Topic prioritization involves both strategic planning for the future and responding to new circumstances as they develop. Topics are prioritized based on the following criteria:

- Relevance to current clinical and scientific needs.
- Potential impact on patient care and clinical practice.
- Urgency, such as emerging research or technological developments.
- The absence of existing guidelines or documents on the topic.
- Feasibility of rapid development based on available evidence.

3.3 Proposal Approval

Topic proposals can originate from various sources and may be submitted to the SDC as just a topic or a complete proposal using a standardized proposal template. This template ensures that all necessary details are included, allowing for a fair and efficient review process. If a member suggests a topic without completing a proposal form, then the SDC will develop the proposal.

- **Review process:** The SDC regularly reviews and prioritizes document topics/proposals throughout the year. Topics/proposals are evaluated against established prioritization criteria (see section above). After discussion, committee members independently rank each topic/proposal, and those receiving majority support move forward for further consideration.
- **Executive approval:** Once a proposal has been developed and prioritized by the SDC, it is submitted to the Executive Committee for final review and approval before the document development process begins.
- **Non-prioritized proposals:** Topics and proposals that are not prioritized by the SDC or approved by the Executive Committee/Board of Trustees will be maintained in a database and may be reconsidered for prioritization during future review cycles.

3.4 Collaboration with Other Organizations

HRS recognizes the value of collaborating with other professional societies and organizations to develop scientific documents that leverage diverse expertise and perspectives. Collaborations and partnerships with external organizations allow HRS to expand the reach and impact of its scientific documents, ensuring that they reflect the consensus of a broader range of professionals in the field of electrophysiology and related disciplines.

When developing a document, HRS may choose to engage external organizations as partners or collaborators, depending on the goals of the project, the level of involvement from each organization, and the resources required. These partnerships or collaborations enable the development of robust, authoritative documents that are trusted and used by healthcare providers around the world.

- **Benefits of collaboration:** Partnering or collaborating with other organizations enhances the quality and credibility of documents by incorporating multiple viewpoints, sharing expertise, and facilitating broader dissemination.
- **Maintaining HRS standards:** Regardless of the level of collaboration, all documents developed with external organizations are expected to adhere to HRS's standards for scientific rigor, transparency, and neutrality to maintain the Society's reputation for excellence.

3.4.1 Partnership

An HRS partner document involves a joint agreement between HRS and one or more

external organizations, where all partners share equal responsibility in the development and dissemination of the document. Each partnering organization has equal approval weight for the final document, and the names of all partner societies appear in the document's title, with the document-leading organization listed first. This approach ensures a balanced and inclusive process that reflects the collective expertise and interests of each partner.

The following are key characteristics of partner documents:

- **Equal representation:** Each partnering organization has nearly equal representation on the writing committee. This ensures that all perspectives are adequately reflected in the document's content and recommendations.
- **Organizational approval:** All partners must provide organizational approval for the final document before publication. The final document represents a consensus among the participating organizations.
- **Joint ownership and copyright:** The document is jointly owned by all partner organizations, with shared copyright over the content.
- **Cost sharing:** The financial cost of developing the document, including writing committee activities, peer review, and dissemination, is shared equally among all partners.
- **Joint publication:** All partner organizations have the right to publish the final document in their respective journals. Each partner organization's name (abbreviation) is included in the title of the document to reflect equal contribution and ownership.

3.4.2 Collaboration

An HRS collaborator document, in contrast, is led and owned solely by HRS, with collaborating societies contributing in a more limited capacity. Collaborators may appoint writing committee members and participate in document review, but HRS retains final approval and full control over the document's content, financial responsibilities, and dissemination. The names of collaborating organizations do not appear in the title; instead, they are acknowledged in a separate statement on the title page.

The following are key characteristics of collaboration documents:

- **Sole ownership by HRS**: HRS retains sole ownership and copyright over the document, ensuring that HRS is the primary driver of the content and recommendations.
- **Limited representation**: Collaborating organizations typically have 1-2 representatives on the writing committee. Their role is to provide expert input, but the document remains under HRS's control.
- **HRS-exclusive publication**: Only HRS has the right to publish the document in their journal, unless otherwise decided by HRS. Collaborators do not have rights to publish the document in their society's journal.
- **Financial responsibility**: HRS bears all financial costs for the development, review, and dissemination of the document.

Chapter 4 RWI Disclosure and Management

4.1 Collection of RWI

To ensure the integrity of HRS scientific documents, all writing committee members must disclose their RWI prior to and throughout the document development process. The RWI disclosure and management policy for scientific documents is consistent with the HRS Code of Ethics and Professionalism.

4.2 Management of RWI

The management of RWI will be handled on a case-by-case basis for each document, allowing for flexibility in determining which relationships are relevant to the document topic(s). To minimize real or perceived conflicts of interest, writing committee members with significant relevant industry relationships related to the document topic(s) may be recused from discussions and voting (if applicable).

Key principles for managing RWI include the following:

- **Case-by-Case Assessment**: For each document, the SDC will set the criteria for what constitutes as a relevant RWI, based on the specific content of the document. This ensures that decisions regarding conflicts of interest are made with full context and relevance, allowing flexibility to tailor RWI management to the unique needs of each document.
- **Recusal from Discussions or Voting**: Committee members with significant or directly related RWIs may be recused from participating in discussions or voting on sections of the document where the conflict may influence objectivity. This decision will be made collaboratively by the committee chair, vice chair, and HRS staff, in consultation with the SDC.
- **Transparency**: All RWI disclosures and decisions regarding recusal or participation will be made transparently, with disclosure information included in the final published document. This promotes accountability and allows stakeholders to understand the context in which decisions were made.
- **Balanced Representation**: While the majority of the committee does not need to be free from relevant RWIs, the final writing committee composition must ensure a balance of perspectives and that the document reflects unbiased expert consensus.

4.3 Document Funding Sources

HRS scientific documents are developed independently from industry funding. Any external funding or partnerships that support document development must be disclosed in the final document.

Chapter 5 Writing Committee Formation

5.1 Selection of Writing Committee Members

The selection of writing committee members, including chairs and vice chairs, follows a structured and transparent process to ensure alignment with HRS goals:

- **Call for Authors**: HRS will issue a call for authors to its membership. Nominations can be submitted via an online form, allowing members to nominate themselves or other members for consideration.
- **Partner/Collaborator Organizations:** For documents with external partners/collaborators, the organizations will provide a list of nominees (in rank order) for consideration and HRS will make the final selection. The number of representatives is determined by HRS and noted in the partner/collaborator agreement.
- **Review by SDC**: The SDC will review all nominations, considering the expertise, RWI disclosures, and suitability of each nominee based on the document's scope. The SDC will then develop a proposed writing committee slate.
- **Approval by HRS Leadership**: The proposed writing committee slate is reviewed and approved by the HRS Executive Committee.

5.2 Writing Committee Composition

The composition of the writing committee is crucial for ensuring the document reflects diverse perspectives and meets HRS's high standards. Writing committees are formed with the goal of fostering inclusivity and representing the diversity in EP practitioners and patients. To achieve this, the committee should consider:

- **Multidisciplinary expertise:** The writing committee should include individuals with a range of expertise, such as clinicians, allied professionals, researchers, and other non-clinicians such as epidemiologists, statisticians, informatics specialists, patients, or consumer advocates. Nominees are assessed for their proficiency in the subject matter and contributions to the field.
- **Broad representation:** To foster inclusive writing committees, HRS actively considers a spectrum of criteria, including geographical location, institutional affiliation, area of expertise, career level, and other demographics. Writing committees should include members from a variety of backgrounds, experiences, and interests to ensure a well-rounded and representative perspective.

5.3 Writing Committee Size

The size of writing committees is determined by the scope and complexity of the document. While many documents may require up to 12 members, HRS maintains flexibility in the number of members needed, recognizing that some highly specific topics may be more efficiently managed by a smaller committee.

- **Standard Size**: For most documents, writing committees are typically composed of 10 to 12 members, including the chair and vice-chair. This size allows for efficient decision-making, manageable coordination, and division of writing tasks.
- **Smaller Committees**: For documents covering highly specialized topics, the writing committee may consist of as few as 5 to 6 members. In these cases, having fewer members ensures that each contributor plays a meaningful role in the development of the document.
- **Expanded Committees**: For partner/collaborator documents or those requiring broader expertise or representation, the committee size may expand beyond 12 members to accommodate additional participants. This ensures that all collaborating organizations or areas of expertise are adequately represented.

5.4 Writing Committee Responsibilities

Writing committee members are expected to actively contribute throughout the document development process. Key responsibilities include the following:

- **Participation in Regular Meetings**: Members should attend scheduled meetings, which may be held via video conference or in person, to discuss the progress of the document, review evidence, and finalize recommendations.
- **Evidence Review and Appraisal**: Members should critically appraise the available evidence and contribute to evidence-based discussions on the statements/recommendations (if applicable).
- **Drafting Sections of the Document**: Members are responsible for drafting sections based on their areas of expertise and reviewing drafts submitted by others.
- **Voting**: Members participate in consensus-building and voting on key statements/recommendations in the document (if applicable).
- **Adherence to Timelines**: Members are expected to meet deadlines for drafting, reviewing, and finalizing sections, in accordance with the overall project timeline.

5.5 Writing Committee Chair Responsibilities

The chair is responsible for the overall leadership of the writing committee, ensuring that the document development process stays on track and adheres to HRS standards. The chair's responsibilities include the following:

- **Document management**: Overseeing the development of the manuscript, including managing references, addressing peer reviewer and public comments, and ensuring the document progresses according to the established timeline.
- **Leading meetings**: Facilitating writing committee meetings, building consensus, and ensuring productive discussions.
- **Primary liaison**: Communicating primarily with HRS staff to provide updates on document progress and address any logistical or procedural needs. The chair may also communicate with the SDC when invited to provide updates or discuss the document in detail during key stages of development.
- **Conflict management**: Ensuring transparency and managing any conflicts of interest within the writing committee.
- **Drafting key sections**: Taking the lead in drafting and finalizing critical sections of the document, such as the introduction, summary, and conclusions.

5.6 Writing Committee Vice Chair Responsibilities

The vice chair supports the chair in all leadership duties and steps in to lead if the chair is unavailable. The vice chair's responsibilities include the following:

- **Assisting in document management**: Supporting the chair in managing the manuscript, references, and comments, ensuring that tasks are completed on time.
- **Leading sections**: Leading specific sections of the document development process or managing discussions on areas of expertise.
- **Communication support**: Helping to ensure that the writing committee remains on track by facilitating communication between the chair, members, and staff.

5.7 SDC Liaison Responsibilities

Each writing committee will be assigned a liaison from the SDC to ensure adherence to HRS methodology and facilitate communication between the writing committee, SDC, and HRS staff. The SDC liaison plays a critical role in maintaining consistency across all HRS scientific documents. The SDC liaison's responsibilities include the following:

- **Methodology oversight**: Ensuring that the writing committee adheres to HRS methodology and guiding the committee through any procedural questions or challenges.
- **Liaison role**: Communicating regularly with both the SDC and HRS staff, providing updates on the document's progress during SDC meetings and reaching out to HRS staff or SDC

leadership with any questions or concerns about methodology, timelines, or potential conflicts of interest.
- **Support and guidance**: Providing advice on document development tasks such as addressing peer reviewer comments or navigating the publication process. While the SDC liaison will not perform these tasks, they will offer guidance on how to approach them.
- **Writing contributions**: Contributing to the writing of the document as a full member of the writing committee.

5.8 HRS Staff Responsibilities

HRS staff will provide administrative support to the writing committees, ensuring that the document development process runs smoothly. The HRS staff's responsibilities include:

- **Kickoff call**: Attending the initial kickoff call (if needed) to provide guidance and ensure the committee has the tools and information needed to begin the document development process.
- **Peer review and public comment coordination**: Managing the logistical process of peer review and public comments, including recruiting reviewers, collecting feedback, and collating responses.
- **Internal review coordination**: Coordinating the internal review process with the SDC, ensuring the document meets HRS standards before final approval.
- **Periodic check-ins**: Periodically checking in with the writing committee to monitor progress and provide reminders on the timeline for major milestones.

5.9 Authorship

Writing committee members who contribute substantively to the development of the document will be listed as authors. HRS follows established guidelines for determining authorship, including:

- **Significant Contribution:** To be listed as an author, members must contribute meaningfully to the drafting, reviewing, or appraising of the document's evidence.
- **Author Order:** The chair and vice chair are listed as the first and second authors, respectively. All other authors will be listed alphabetically by their last name, ensuring an equitable recognition of contributions.
- **Acknowledgments:** Individuals who contribute to the process but do not meet authorship criteria will be acknowledged in the final document, along with their roles.

5.10 Declaration of RWI

Authors, advisors, and peer reviewers' disclosures of relationships with industry will be published as an appendix in the manuscript.

5.11 HRS Representatives on External Scientific Documents

When HRS participates in scientific documents led by other organizations, it appoints representatives to the external writing committees. HRS representatives' responsibilities include:

- **HRS Perspective:** Representatives ensure that the HRS perspective and interests are reflected in discussions and document content.
- **Compliance with HRS Policies:** HRS representatives must adhere to all HRS policies related to conflict of interest, disclosure, and confidentiality while participating in external writing committees.
- **Reporting Back:** Representatives are required to keep HRS leadership and the SDC informed of key decisions, progress, and any challenges that arise during the document development process.

Chapter 6 Methodology for Document Development

6.1 Document development process

The development process for scientific documents is designed to be agile and streamlined, emphasizing timeliness and clarity. Writing committees should aim to produce, review, and revise the manuscript within 4–7 months (including peer review and public comment), with the full document development process (from topic approval to final submission to the journal) not to exceed 9 months for most document types. The SDC will oversee the development of multiple documents simultaneously, with the target of publishing approximately ten documents per year.

6.2 Scoping and evidence review

The SDC defines the scope of the document during the proposal phase, focusing on critical areas where guidance is needed. In consultation with the SDC, the writing committee chair and members may further refine the scope of the document. Evidence is gathered from available literature, ranging from clinical trials to case series, and may reflect expert consensus when data is limited.

6.3 Recommendations

Not all scientific documents will include formal recommendations. For those that do, the development process will follow a pre-established methodology designed to ensure transparency and consistency. Recommendations will be supported by the best available evidence, which will be summarized in a table format to facilitate interpretation.

Types of recommendations

- **General guidance:** Scientific documents may include general guidance or suggestions based on available evidence, clinical expertise, and emerging data. These recommendations are meant to inform clinical practice and highlight areas for consideration, rather than provide strict directives.
- **Best practices:** Some documents may present recommendations on best practices in specific areas, such as procedural techniques, research standards, or institutional protocols. These recommendations are not prescriptive but aim to guide practice in areas where high-quality evidence may be limited.
- **Consensus-based recommendations:** In cases where the evidence is low-quality or lacking, recommendations may be based on a consensus of clinical expertise. These recommendations reflect the collective judgment of the writing committee and are aligned with current clinical practice standards.

Exclusions

Formal recommendations that appear in clinical practice guidelines, such as those developed using a class of recommendation and level of evidence framework, will not be included in scientific documents. Scientific documents are intended to provide flexible, evidence-informed guidance without the structured grading system used in clinical practice guidelines.

The writing committee will collaborate to reach consensus, and the process for developing and agreeing upon recommendations will be tailored to the document type, ensuring it aligns with the scope and nature of the content.

6.4 Writing the manuscript

The writing committee divides the workload to draft sections of the document, with regular review and feedback cycles to ensure timely progress. Each manuscript outlines the process, evidence, and judgments that support the document's conclusions. While the specific structure may vary depending on the document type, most documents will follow a standard format:

- **Masthead:** Includes the title (document type and topic), author names and affiliations, details of any endorsements, and disclosures of funding sources.

- **Abstract:** Provides a concise overview of the document's main points and key findings.
- **Introduction:** Offers context for the topic, explains the rationale for developing the document, and outlines the central questions or issues addressed.
- **Methods:** When applicable, it explains how the document was developed, including the formation of the writing committee, management of RWI, collection and synthesis of evidence, and the development of any recommendations. Not all document types will require a detailed methodology section.
- **Analysis:** If appropriate, outlines the discussions and decisions of the writing committee, including how evidence was evaluated and applied to form recommendations. This section may not be necessary for all documents.
- **Conclusion:** Summarizes the responses to the key issues or questions raised in the introduction, including any recommendations if applicable, and may identify areas for future research.

Unless otherwise decided, the chair and vice-chair have primary responsibility for compiling the manuscript, with input from other writing committee members, and preparing it for review and journal submission.

6.5 HRS cross-committee collaboration

While the SDC oversees the development of all scientific documents, there may be instances where collaboration with other HRS committees is desired. This collaboration can occur at various stages, including the proposal, writing, and approval processes. The involvement of other committees ensures that the document benefits from additional expertise and perspectives relevant to the subject matter. The SDC will coordinate with these committees to ensure seamless integration of their input and contributions throughout the document development process.

6.6 Publication requirements

HRS-sponsored scientific documents are the intellectual property of the Society and are submitted for publication in HRS journals. Any additional venues for distribution, if applicable, must be reviewed and approved by the SDC, following the models for collaboration defined in this manual.

Chapter 7 Peer Review and Public Comment

7.1 Peer review process

Scientific documents are peer-reviewed by subject matter experts. The peer review period is not to exceed 30 days to expedite feedback while ensuring a thorough review.

7.2 Public comment process

When appropriate, high-impact scientific documents will be made available for public comment, to run concurrently with the peer review period. This period allows stakeholders, including HRS members and the public, to provide input before finalization.

7.3 Response to feedback

The writing committee chair is responsible for addressing all comments received from peer reviewers. Responses to these comments must be documented in a table, which should include the original comment, the chair's response, and any resulting changes to the document. For comments received during the public comment period, the chairs are required to review and consider the feedback but are not obligated to respond to or document each comment.

Chapter 8 Endorsement

8.1 SDC Approval

Before submission to the HRS journal, the SDC must formally endorse each scientific document. Endorsements from external organizations may also be sought if the document has broad relevance.

8.2 Endorsement by Partner/Collaborator Organizations

HRS may seek endorsement from collaborating societies or external bodies. Endorsement processes must align with HRS policies and the strategic goals of each document.

8.3 Criteria for HRS Endorsement of Other Society's Scientific Documents

HRS offers two levels of endorsement for scientific documents from external societies: full endorsement and affirmation of value. For either category, the external document must include full disclosure of relevant RWI for all authors, and no industry participation is allowed in the document's development.

- **Full Endorsement:** Reserved for scientific documents whose key statements/findings align with HRS standards and whose development align with the HRS standards.
- **Affirmation of Value:** Granted to scientific documents recognized by HRS as having educational or scientific value for its members, but which:
  - (a) Were developed using a methodology not fully aligned with HRS standards, or
  - (b) Contain statements or recommendations that significantly differ from existing HRS scientific and/or clinical documents or generally accepted practice in the United States.

Scientific documents may be submitted to HRS for endorsement by related specialty society organizations or through other channels (e.g., members or HRS staff). HRS encourages these organizations to inform HRS of documents in development that may be considered for endorsement. While endorsement does not require HRS involvement in the document's development, the likelihood of endorsement increases with HRS collaboration. The use of the HRS name in the final document must be approved by the Society.

Chapter 9 Currency and Updates

9.1 Evaluating the Document Currency

Scientific documents are considered current for a period of 3–5 years, depending on the topic and developments in the field. Regular reviews are conducted to assess whether updates or retirements are necessary.

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

9.2 Criteria for Updating Documents

A document update may be initiated any time between 2 and 5 years after publication. Documents are updated when significant new evidence, technologies, or practice patterns emerge. An immediate update is triggered if any of the statements in the document are discovered to be harmful to patients. Updates are prioritized according to the criteria described in the topic identification and prioritization section.

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

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

Author Disclosures of Relationships with Industry and Other Entities

Committee member	Honoraria/ Speaking/ Consulting	Speakers' bureau	Research/ Fellowship support*	Ownership/ Partnership/ Principal/ Majority stockholder	Stock or stock options	Intellectual property/ Royalties	Other
David S. Frankel, MD, FHRS (Chair)	• Biosense Webster, Inc. • Huxley Biomedical • Medtronic, Inc.	• None	• None	• None	• None	• None	• None
Jayanthi N. Koneru, MD (Vice Chair)	• Abbott Medical • Baylis Medical Company • Biosense Webster, Inc. • Medtronic, Inc.	• None	• Abbott Medical • Biosense Webster, Inc. • Boston Scientific • Medtronic, Inc.	• None	• None	• None	• None
Nazem Akoum, MD, MS, FHRS	• None	• None	• None	• None	• None	• None	• None
Michael J. Cutler, DO, PhD, FHRS	• Biosense Webster, Inc. • Boston Scientific • Janssen Pharmaceuticals	• None	• None	• Tinuum	• Amplifica • Focused Therapeutics	• None	• None
Luigi Di Biase, MD, PhD, FHRS	• Baylis Medical Company • Biosense Webster, Inc. • Biotronik • Boston Scientific • I-rhythm • Medtronic, Inc. • Stereotaxis, Inc. • Zoll Medical Corporation	• None	• None	• None	• None	• None	• None
Angela Fix, MPH, MWC	• None	• None	• None	• None	• None	• None	• None

Appendix A Author Disclosures of Relationships with Industry and Other Entities

Committee member	Honoraria/ Speaking/ Consulting	Speakers' bureau	Research/ Fellowship support*	Ownership/ Partnership/ Principal/ Majority stockholder	Stock or stock options	Intellectual property/ Royalties	Other
Melanie A. Gunawardene, MD	• Abbott Medical • Biotronik • Boston Scientific • Bristol Myers Squibb • Farapulse • Luma Vision • Medtronic, Inc.	• None	• Boston Scientific • Medtronic, Inc.	• None	• None	• None	• None
Roy M. John, MD, PhD, FHRS, CCDS	• Abbot Medical	• None	• None	• None	• None	• None	• None
Jacqueline E. Joza, MD, MS	• None	• None	• Medtronic, Inc.	• None	• None	• None	• None
Ammar M. Killu, MBBS, FHRS	• Abbott Medical • AtriCure, Inc. • Boston Scientific	• None	• Boston Scientific	• None	• None	• Access Point Technologies	• None
Jeremy P. Moore, MD, MS, FHRS, CCDS, CEPS-P	• Abbott Medical • AltaThera Pharmaceuticals • Johnson and Johnson	• None	• None	• None	• None	• None	• None
Naga Venkata K. Pothineni, MD	• Biosense Webster, Inc. • Boston Scientific	• Medtronic, Inc.	• None	• None	• None	• None	• None
John L. Sapp, Jr., MD, FHRS	• Biosense Webster, Inc. • Medtronic, Inc. • Varian Medical Systems	• None	• Abbott Medical • Biosense Webster, Inc.	• None	• None	• None	• None
Konstantinos C. Siontis, MD, FHRS	• AskBio • EBAMed SA	• None	• Anumana • Varian Medical Systems	• None	• None	• Anumana	• None
Pugazhendhi Vijayaraman, MD, FHRS	• Abbott Medical • Biotronik • Boston Scientific • Medtronic, Inc.	• None	• Medtronic, Inc.	• None	• None	• None	• None

Appendix A Author Disclosures of Relationships with Industry and Other Entities

Committee member	Honoraria/ Speaking/ Consulting	Speakers' bureau	Research/ Fellowship support*	Ownership/ Partnership/ Principal/ Majority stockholder	Stock or stock options	Intellectual property/ Royalties	Other
Xander H.T. Wehrens, MD, PhD, FHRS	• None	• None	• None	• None	• None	• None	• None
Erica S. Zado, PAC, FHRS	• iRhythm Technologies	• None	• None	• None	• None	• None	• None

This table is a comprehensive list of the relationships with industry (RWI) and other entities disclosed by the authors at the time that the document was under development. Please refer to the HRS Code of Ethics and Professionalism for definitions of disclosure categories or additional information about the HRS policy on the disclosure of RWI.