
Julia H. Indik, MD, PhD, FHRS,* Kristen K. Patton, MD, FHRS,† Marianne Beardsall, MN, FHRS, CCDS,‡ Carol A. Chen-Scarabelli, ARNP, MSN, PhD,§ Mitchell I. Cohen, MD, CCDS, CEPS, FHRS,‖ Timm-Michael L. Dickfeld, MD, PhD, FHRS,¶ David E. Haines, MD, FHRS,‖ Robert H. Helm, MD, FHRS,** Kousik Krishnan, MD, FHRS,†† Jens Cosedis Nielsen, MD,‡‡ John Rickard, MD,§§ John L. Sapp, Jr., MD, FHRS,|| Mina Chung, MD, FHRS***

From the *University of Arizona, Sarver Heart Center, Tucson, Arizona, †University of Washington, Seattle, Washington, ‡Southlake Regional Health Centre, Newmarket, Ontario, Canada, §VA Ann Arbor Healthcare System, Ann Arbor, Michigan (Dr. Chen-Scarabelli is now with the hunter Holmes McGuire VA Medical Center, Richmond, Virginia), ‖Phoenix Children’s Hospital, Phoenix, Arizona, ||University of Maryland School of Medicine, University of Maryland Hospital, Baltimore, Maryland, **William Beaumont Hospital, Division of Cardiology, EP Services, Royal Oak, Michigan, ††Rush University Medical Center, Chicago, Illinois, §§Aarhus University Hospital, Aarhus, Denmark, §§§Cleveland Clinic, Cleveland, Ohio, and ||| QEII Health Sciences Centre, Halifax, Nova Scotia, Canada.

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 and approval from the HRS Executive Committee and the Board of Trustees. As of May 2017, the HRS has produced more than 80 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 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.

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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 to other entities (eg, the U.S. Food and Drug Administration [FDA], industry, and health care providers), on timely issues in need of new or updated guidance. This document is a summary detailing the key points of the current policies for the development of clinical practice documents, as evaluated by the Scientific and Clinical Documents Committee (SCDC). The full version of the HRS Clinical Document Development Methodology Manual and Policies is available on the Society’s website (http://www.hrsonline.org).

Address correspondence: Dr Julia H. Indik, University of Arizona, Sarver Heart Center, 1501 N Campbell Ave, Tucson, AZ 85724. E-mail address: clinicaldocs@hrsonline.org.
Chapter 1 Overview of the Clinical Document Development Process

1. HRS-led document development proceeds from identification of the topic, establishment of the writing committee Chair and Cochairs, document outline and assignments, evidence review, consensus recommendation development, public comment on recommendations, and writing of the text, tables, and figures. The document then proceeds through internal review (the SCDC and HRS), external review, and the endorsement process, followed by presentation at the HRS Scientific Sessions and publication (Figure 1).

2. Clinical practice guidelines require a systematic review to support at least one recommendation. Expert consensus statements are not based on a systematic review of the evidence and therefore do not meet a standard of a guideline. Both types of documents, and the recommendations they contain, must be informed by an evidence review. Recommendations supported only by expert opinion are permitted but should be limited.

3. Clinical practice documents include clinical practice guidelines, expert consensus statements, scientific statements, clinical competency statements, task force policy statements, and proceedings statements.

Chapter 2 Initiating Clinical Documents

1. When collaborating with other organizations, the Society has a strong preference for working with societies that are regional (multinational) in representation. 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.

2. All document topics are proposed by the SCDC and submitted to the Executive Committee and the Board of Trustees for ultimate approval.

3. There are three tiers of document involvement by the societies:
   a. Partnership—a joint agreement between two or more societies with equal approval weight for the final document. The names of all partnering organizations are included in the title of the document with the document-leading organization listed first.
   b. Collaboration—collaborating societies appoint writing committee members and review the document, but with final approval granted by the lead society or partner. The names of collaborating organizations are not listed in the title but are noted in a separate statement on the title page.

Figure 1 Clinical Document Development Process.
<table>
<thead>
<tr>
<th>Study name or author</th>
<th>Year</th>
<th>PubMed PMID</th>
<th>Study type</th>
<th>Study size</th>
<th>Inclusion criteria</th>
<th>Endpoints</th>
<th>Findings</th>
<th>Outcome results</th>
<th>Limitations</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wilkoff et al.</td>
<td>2011</td>
<td>20933098</td>
<td>Prospective, RCT, MCT</td>
<td>464 with PM, 9-12 weeks post-PM implant within 1 month after</td>
<td>Complication during MRI or within 1 month after (complication = adverse event that resulted in an invasive intervention or the termination of significant device function)</td>
<td>Pacing capture threshold and sensed electrogram amplitude changes were minimal and similar between study groups</td>
<td>No MRI-related complications occurred during 226/226 (100%) or after MRI 211/211 (100%)</td>
<td>One-sided 97.5% CI of 98.3%. When analyzed against the comparison rate of 90%, ( P, .001 )</td>
<td>Use of MRI scanners on PM patients was specifically limited to well-defined anatomic regions</td>
<td>EnRhythm SureScan Medtronic; 1.5T MRI; max SAR 2 W/Kg; brain/ lumbar MRI sequences</td>
</tr>
</tbody>
</table>
c. Endorsement—the HRS may seek endorsement from other societies that have joined neither in partnership nor in collaboration. They do not conduct peer review or suggest changes. Endorsing societies are acknowledged in a separate statement on the title page.


a. The writing committee Chair and one Cochair may not have relevant relationships with industry.

b. No member of the writing committee may own equity interests, stocks, or stock options or have ownership, partnership, or principal interests in a financially interested enterprise, excluding mutual funds.
Table 2 Example of Recommendation with Class, Level of Evidence, Supporting References, and Supporting Text

<table>
<thead>
<tr>
<th>COR LOE</th>
<th>Recommendations</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIa C-LD</td>
<td>For the patient with an MR nonconditional CIED, it is reasonable to perform repeat MRI when required without restriction regarding the minimum interval between imaging studies or the maximum number of studies performed.</td>
<td>8,52,57,61</td>
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</tbody>
</table>

It is reasonable to perform repeat MRI when required without restriction regarding the minimum interval between imaging studies or the maximum number of studies performed. Studies that included patients with multiple MRI scans have not shown changes in device function related to the number of MRI scans performed or interval between studies.5,52,57,60

that may hold such stock in its portfolio, or have the potential to profit financially from the recommendations of the document.

5. 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 in the scientific documents.

Chapter 3 Determining the Scope, Clinical Objectives, Outline, and Writing Group Assignments

1. The scope of the document defines the target condition or procedure, patient or clinical presentation, intended audience and practice setting, interventions and outcomes.
2. Primary authors are assigned to the sections within the document outline. If feasible, the Chair is encouraged to select primary authors who are free of relationships with industry, particularly for sections that present recommendations. The document outline is presented to the SCDC for review.
3. It is critical to adhere to the document timeline. The SCDC liaison, who is a member of the writing committee, reports to the SCDC Chair and will assist with the mediation of any difficulties.

Chapter 4 Supporting with Evidence

1. Guidelines require a systematic review (either performed for that document or already existing) to address key components; otherwise, the clinical document will be categorized as an expert consensus statement.
2. Literature searches should focus on evidence to support recommendations and be categorized by quality of the evidence, with the highest quality being well-performed, randomized controlled trials. Case studies or opinion documents may be helpful as references to support the text but not to support the recommendations.
3. All evidence used to support the recommendations must be summarized in an evidence table, according to a prescribed template (Table 1) that includes description of the study type, inclusion and exclusion criteria, findings including statistical results, limitations, and other comments.

Chapter 5 Writing Recommendations

1. Recommendations stem from the review of evidence. Committee members should avoid the temptation to formulate a recommendation and then search for evidence to support that idea. The evidence review comes first.
2. The ACC/AHA COR/LOE (American College of Cardiology/American Heart Association Class of Recommendation/Level of Evidence) classification scheme is to be used to assign a COR and LOE (Figure 2).
3. Recommendations should be stand-alone text written in complete sentences and using the appropriate terminology (from the ACC/AHA COR/LOE classification scheme). There should be a brief paragraph of text that summarizes the evidence used to support the recommendation and references. An example is shown in Table 2.
4. Recommendations must be agreed upon by a minimum percentage of the writing committee members (at least 67%). This minimum percentage for consensus is determined by the Chair and is stated in the introduction of the document.
5. If a recommendation is discordant with a recommendation in a previously published HRS-led document, the reasoning for the change should be clearly detailed.

Chapter 6 Writing Group Discussions and Consensus Development

1. Clinical practice documents are created by a process of consensus, with a predetermined threshold of consensus for each recommendation.
2. Recommendations should be consistent across HRS clinical practice documents, unless the field has advanced scientifically.
3. All recommendations are subjected to anonymous vote.
4. The writing committee will be asked to give formal approval of the document before proceeding to peer review.
Chapter 7  Peer Review and Endorsement

1. Peer review is a fundamental aspect of the clinical practice document development process and includes a review by the SCDC, a review by official HRS-appointed peer reviewers, and an external review by collaborating societies.

2. Once the SCDC approves the clinical practice document, it is sent to the Executive Committee with a recommendation for endorsement; after confirmation by the Executive Committee, it is sent to the HRS Board of Trustees. A two-thirds vote of approval by the Board of Trustees is needed for endorsement.

3. Following endorsement by the HRS Board of Trustees, the document can be sent for endorsement by external societies.

Chapter 8  Publication and Presentation

1. Clinical practice documents initiated by the HRS are published in HeartRhythm.

2. Documents from external societies that are endorsed by the HRS can be considered for publication in HeartRhythm on a case-by-case basis by the HRS and the Editor-in-Chief of HeartRhythm.

Chapter 9  Dissemination and Implementation of Clinical Practice Documents: Development of Educational Content

1. Better implementation of clinical practice document recommendations is critical to improving patient care.

2. Implementation depends on writing clear and usable recommendations with measurable outcomes.

3. Implementation is also strengthened by planning throughout the clinical practice document development process, and involvement of patient and policy experts as well as scientific and medical experts.

Chapter 10  Focused Updates or Revisions to Clinical Practice Documents

1. A focused update or revision to a prior clinical practice document is considered by the SCDC when new published evidence has a significant impact on the previously published recommendations or there is a compelling reason to change the scope or focus.

2. Focused updates and revisions are managed in the same way as a new guideline or consensus statement.

Chapter 11  HRS Endorsement Policy of Externally Developed Clinical Practice Documents

1. When documents are submitted to the HRS for consideration of endorsement, the SCDC will evaluate these documents and make a recommendation to the Executive Committee and the Board of Trustees. External clinical practice documents include partner, collaborator, and endorsement-requested documents.

2. Externally developed documents that adhere to or exceed the rigor of the HRS Clinical Document Development Methodology Manual and Policies are eligible for full endorsement. Documents that do not fulfill these criteria may be eligible for Affirmation of Value. In the case of Affirmation of Value, the HRS may not agree with every recommendation or statement in a document but considers the document to be of educational value to its members.

Appendix 1  Author Relationships with Industry and Other Entities (Relevant)

<table>
<thead>
<tr>
<th>Committee member</th>
<th>Consultant/Advisory board/Honoraria</th>
<th>Speakers' bureau</th>
<th>Research grant</th>
<th>Fellowship support</th>
<th>Stock options/Partner</th>
<th>Board Mbs/Other</th>
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<tbody>
<tr>
<td>Julia H. Indik, MD, PhD, FHRS</td>
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<td>Timm-Michael L. Dickfeld, MD, PhD, FHRS</td>
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