2026 Methodology Manual and Policies of the ACC/AHA Joint Committee on Clinical Practice Guidelines

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Table of Contents

What is New

Table 1 highlights new and/or substantially revised sections since the last iteration of the guideline methodology manual and is not a comprehensive list of all updates.

Table 1. What Is New

New or Revised	Section Title	Summary of Changes or Additions
Revised	Section 3.4.5. Writing Committee Approval	Text revised to include change to consensus threshold from >51% to >75%.
New	Section 3.7. Phase 4. Post-Publication Surveillance Review and Guideline Revision	New section on Phase 4 Post-Publication (Section 3.7.) added, which includes the following subsections: 3.7.1. Purpose and Scope 3.7.2. Surveillance Review Process 3.7.3. Criteria for Considering Guideline Updates or Revisions 3.7.4. Proposal Development, Adjudication, and Reaffirmation 3.7.5. Guideline Update and Revision Pathways 3.7.6. Documentation, Transparency, and Dissemination 3.7.7. Continuous Process Evaluation

Preface

In this update of the "2010 Methodology Manual and Policies From the ACCF/AHA Task Force on Practice Guidelines", the document describes the approach that the American College of Cardiology (ACC) and American Heart Association (AHA) employ to develop evidence-based, clinical practice guidelines. The creation of these clinical practice guidelines has been a joint activity between the ACC and the AHA since the 1980s. The development of these guidelines is evidence-based, transparent, and systematic based on review of comprehensive literature searches by experts from the cardiovascular community. Guidelines advance the missions of both organizations by creating an official policy of clinical recommendations to clinicians for the purpose of improving cardiovascular health.

Over a series of meetings in 2019, ACC leadership, AHA leadership, Joint Committee on Clinical Practice Guidelines (Joint Committee) members, key staff from ACC and AHA, and invited individuals from previous guideline development efforts, engaged in strategic discussions on optimizing evidence-based clinical practice guidelines. In response to the needs of the cardiovascular community for up-to-date, evidence-based guideline recommendations and in response to concerns on the time it takes to publish guidelines thereby missing to incorporate recently published clinical trials, the ACC and AHA through the Guideline Optimization efforts identified several areas for improvement and developed a multi-year plan to address operational issues, making recommendations to achieve the goal of producing guidelines that are trustworthy, timely, and accessible.

1. Introduction

This document is divided into a "Background" section and a "ACC/AHA Guideline Development Methodology" section followed by a "Appendices and Supporting Documents" section. The "Background" section reviews the background and history of ACC/AHA guidelines, as well as the ACC/AHA missions, governance, values and principles related to guideline development, format of guideline documents, and guideline optimization. The "ACC/AHA Guideline Development Methodology" section describes how the processes of ACC/AHA guideline development are applied to ensure there is consistency across all

guidelines. The "Appendices and Supporting Documents" section provides a more detailed look at the processes and methodology followed during guideline development. The audience of this document is intended to include guideline developers, panelists, and other stakeholders in guideline development and implementation, but it is not intended to be an all-encompassing document on the processes and procedures used in the development of ACC/AHA clinical practice guidelines.

2. Background

ACC/AHA clinical practice guidelines are intended to assist clinicians in clinical decision making by describing a range of generally acceptable approaches for the evaluation and diagnosis, prevention, or management (includes medical therapy, treatment, and surgical interventions) of specific diseases or conditions. The goal is to define practices that meet the needs of most patients in most circumstances. The guidelines reflect a consensus of expert interpretation of current, high-quality, scientific evidence.

ACC/AHA guidelines are written for the general cardiovascular clinician. Secondary audiences include regulatory and payer organizations. While the aim of guidelines is to inform patient care based on the published available evidence, they are not intended to replace nuanced clinical judgment in patient care. The following, non-exhaustive list includes important common uses of ACC/AHA clinical practice guidelines:

- Improve patient outcomes
- Identify gaps in the evidence base
- Influence public policy
- Inform performance measures and appropriate use criteria
- Promote efficient use of resources
- Reduce practice variation
- Synthesize latest clinical research

2.1. History of Guidelines and ACC/AHA Guidelines

The ACC and AHA have jointly developed clinical practice guidelines since the 1980s in response to the demand for clarity surrounding the ever-accumulating evidence and treatment options for cardiovascular disease. In compliance with stated standards from institutions such as the National Academies of Sciences, Engineering, and Medicine, the ACC/AHA Joint Committee on Clinical Practice Guidelines (Joint Committee) frequently analyzes, updates, and improves the methodology of its guidelines,[1,2] which is also on the basis of internal reevaluation of the state of the art, clinical research design, and conduct. Similarly, presentation and delivery of guidelines are reevaluated and modified in response to evolving technologies and other factors to optimally facilitate dissemination of information to clinicians at the point of care.[3] Recommendations for improvement in the areas of inclusion of patient representatives on guideline writing committees (WCs) and the use of standardized criteria and a protocol for conducting systematic reviews[4] have also been incorporated into the methodology for ACC/AHA guideline development.

2.1.1. Inclusion of Patient or Lay Stakeholder Representatives

The Joint Committee appoints at least 1 patient or lay stakeholder representative to participate on each guideline WC. Currently, the patient or lay stakeholder representative assignments and processes have been streamlined and can be found under Patient or Lay Stakeholder Representatives in Appendix 1.

2.1.2. Use of Standardized Criteria and Protocols for Systematic Reviews

A formal systematic review (SR) of the evidence is performed when warranted by the available evidence using a focused approach to a well-defined topic. Based on the work done by the Joint Committee on Guideline Optimization, a workgroup revised the criteria for determining when an SR is warranted in 2023. Evidence Review Committees are commissioned if the SR criteria are met based on WC and Joint Committee deliberations (see Appendix 2 and Appendix 3). The criteria for determining when an SR is warranted were reevaluated and revised based on the principles espoused by the Institute of Medicine, as outlined in Appendix 4.[2]

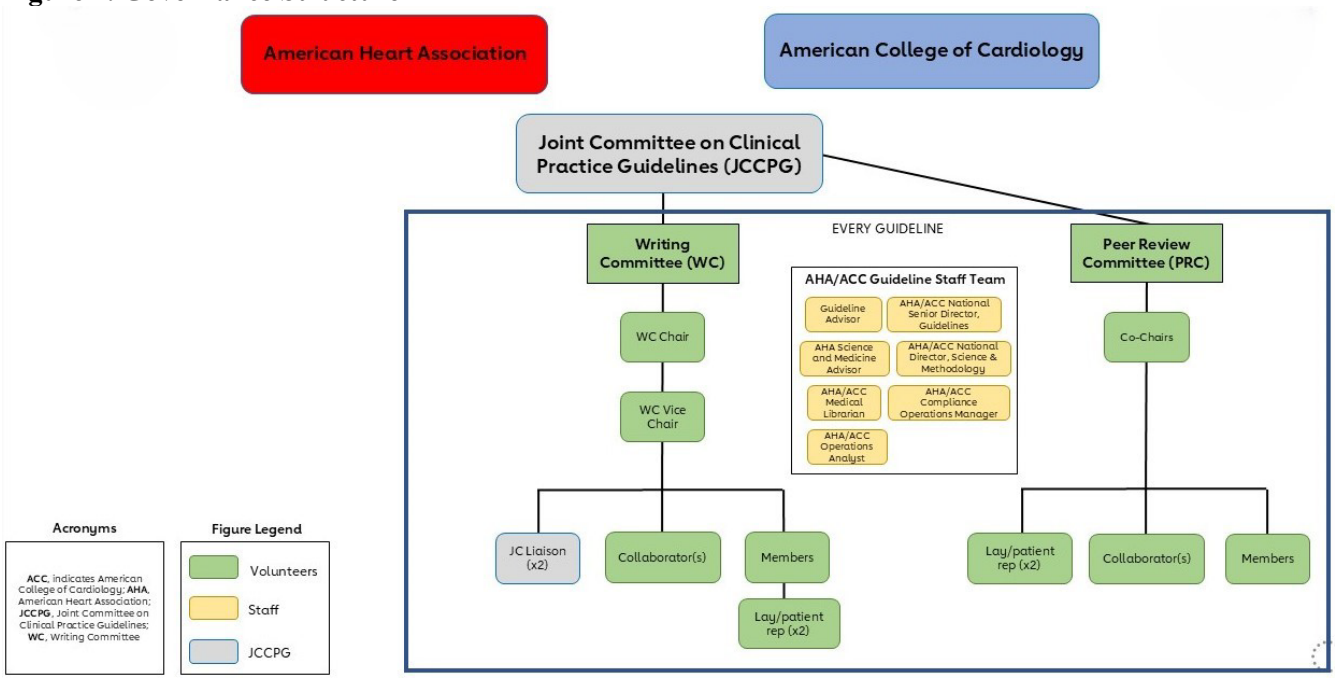
2.2. Alignment of ACC/AHA Missions With Guidelines

The ACC and AHA are committed to transforming cardiovascular care and improving heart health for all (ACC Mission Statement)[5] and to being a relentless force for a world of longer, healthier lives. As we move into the second century of our work, we are advancing health and hope for everyone, everywhere (AHA Mission Statement).[6] As such these guidelines reflect the best interpretation of the best evidence to achieve these goals.

2.3. Guideline Governance

ACC/AHA clinical practice guidelines are governed by the ACC/AHA Joint Committee on Clinical Practice Guidelines (referred to as the Joint Committee). The Joint Committee is responsible for delegating individual WCs to construct guidelines to promote the optimal evaluation, management, and prevention of cardiovascular disease with emphasis on patient wellness and shared decision-making where appropriate. The Joint Committee is comprised of members who represent ACC and AHA's diverse membership groups and professional specialties and includes members who have prior experience as guideline authors or peer reviewers (at a minimum). The Joint Committee consists of a core of 16 members including the Chair, Chair-Elect, and 14 voting members. The Chair and Chair-Elect are appointed in the same year and serve a 2-year term. The Chair serves 1 non-renewable 2-year term, and the Chair-Elect becomes the Chair at the end of the current Chair's term. Seven of the voting members are appointed by ACC and 7 are appointed by AHA. At least 1 of the 14 voting members appointed to the Joint Committee is a Fellow-in-Training (FIT) or an Early Career (EC), and the appointment of these members rotates between the 2 organizations. All voting members except for FIT and EC members are appointed to 2-year terms with the opportunity for reappointment, for a maximum of 4 consecutive years. FIT and EC appointees are eligible for 1 non-renewable, 2-year term. The processes for the nomination and approval of Joint Committee member candidates are determined by existing ACC and AHA policies. Additional information regarding the structure and charge of the Joint Committee can be found in the charter in Appendix 5. The Governance Structure is depicted in Figure 1.

Figure 1. Governance Structure



2.4. Values and Principles of Recommendation Formulation

All guidelines are developed under a set of principles and values that inform an evidence-based benefit and harms clinical decision. The principles used in the development of ACC/AHA recommendations are:

- Transparency
- Evidence-based
- Patient Centered

The primary approach to recommendation formulation is a critical evaluation of the published scientific evidence to support a specific diagnostic or treatment approach for each medical condition, with levels of evidence as defined below. Some recommendations may be based on clinical experience and expertise when the evidence base is inadequate, however, recommendations based only on clinical experience are avoided whenever possible. These knowledge gaps are highlighted in each guideline document.

ACC/AHA guidelines are intended to be comprehensive, patient centered, and actionable. There are many situations including comorbidities that might be outside the scope of the recommendations and not all clinical situations can be anticipated. While the guidelines endeavor to provide sound guidance in areas where there may be gaps in knowledge, they do not replace expert clinical judgment.

In addition to survival and major adverse events, other values that may be included in the recommendation development process, and detailed when they apply, are:

- Symptom relief
- Quality of life
- Patient reported outcomes
- Shared decision-making and multidisciplinary care
- Cost
- Comparative effectiveness

While the ACC/AHA guidelines have multiple audiences and uses, primarily they are intended to aid in clinical decision making. Collaboration with the patient, sharing values and clinical reasoning, and including patients in decision making are encouraged in all clinical situations.

2.5. Guideline Documents

2.5.1. Structured Publication Format

The ACC and AHA guidelines are presented in a standardized format for all guidelines with each set of recommendations for a specific disease state including sections on (1) evaluation and diagnosis, (2) prevention, and (3) management (includes medical therapy, treatment, and surgical interventions). Guidelines are not meant to be review articles or textbook chapters, instead the central focus is the recommendations themselves which are supported by evidence tables, brief explanatory text for each recommendation, and a short synopsis for each section. Basic principles that apply across all guidelines–such as primary prevention of cardiovascular disease, shared decision-making and multidisciplinary teams–are summarized in a separate document rather than being included in each guideline. This modular format will allow digital integration of all guidelines in the future.[7,8]

2.5.2. Class of Recommendation and Level of Evidence

The Joint Committee continually reviews, updates, and amends its guideline development methodology on the basis of *de novo* research by the in-house methodologists, its methodology summit,[4] and the published standards from organizations, including the IOM, now known as the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine (the National Academies).[1,2] In particular, the Joint Committee recognizes the need to rigorously reevaluate its approaches according to consensus-based standards from the National Academies and the immense experience brought to producing these authoritative documents in the field.

In this context, the ACC and AHA begin with ensuring compliance with National Academies' standards for developing clinical practice guidelines (CPGs). In 2011-2012, the ACC and AHA convened a methodology summit resulting in the publication of a summit report in 2013.[4] The summit confirmed the ACC and AHA's compliance with National Academies standards and highlighted the need for innovative approaches to maintaining compliance.[4] These CPG standards are summarized on the National Academies website (http://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Report-Brief.aspx).

Building upon the National Academies standards, the ACC and AHA provide granular frameworks on Class of Recommendation (COR) and Level of Evidence (LOE) pertinent to the CPGs, as shown in Table 2. However, for certain areas, the ACC and AHA have further enhanced methodology to account for findings and experience gathered through methodology summits and internal discussions and approval through the Joint Committee.[3] In these areas, the ACC and AHA's goal is to maintain concordance with the National Academies Health and Medicine Division recommendations and build upon them, by placing a recommendation aside its proposed actions and current actions taken. These areas include managing conflicts of interest (relationships with industry and other entities), inclusion of patient representatives, comprehensive evidence/systematic reviews, and peer review processes.

Table 2. Applying American College of Cardiology/American Heart Association Class of Recommendation and Level of Evidence to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care* (Updated December 2024)

2.5.3. Cost and Value Analyses

Evaluations assessing the costs of implementing guidelines compared with the value added by implementation are encouraged whenever feasible. The ACC and AHA have developed methodology guidance to help with such analyses, which can be found using the following link: https://doi.org/10.1016/j.jacc.2025.05.009.[9,10] These assessments allow a more tangible recognition of the use of the guidelines (see Table 3).

Table 3. Mock-Up of Economic Value Statements

A. Economic Value Statements (adapted from existing ACC/AHA guidelines, with additional information obtained from key publications)

COR	LOE	Recommendation
1	A	In patients with symptomatic chronic heart failure with reduced ejection fraction, SGLT2 inhibitors are recommended to reduce hospitalization for heart failure and cardiovascular mortality, irrespective of the presence of type 2 diabetes.[11]
Economic Value: Cost-Effective (High Level of Certainty)		In patients with heart failure with reduced left ventricular ejection fraction, addition of an SGLT2 inhibitor to guideline-directed medical therapy at 2024 prices is projected to be a cost-effective strategy compared with prior guideline-directed therapy. OR In patients with heart failure with reduced left ventricular ejection fraction, addition of an SGLT2 inhibitor to guideline-directed medical therapy at a cost of $4,192 per patient per year is projected to be a cost-effective strategy compared with prior guideline-directed therapy, with an ICER of $68,300 per QALY gained (<$120,000 per QALY gained in 97% of probabilistic simulations).[12]
1	A	In patients with chronic coronary disease, high-intensity statin therapy is recommended with the aim of achieving a ≥50% reduction in low-density lipoprotein cholesterol levels to reduce the risk of major adverse cardiac events.[13]
Economic Value: Cost-Saving (High Level of Certainty)		In patients with chronic coronary disease, the use of generic formulations of maximally tolerated statin therapy is projected to be cost-saving compared with not using statin therapy.[14]

B. Mock-Up Economic Value Statements (not based on current ACC/AHA guidelines)

Economic Value: Not Cost-Effective (High Level of Certainty)	In patients with transthyretin amyloid cardiomyopathy, treatment with tafamidis at an annual price of $225,000 per person per year is projected to be not cost-effective compared with placebo, with an ICER of $880,000 per QALY gained (<$120,000 per QALY gained in 0% of probabilistic simulations). The use of tafamidis in transthyretin amyloid cardiomyopathy would be cost effective compared with placebo at a threshold of $120,000 per QALY gained if the cost of tafamidis is <$20,700 per year.[15]
Economic Value: Indeterminate (Insufficient Evidence)	In patients with a body mass index ≥27 kg/m^2 and established atherosclerotic cardiovascular disease but without diabetes, the cost effectiveness of semaglutide for secondary prevention of cardiovascular disease is uncertain.

ICER indicates incremental cost-effectiveness ratio; and QALY, quality-adjusted life year.

2.6. Guideline Optimization and Living Guidelines

In 2019, the ACC and AHA embarked on an optimization initiative to address the concerns from guideline readers, AHA members, and ACC members, and set the stage for modernizing our guideline documents. The standards and oversight process set by the Joint Committee establishes the foundation necessary to enhance timeliness, trustworthiness, and accessibility,[16] and lays the foundation for the Living Guidelines Model. The overall Living Guidelines effort is for the development of guidelines that are trustworthy, timely, and accessible by:

- Making timely updates to guideline content in response to critical practice-changing evidence.

Reducing the time and effort to develop guidelines (volunteers and staff).

- Supporting a consistent process for creating guidelines and a consistent set of outputs.
- Enabling content to be created and updated as "structured content" rather than published documents (eg, journal articles, in PDF files).

- Facilitating publication in a journal format.
- Ensuring content can be retrieved in formats for other uses (ie, derivatives other than journal publication).

There is a need for the guideline processes—from pre-production review, to consensus building and document writing, to peer review and approval, to dissemination—to be timelier and more efficient to keep up with the changing technological landscape, the speed and quantity of new research, and the corresponding needs of the cardiovascular community.[17] To realize the goals laid out through the guideline optimization initiative and to carry out the plan for a living guidelines model, ACC and AHA are developing a living guidelines platform to facilitate the development and continual update of guidelines. The living guidelines platform will be a cloud-based resource that will improve efficiency and time to publication for creating clinical practice recommendations for patients affected by cardiovascular diseases. This project will focus on implementing a work or project management system, a structured content management system, and a volunteer and relevant company management system. These tools in combination will provide significant process and efficiency improvements to both the joint guidelines staff and the volunteers who author, edit, review, and approve the guidelines.

3. ACC/AHA Guideline Development Methodology

The ACC/AHA guideline development process includes a rigorous approach: (1) identifying and defining the scope of clinical topics, (2) reviewing and conducting ongoing surveillance of the evidence base, (3) selecting of multidisciplinary WCs, (4) developing of PICO(TS) recommendations classified by strength of the recommendation and level of evidence, (5) applying a standardized publication style using a modular format, (6) implementing an iterative review process, (7) obtaining formal approval from the ACC and AHA, and (7) collaborating with other societies to ensure stakeholder representation and facilitate guideline implementation. The core principles summarizing the best practices and common elements employed in the guideline development process are presented in the "2025 ACC/AHA Guideline Core Principles and Development Process", which can be found using the following link: https://doi.org/10.1016/j.jacc.2025.06.013.[3] The paper will be referenced in subsequent guidelines as a concise explanation of the guideline development processes.

The ACC/AHA guideline development process is defined by four phases (Figure 2): Phase 0. Pre-Production, Phase 1. Document Development, Phase 2. Review and Approval, and Phase 3. Publication. Phase 0 includes WC formation, outline completion, relationships with industry (RWI) mapping, completion of WC assignments, and appointment of peer review committee (PRC) co-chairs. Phase 1 includes a comprehensive literature search, evidence synthesis, the evolution of evidence findings into recommendations, and the compilation of the guideline manuscript. Phase 2 encompasses peer review and approval by the WC and the Joint Committee. Finally, in Phase 3, the manuscript undergoes organizational approval and endorsement by the collaborator organizations, before being submitted to the ACC and AHA journals for publication.

Figure 2. Phases of ACC/AHA Guideline Development

3.1. Topic Selection

The Joint Committee maintains a portfolio of roughly 20 guideline topics that pertain to evaluation and diagnosis, prevention, and management (includes medical therapy, treatment, and surgical interventions) of patients with cardiovascular conditions. These topics are reviewed at least twice per year by the Joint Committee and staff to identify and evaluate any new clinical trial evidence available and decide which topics will be selected for the next revision. Once the guideline topic selection form has been completed for all topics, the Joint Committee will review and determine the priority order for project development. The surveillance process feeds into the topic prioritization process. The guideline topic selection form is available in Appendix 6. The surveillance process is described further in Section 3.7.

3.1.1. Maintenance Surveillance

In addition to the topic prioritization process, the ongoing surveillance of topics addressed in guidelines that are part of the guideline portfolio is conducted by a Surveillance Committee. The methodology followed by the Surveillance Committee is outlined in Section 3.7., Phase 4.

3.2. Clinical Questions PICO(TS) Format

The Joint Committee encourages WCs to use the PICO(TS) format wherever possible to define critical questions that lead to recommendations. See Table 4 for more information regarding the PICO(TS) format. This results in a more comprehensive and usable recommendation, especially for therapeutic and diagnostic-based topics. The literature searches are performed by the WC authors with help from staff (see Appendix 7 for the Literature Request Form). The authors then create evidence tables and analyze the evidence independently. Recommendations are then written based on the synthesized conclusions and finalized by the WC. More information on clinical question generation can be found in Appendix 8.

Table 4. PICO(TS) Table

Population*	**I**ntervention†	**C**omparator‡	**O**utcomes§	**T**iming‖	**S**etting¶
Group of people to be investigated	Treatment to be tested	The main alternative to the intervention	Expected result to be accomplished	Duration of treatment	Locale of the treatment

*Patient, Population, or Problem (P): Patient(s) of interest. It includes the condition(s), populations or subpopulations, disease severity or stage, comorbidities, and other patient characteristics or demographics. †Intervention or Exposure (I): Specific treatments or approaches with the patient or population. It includes dose, frequency, method of administering treatments, and so on. ‡Comparison (C): The Comparator to the intervention. It includes alternatives such as placebo, drugs, surgery, lifestyle changes, and the standard of care. §Outcome (O): Specific results of interest. It refers to short, intermediate, and long-term outcomes, and includes specific areas such as quality of life, complications, mortality, and morbidity. ‖Timing (If Applicable) (T): Duration of time that is of interest for the particular patient outcome, benefit, or harm to occur (or not occur). ¶Setting (If Applicable) (S): Setting or context of interest. Setting can be a location (such as primary, specialty, or inpatient care) or health policy that frames or restricts important questions to be answered.

3.3. Phase 0. Pre-Production

Phase 0, the pre-production phase, includes identification of the chair, vice chair, Joint Committee liaison, RWI mapping, formation of the WC, agreement from collaborators, identification of the PRC co-chairs, finalization of outline, WC section assignments, and guideline leadership kick off.

Phase 0 also includes defining the scope of the guideline. The primary audience of ACC/AHA guidelines is the practicing cardiovascular clinician. These guidelines are intended to assist the cardiovascular clinician in clinical decision making by identifying and applying the best, most current evidence to address important questions or gaps in understanding in clinical practice. Secondary audiences include, but are not limited to primary care clinicians, other specialties, patients, payers, and healthcare systems. However, available evidence may only address a single or few clinical questions within a range of other clinical needs. These needs represent boundaries that define the scope of the guideline and may include patient characteristics (ie, gender, age, co-morbidities), disease progression (ie, heart failure classification), and diagnostic, therapeutic or interventional options. Other considerations that define the scope of the guideline are whether it is a *de novo* effort, or a revision, whether it incorporates outside systematic reviews or performs new ones, and others. The guideline scope is defined by the Joint Committee Liaisons, refined by the WC Chairs, and iterated upon by the WC.

3.3.1. Inviting Collaborators

The ACC/AHA guidelines policy advocates inclusiveness of stakeholder organizations in developing new or revised guidelines. The primary way organizations may participate in ACC/AHA guidelines is through collaboration. Collaboration relationships include representation of the organization on the WC and the PRC.

Collaborations are proposed by the Chair and Chair-Elect of the Joint Committee, the WC leadership, and the liaison from the Joint Committee assigned to the guideline project, and they are approved by the ACC and AHA Science Leadership. A summary of the collaborator role on the guidelines and the Memorandum of Understanding can be found in Appendix 9.

3.3.2. Writing Committee Formation

ACC/AHA guidelines are developed by a WC consisting of cardiologists, clinical and scientific experts, lay stakeholders, which may include patients or patient representatives, methodologists, statisticians, or other stakeholders (see Appendix 1 and Appendix 1a). Members of the WC are selected with the goal of

achieving a balance in regards to relationships with industry, expertise, geography, and demographics. The WC is led by either a chair and a vice chair or multiple co-chairs who are responsible for deciding on key clinical questions to be addressed in the scope, conducting the evidence review or reviewing/confirming evidence collected by the surveillance committee, formulating the evidence-based recommendations, and finally developing the document, which includes peer review, responding to comments and editing. The guideline advisor, librarian, and other members of the staff team support the document development (see Appendix 1 and Appendix 1b). In addition to scientific and clinical expertise germane to the topic, other stakeholders are invited to join the committee including other specialties, disciplines, and patient representatives. In forming WCs, the Joint Committee attempts to balance stakeholders with content experts and senior clinicians in a transparent process that results in a productive, unbiased panel that aligns with the policies of the ACC and AHA. The Joint Committee is the final approver of the chair, vice chair, WC members, and peer reviewers for the document. The Joint Committee will also appoint at least 1 liaison from the Joint Committee to the WC.

3.3.3. Peer Review Committee Formation

At the time of project approval, an initial list of reviewers is compiled, which is generated from the nominees provided by the ACC, AHA, collaborating organizations, and the Joint Committee. All proposed nominees must provide RWI disclosures before the start of the review period, as well as an executed nondisclosure and confidentiality agreement.

From the aforementioned list, a slate of nominees are generated based on clinical competencies and general competencies for appointment to the PRC that align with the competencies for the WC. Approximately 20-30 individuals are appointed to the PRC. The appointed PRC co-chairs are then invited to the guideline kick-off meeting. The full list of competencies and expectations is available in the PRC section in Appendix 1.

3.3.4. Policies for Authors

3.3.4.1. Relationship With Industry Disclosures

All prospective guideline WC members as well as peer reviewers must fully disclose all financial, intellectual and industry related relationships and interests according to the ACC/AHA Relationships with Industry Policy (Relationships With Industry Policy). Notably, the ACC and AHA Science leadership are the final arbiters of the relevance of the interests to the guideline topic, not the discloser, therefore all relationships must be disclosed.

3.3.4.2. Confidentiality and Copyright Assignment

The development process is strictly confidential. WC and members must not discuss or comment on any information including their role or other members of the committee specific to the guideline in any venue outside the WC. Peer reviewers are also prohibited from disclosing any details of their reviews but may acknowledge their inclusion in the review process after guideline publication. Any communication that is needed post-publication comes only from official organizational representatives. Each panelist must sign and abide by a formal confidentiality agreement that prohibits discussion of the guideline under development or sharing of any confidential material until after release. A copyright transfer agreement is also signed which gives copyright of all guideline materials to the ACC/AHA.

3.4. Phase 1. Document Development

Phase 1, the document development phase, begins with the kickoff of the guideline. Phase 1 includes the first evidence review, as well as subsequent evidence reviews, first peer review, the consensus conference, manuscript revisions, and WC formal recommendation voting.

3.4.1. Guideline Writing Committee Orientation and Kick-Off Meeting

All guidelines have a synchronous kick-off meeting with orientation materials and documents to support the development process. WC members receive an introduction to the ACC/AHA guideline development process and methodology, and they are asked to weigh in on the guideline outline and scope of the document during the kick-off meeting. During the kick-off meeting, the JC liaison presents an evidence review of a section that demonstrates how an evidence review is conducted. Prior to the kick-off meeting, guideline WC members are required to complete 3 training modules that provide an overview of the guideline development process, RWI compliance, and guideline writing. After completing the training modules, WC members are also required to take a post-test. The links to the training modules are included below.

- GO: Guideline Strategic Overview Module
- GO: Guideline RWI Compliance Module
- GO: Guideline Writing Module

3.4.2. Applying Classifications of Recommendations and Evidence

Applying the ACC/AHA COR/LOE methodology standards for the development of practice guidelines have evolved over the years as the principles of evidence-based medicine have been adapted and adopted (see Table 2 above). While a great deal of clinical evidence is published, guideline developers are challenged to comprehensively identify high quality evidence to support the formulation of recommendations. Furthermore, any bias in the evidence must be identified and quantified when warranted. These principles are incorporated into the ACC/AHA's processes to produce clinical practice guidelines of the highest quality.

Because recommendations are structured statements including COR/LOE for clinical interventions in specific populations supported by high-quality evidence, summaries of harms and benefits, patient preferences and other supporting text, they are classified based on the expected benefit or risk in the associated population:

- Class 1–Strong: Benefit >>>Risk
- Class 2a–Moderate: Benefit >>Risk
- Class 2b–Weak: Benefit ≥Risk
- Class 3–No Benefit (Moderate): Benefit=Risk
- Class 3–Harm (Strong): Risk >Benefit

Each recommendation also has an associated Level (Quality) of Evidence based upon a comprehensive review of the evidence:

- Level A–High quality evidence from more than 1 RCT, meta-analyses of high-quality RCTs, or one or more RCTs corroborated by high-quality registry studies.
- Level B-R–Moderate-quality evidence from 1 or more RCT or Meta-analyses of moderate-quality RCTs.
- Level B-NR–Moderate-quality evidence from 1 or more well-designed well-executed nonrandomized studies, observational studies or registry studies, or meta-analyses of such studies.
- Level C-LD–Randomized or nonrandomized observational or registry studies with limitations of design or execution.
- Level C-EO–Consensus of expert opinion based on clinical experience.

The guideline document is based on published research in peer reviewed publications so no de-novo research should be used as a reference unless systematically reviews are performed on the published studies.

The COR/LOE table (Table 2 above) applies to the clinical strategies, interventions, treatments, or diagnostic testing in patient care. RCTs of diagnostic tests are uncommon but do reflect the highest potential quality of evidence for such a test (ie, a trial that compares a testing strategy versus no testing strategy). In general, though, these tests are evaluated using non-randomized studies, which should be high quality in design (eg, B-NR).

Often, the WC is faced with the challenge of analyzing the evidence based on study subgroups. First and foremost, evidence from subgroups should be approached with caution. In order to be credible, all evidence should come from high-quality studies, with the results replicated in follow-up studies. Replicability pertains to replicating subgroup findings in trials focused on the subgroup of interest–this is important where feasible (Appendix 10).

It is reasonable to cite the largest and most recent RCT meta-analysis alone in the evidence table provided that:

- The population, interventions and outcomes used in the MA are most consistent with the issue being discussed in the GL recommendation.
- The results of the MA are consistent with other contemporary MA publications.

If the other MA publications are **largely similar**, it would be reasonable to cite them in the text for the sake of transparency, while indicating the qualitative and quantitative similarity to the MA presented in the evidence table. On the other hand, if two contemporary MA publications have **divergent conclusions** and findings, it is important to present both the evidence tables with explanations as to why the results might differ (new included studies, different study inclusion criteria, etc).

3.4.3. Evidence Synthesis and Recommendation Drafting

The guideline document is a collection of structured recommendation statements reflective of the published and available supporting evidence as interpreted through the expertise of the guideline panel WC. WC members are assigned as either primary authors or reviewers to each section of the guideline. See Appendix 1, Writing Committee, for more information on the primary author and primary reviewer roles. As each primary author finalizes their sections, the ACC/AHA Guideline Advisor combines each section into the draft template, including background if needed, evidence tables, recommendations, citations, algorithms, and support from the systematic review if one is performed. The full draft is completed, reviewed by the full committee, and undergoes the first round of peer review prior to the consensus conference and recommendation voting.

3.4.3.1. Reviewing the Evidence

Members of the WC are assigned by the WC leadership to review the evidence, draft clinical practice recommendations (Appendix 3) with supporting evidence tables and provide recommendation-specific supportive text for their assigned section(s) of the outline. WC members should enlist the support of the AHA/ACC Medical Librarian to conduct literature searches, which are based on the PICO(TS) questions developed by the WC. Once the literature search form is completed (Appendix 7) the primary author will review the results of the search to generate the evidence and draft the clinical practice recommendations.

3.4.3.2. Generating Evidence Tables

Once the relevant literature has been identified from the systematic literature search, the primary author will generate an evidence table (see Appendix 11) that summarizes the strength of the evidence. Tables should include pivotal evidence to support the recommendations. An entry must be created in the evidence

table for each reference that supports a clinical practice recommendation that is Level of Evidence A, B-R, or B-NR or for conflicting evidence if C-LD. Evidence tables accompany the guideline and are published in the ACC and AHA journals.[18]

3.4.3.3. Modular Recommendation Format

Recommendations are actionable statements based on evidence reviewed by the WC members and are supported by synopses and recommendation-specific supporting text. While there are several options for recommendation phrasing, a general structure reflecting the PICO(TS) questions that is patient centered and actionable is often the best (see Appendix 3).

The modular format allows recommendations to be packages of information on a disease-specific topic or management issue.[8] The format consists of 1) a table of recommendations; 2) a brief synopsis (no more than 200 words); 3) detailed recommendation-specific supportive text for each recommendation in the section (no more than 200 words); 4) a diagram (where appropriate); 5) additional informative tables (where appropriate); and 6) references for each modular recommendation. This format has been adopted in 2017, starting with the high blood pressure guideline,[19] and will carry through ACC/AHA guidelines to allow for easier updating of recommendations as published literature becomes available.

3.4.3.4. Discussing Pharmacotherapy in Guidelines

The Joint Committee has provided a detailed list of policies on discussing pharmacotherapy in guidelines (see Checklist 1)**.** In addition, when necessary, a pharmacologist is assigned to a guideline or is used in a consulting role to review the guideline's pharmacotherapy discussions before publication.

The Joint Committee also commissioned a guiding document that is meant to ensure the alignment between the US Food and Drug Administration (FDA) approval processes for drugs and devices and the ACC/AHA guideline recommendations,[20] which can be found using the following link: https://doi.org/10.1016/j.jacc.2025.05.006. Investigational treatments or drugs that are not available for general use may be mentioned in the text but should be clearly described as such and not given recommendations. The presence or absence of FDA approval of a drug or device for a specific purpose should generally not be mentioned. When addressing recently published or approved drugs, recommendations will be based on the available strength of evidence rather than wait for FDA post-marketing surveillance data. The criteria used by regulatory authorities to approve and to follow approved drugs and issue recommendations and alerts when necessary are frequently different, and the ACC/AHA process should be independent of these regulatory issues.

Checklist 1. Discussing Pharmacotherapy in Guidelines

Pharmacotherapy and Uses

- ❑ Use generic or chemical name, not trade name
  - eg, simvastatin, not Zocor
- ❑ Use broadest and most generic name of class appropriate
  - eg, sirolimus-eluting stent, not Cypher stent
- ❑ List classes of drugs or drugs within classes according to evidence-based rationale, and state rationale
  - eg, first-line, second-line or side effects or cost effectiveness
  - If no evidence-based rationale for listed order, list alphabetically
- ❑ List all drugs (or none) within class
  - Indicate whether each is approved for the indication(s) under discussion
    - eg, statins for primary prevention
  - Indicate whether each has evidence for the indication(s) under discussion
    - eg, GP IIb/IIIa inhibitors
- ❑ Discuss evidence for or against "class effect"
  - eg, issue raised by ramipril in HOPE study
- ❑ When so-called "alternative medicines" are known to be widely used, discuss the evidence about them and the issues raised by their use
  - eg, possible interactions
- ❑ Avoid the use of symbols and abbreviations when discussing drug dosing and timing
  - eg, use "micrograms" or "mcg" instead of "µg"
  - The Institute for Safe Medication Practices has issued a drug error alert regarding some commonly used abbreviations (included in this section)
- ❑ Whenever a guideline includes specific drug information, such sections of the guideline should be reviewed by a pharmacologist during peer review

In the case of international guidelines, there may be occasions requiring a discussion of international availability of certain medications. However, such content should be addressed from the perspective of the patient or clinical use, and not from a policy (ie, drug-approval) perspective.

3.4.3.5. Therapeutic Substitution

The Joint Committee recommends that in developing recommendations for drugs, the WC should consider the following major criteria that must be present for a therapeutic class effect:

- A clearly defined biological target or pathway.
- Comparable efficacy demonstrated for multiple agents within the class (with multiple randomized trials for each agent).
- Absence of convincing evidence that there is a member of the class that does not have comparable benefit to that of other agents within the class.
- No demonstrated ineffectiveness for any of the class members for the recommended indications.

In practice it is unusual for all these criteria to be met, making it difficult to determine if a class effect is truly present.

Additional considerations that should be reviewed when evaluating the interchangeability of drugs:

- Absolute and relative degree of benefit

- Cost
- Inclusion and exclusion criteria in supporting clinical trials.
- Side-effects
- The subgroups in which benefit, or lack of benefit, was demonstrated.

Where appropriate, drugs in a therapeutic class are listed in tables in alphabetical order unless there is a preference, along with indications for their use and recommendations as to which agents can be substituted within the class.

3.4.3.6. Mendelian Randomization

Mendelian Randomization (MR) studies may be used to support and strengthen a recommendation of B-NR or C-LD based on their quality, consistency, and adherence to principles of instrumental variable analysis. See Appendix 12 for more information on MR.

3.4.3.7. Incorporation of Patient-Reported Outcomes

ACC/AHA clinical practice guidelines incorporate patient-reported outcomes (PRO) in recommendations when possible.[3] While creating a recommendation, guideline WCs can incorporate PROs (as an experience that comes directly from the patient or, in some cases, a caregiver or surrogate) as follows:

- As part of clinical assessments and serial follow-ups (algorithms/tables, in some cases).
- As part of guiding treatments about expected benefits.
- To assess adherence.
- During shared decision-making guided by the patient's preferences.
- To integrate level of value (ie, high, intermediate, low, or uncertain value associated with quality-adjusted life years (QALY) based on cost-effectiveness studies).[9]
- Or 'standalone section' toward the end of the GL which advocates for the use of patient-reported outcome measures (PROM) in future clinical trials and patient care. The latter would be appropriate if there are no PROMs reported or summarized in other areas noted above in the GL.
- The chairs of the guideline WCs can empower the patient representatives to express their thoughts about which PROMs should be addressed in the GL or future research studies.

COR/LOE guidance:

- COR will be guided by net benefit based on expert consensus that signifies meaningful benefit represented by the patients in conjunction with the available evidence.
- LOE will be guided by positive, prespecified primary and secondary endpoints generally representing the highest quality evidence and are generally recognized as such in FDA evaluations.

- LOE A might require randomized study primary and secondary PRO endpoints (including PROM tools) to be prespecified as described and be noted in at least 2 and preferably more high-quality studies.
- LOE B-R might involve the same but from 1 moderate-quality randomized study or 2 or more studies of lesser quality or with less definitive results for the sub-study (looking at the test for interaction between subgroups and treatment).
- LOE B-NR might involve moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized, observational studies, or registry studies following the ACC/AHA COR/LOE schema. Valid, sensitive, and disease-specific health status measure studies can be rated as B-NR. Given the limitations of nonrandomized studies, an even more cautious approach with interpreting subgroup effects should be adopted.

- LOE C-LD might involve evidence from lower-quality studies, or when the primary endpoint is conflicting for various studies or the PROM tools are of lower quality and the authors would still like to formulate a recommendation.
- LOE C-EO will not apply as the PRO incorporation in guidelines is based on patient reported outcomes and the available literature, not the interpretation of expert experience.

More information on incorporating PROs into clinical practice guidelines can be found in Appendix 13.

3.4.3.8. Shared Decision-Making in Clinical Practice Guidelines

Shared decision-making (SDM) is frequently mentioned in several ACC/AHA Guideline recommendations, many of which receive a COR I, LOE B-R recommendation. The intention of this guidance is to advise JCCPG on how WCs could enhance SDM recommendations in the guidelines by specifying rules on SDM evidence incorporation within our COR/LOE framework. There are many barriers to implementing shared decision-making, including a lack of accessible tools (also known as decision aids) to support shared decision-making during the clinical encounter, and a paucity of measures to evaluate whether it has occurred. The shared decision-making workgroup offers suggestions on how the guidelines can be expanded to provide tools that clinicians could use to support implementation. More information on shared decision-making in clinical practice guidelines can be found in Appendix 14 as well as in the "2025 ACC/AHA Guideline Core Principles and Development Process" paper.[3]

3.4.3.9. Recommendation-Specific Supportive Text

The Joint Committee realizes that a clinical practice recommendation may require some additional clinical context that should not be included in a pithy, PICO(TS)-formatted recommendation. The recommendation-specific supportive text section accompanies each recommendation that can describe the nuances or details of the recommendation that may be beneficial to clinicians, should discuss the benefits and harms of the intervention (if applicable), and summarize the body of evidence that support the recommendation. These statements should not exceed 200 words. The recommendation-specific supportive text should not be a restatement of the recommendation, nor should it utilize COR/LOE recommendation verbiage.

3.4.4. Consensus Conference

During a consensus conference held over a few days, all recommendations and associated text are reviewed, discussed by the full committee, and revised where needed based on peer reviewer feedback. The WC also utilizes this meeting to discuss items that can be incorporated into the Top Ten Take-Home Messages, the future research suggestions/directions and gaps, development of tables, figures, checklists, or other items that would help the guideline reader operationalize the clinical practice recommendations. The first round of informal recommendation voting by the WC takes place during the consensus conference and formal voting occurs after the consensus conference.

3.4.5. Writing Committee Approval

Every clinical practice recommendation is voted upon by the eligible members of the WC (RWI notwithstanding) for inclusion into the manuscript. Consensus is achieved when ≥75% of the voting members have accepted the recommendation with anonymous voting. The AHA/ACC guideline staff will have access to all vote decisions on every recommendation to confirm that all members of the WC have cast their vote. If consensus is not achieved in the first round, a second and third round of voting may take place to achieve consensus. During each round of voting, eligible WC members vote to accept or reject the recommendation. More information regarding the RWI policy on voting can be found at Relationships With

Industry Policy. All WC members have an opportunity to provide comments on each recommendation to improve the clarity of the recommendation and to suggest changes to the wording/phrasing, as well as changes to the COR/LOE.

In the event that consensus cannot be reached after the third round of voting, the recommendation, the recommendation-specific supportive text, the references, and the entries in the evidence table are removed from the guideline. A minority report summarizing the discord IS NOT included in the published guideline. All WC members must vote for all the recommendations depending on their industry relationships. Members with relevant RWI are recused from voting on sections related to their RWI. Various rounds of anonymous voting and multiple expert reviews regularly result in a majority consensus (≥75%) on each recommendation.

3.5. Phase 2. Review and Approval

3.5.1. Peer Review

Phase 2, or the review and approval phase, includes the second peer review, WC sign-off, and Joint Committee approval. The Joint Committee is committed to a robust peer review process that is reflective of all stakeholders of the guideline topic. The guideline document approved by the WC, as well as the systematic review report if the guideline commissioned one, and any other supporting materials, are reviewed by the PRC.

3.5.1.1. Conducting the Review

The peer review period is typically 4 total weeks for a full guideline, which is broken up into 2 review stages. The first peer review occurs prior to the WC consensus conference and the second peer review occurs after the WC consensus conference. The full Joint Committee also reviews every guideline concurrently with the PRC during the second review. The PRC is asked to focus their review on the following 4 questions:

1. Is the document content clear, accurate/complete, and balanced?
2. Are the class of recommendations appropriate and levels of evidence well supported?
3. Do the tables, figures, algorithms, appendices, and data supplements complement the text?
4. Are recommendations executable in professional/clinical practice?

The PRC names are withheld and unknown to the WC in an effort to minimize bias.

3.5.1.2. Responding to the Peer Review Committee Comments

Once the peer review process concludes, the WC receives a summary of the substantive comments. This process streamlines addressing the most pertinent comments for improving the clinical recommendations. The WC provides a response to each clinical comment and starts addressing the peer review concerns at the consensus conference. While they are discouraged, editorial or stylistic comments are also often submitted by the PRC. These comments are triaged and addressed by the Guideline Advisor.

Once the WC has responded to the feedback from the PRC, and the WC chairs and PRC co-chairs are in agreement, any recommendations requiring a change to the COR/LOE, or addition or removal of recommendations require a revote for acceptance.

3.5.1.3. Writing Committee Approval

The WC will formally vote to approve the guideline document after edits have been incorporated into the document based on comments submitted by the PRC. During the WC review, any dissenting opinions or

votes not to approve the manuscript are discussed with the WC Chair and the WC to come to a resolution. The document does not move forward to the Joint Committee for approval until all members of the WC have approved the document.

3.5.1.4. Joint Committee Approval

The Joint Committee is the next step in the approval process after the WC has approved the guideline document. The Joint Committee receives the following materials for review and approval: 1) the full manuscript with all changes incorporated after the second peer review; 2) the WC responses to the first and second rounds of peer review; 3) the evidence tables; and 4) any additional supporting documents or supplements that will be published with the guideline.

3.6. Phase 3. Organization Approval and Publication

Phase 3, the organization approval and publication phase, includes ACC and AHA approval, collaborating organization endorsement, production, and publication.

3.6.1 ACC/AHA Governing Bodies Approval

Following Joint Committee approval, the guideline and all supporting materials described in Section 3.5.1.4. are sent for review and approval by the ACC and AHA.

3.6.1.1. ACC Clinical Policy Approval Committee and AHA Science Advisory and Coordinating Committee

The ACC Clinical Policy Approval Committee (CPAC) and AHA Science Advisory and Coordinating Committee (SACC) are the first layer of organization approvals.

3.6.1.2. ACC Science and Quality Committee, AHA Executive Committee Review, and Collaborator Endorsements

After SACC and CPAC approval, the document is sent to the highest governing bodies, the ACC Science and Quality Committee and the AHA Executive Committee, for approval, and to the collaborating organizations for endorsement. ACC (Science and Quality Committee) and AHA (Executive Committee) give approval of the final document before it is published.

3.6.1.3. Endorsement by the Collaborating Societies

The collaborating societies receive the guideline for endorsement when it is sent to the AHA EC and the ACC SQC for their approvals. Collaborators that endorse the document are included on the cover page of the published document.

3.6.2. Publication

The guideline document and supporting materials (eg, evidence tables) are published in the *Journal of the American College of Cardiology* and *Circulation*. Collaborating organizations that endorse the guideline must request permission from ACC and AHA to reprint the guideline in their journal. After a guideline is published, a series of processes are followed (see Section 3.1. Topic Selection and Appendix 6).

3.7. Phase 4. Post-Publication Surveillance Review and Guideline Revision

Phase 4 formalizes the post-publication activities required to ensure ACC/AHA clinical practice guidelines remain current, scientifically accurate, and responsive to emerging evidence. This phase operationalizes guideline maintenance through structured literature surveillance, impact assessment, and, when warranted, timely guideline updates, revisions, or reaffirmation.

3.7.1. Purpose and Scope

The purpose of Phase 4 is to provide a standardized, transparent process for:

- Ongoing monitoring of newly published evidence following guideline publication.
- Identification of practice-changing evidence that may warrant modification, removal, or creation of recommendations; and
- Determination of whether guideline content should be fully updated, pragmatically revised, or reaffirmed as current.

Phase 4 supports both full guideline revisions and pragmatic updates when a comprehensive revision is not warranted, enabling rapid incorporation of new evidence while preserving methodological rigor. This phase applies to all ACC/AHA clinical practice guidelines within the active guideline portfolio.

3.7.2. Surveillance Review Process

Post-publication surveillance is conducted by a Surveillance Committee operating under Joint Committee oversight. Surveillance activities may include pragmatic, technology-enabled literature review approaches, including the use of multiple ACC/AHA-approved large language model (LLM) tools to identify evidence published since the last search date in addition to content experts' assessment of the evidence, resulting in reaffirmation, or initiation of a pragmatic revision or full guideline update.

Surveillance activities may occur on a scheduled basis or be initiated ad hoc in response to high-impact external signals, such as publication of pivotal trials, regulatory actions, safety alerts, or significant changes in clinical practice standards.

These approaches acknowledge that full-text review of all cited literature may not occur during surveillance review and are intended to inform, not replace, expert interpretation, deliberation, and adjudication.

3.7.3. Criteria for Considering Guideline Updates or Revisions

Findings from surveillance review may prompt consideration of a guideline update or pragmatic revision when 1 or more of the following criteria are identified:

- New studies that may result in a full Class change in the COR (eg, Class 2 to Class 1 or Class 3). In addition, if new studies support a full Level change in the LOE (eg, from B to A or C). Also, if there is data to support the removal of a recommendation (eg, scientific retractions) or institution of a Class 3 (harm/no benefit) recommendation (eg, new data on harm/adverse events, box warnings, recalls, etc).
- New studies that may result in the creation of new recommendations that, heretofore, did not exist (eg, medications newly available and approved by the FDA, new devices or uses of devices approved by the FDA).

3.7.4. Proposal Development, Adjudication, and Reaffirmation

The Surveillance Committee prepares a proposal summarizing key findings, mapped recommendations, and suggested actions. Proposal statements may include evidence summaries generated through artificial intelligence (AI)-assisted surveillance tools; these summaries serve as decision-support resources and do not independently determine recommendation changes. Proposals are submitted to Joint Committee leadership, which adjudicates whether:

- No action is required and the guideline remains current and is reaffirmed.
- A pragmatic revision or targeted guideline update is warranted; or
- A broader guideline revision process should be initiated.

When the Surveillance Committee recommends that no update or revision is necessary and that the guideline remains current, this recommendation is reviewed by the Joint Committee. Upon Joint Committee approval, the guideline is reaffirmed as current based on surveillance review.

3.7.5. Guideline Update and Revision Pathways

When a full update or pragmatic revision is approved, appropriate WC leadership is convened or reconvened. For pragmatic revisions, the former WC members, PRC members, and collaborating organizations may be invited to opt-in for continued service, subject to reassessment of RWI balance and Joint Committee approval.

Updated recommendations follow established ACC/AHA methodology, including evidence review, synthesis, COR and LOE assignment, voting procedures, and peer review. Updates may include targeted pragmatic revisions, full updates, or incorporation into a living guideline framework.

3.7.6. Documentation, Transparency, and Dissemination

All surveillance activities, adjudication decisions, and resulting updates or reaffirmations are documented, including:

- The rationale for update, revision, or reaffirmation decisions.
- A summary of supporting evidence; and
- Version history and status of guideline recommendations.

For guidelines reaffirmed as current following surveillance review, AHA/ACC staff coordinate with AHA and ACC publishing staff to communicate this determination. At a minimum, reaffirmation decisions are documented or noted in the scientific journals, (with an understanding that although the guideline is reaffirmed based on an updated literature review, the references within the text of the guideline are not updated) with additional dissemination through digital platforms or other channels as appropriate.

3.7.7. Continuous Process Evaluation

The surveillance, reaffirmation, pragmatic revisions, and full guideline update process is periodically reviewed by the Joint Committee to evaluate efficiency, timeliness, impact, and methodological integrity. Process refinements may be implemented to align with evolving evidence ecosystems, digital technologies, artificial intelligence tools, and stakeholder feedback.

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Appendices and Supporting Documents

Appendix 1. Roles and Responsibilities for Writing Committees, Peer Review Committees, and Surveillance Committees

Guideline Chair

The chair has primary responsibility for the guideline development process including adjudication of consensus development and adherence to all policies and procedures. The chair is ultimately responsible for moving along the guideline process, keeping the group focused, task-oriented, and encouraging balanced participation of all working group members.

Pre-requisites/Competencies for the Guideline Chair

- Recognized content expertise/leadership at organizational/society level.
- Experience with guideline writing as well as an understanding of evidence-based medicine.
- Previous experience serving as a guideline vice chair, a guideline WC member, a peer reviewer, or in a leadership position on the ACC/AHA Joint Committee on Clinical Practice Guidelines or a leadership position within the American College of Cardiology or American Heart Association.
- Must be free of relevant RWI.
- Ability to manage groups in fair, balanced manner; establish expectations/schedules.
- Ability to work with staff.
- Ability to communicate with Joint Committee, parent organizations, and the media.
- Complete assignments in a timely manner.
- Possess a collaborative demeanor and establish a climate of trust and mutual respect among WC members.
- Objective viewpoint about trial data.
- Encourage constructive debate without forcing agreement.
- Work in an embargoed environment and maintain confidentiality.
- Abstain from new or additional RWI during the entire WC process.
- Participate actively in all in-person and virtual meetings.
- Be a diligent member with respect to prompt attendance to all in-person and virtual meetings.

Specific responsibilities of the guideline chair/vice chair include the following:

- Weekly conference calls with the Joint Guideline staff and the Joint Committee on Clinical Practice Guidelines (JC) liaison to address the following issues:
    - Work with the JC to determine WC composition (eg, required expertise, organizational involvement).
    - Discuss document scope and draft outline.
    - Review development process.
    - Discuss guideline structure.
- Manage RWI, intellectual bias, and consensus development process:
    - Enforce disclosure policy during conference calls.
        - Chair reads RWI statement/reviews RWI on each conference call.
        - Disclosure table distributed to each member for conference call or face-to-face meeting. Chair invites each member to confirm RWI or state new RWI not listed on table.

    - Require members with relevant RWI to recuse themselves from drafting original text and/or voting per current policy – including the Vice Chair, if applicable.
- Confer with JC Liaison, JC and ACC/AHA staff when issues are unclear or problematic.
- Manage minority opinions and differing perspectives. Encourage all members to contribute to discussions and activities of the group.
- Establish a climate of trust and mutual respect among members while remaining sensitive to preexisting interprofessional tensions and hierarchies.
- Facilitate conference calls, ensuring opportunity for all to participate/discussion is balanced.
- Facilitate first conference call or meeting:
    - Guide process to refine document scope and finalize outline.
    - Support the ACC/AHA RWI policy.
    - Review WC member expertise and relevant RWI to determine appropriate assignments.
    - Determine strategy for reviewing studies and data.
- Manage and maintain the document/timeline and encourage WC to meet deadlines.
- Write or facilitate writing of sections if WC members fail to submit sections—vice chairs cannot fill this role if relevant RWI applies to section(s).
- Summarize main points and key decisions of discussions.
- Enforce adherence to document outline and scope (or work with JC if scope needs to be altered).
- Review and approve (when applicable) all edits to the manuscript.
- Respond to peer review comments (and enlist other WC members as needed) using an electronic peer review system (Indico).
- Respond to ACC and AHA organization comments at the time of organizational approval.
- Assist throughout publication and promotion phases of document, eg, page proof review, press release, interviews.
- Remind WC throughout the process about the confidentiality and embargo policies.

Guideline Vice Chair

The vice chair should work with the chair and the staff to delegate writing assignments and to integrate assignments and group feedback into the draft guideline. The vice chair will serve as the acting chair should the chair be unable to attend in-person or virtual meetings.

Pre-requisites/Competencies for the Guideline Vice Chair

- Experience with guideline writing as well as with evidence-based medicine.
- Served as a guideline vice chair, a guideline WC member, an official guideline peer reviewer, or in a leadership position on the ACC/AHA Joint Committee on Clinical Practice Guidelines or a leadership position within the American College of Cardiology or American Heart Association.
- May have RWI.
- Complete assignments in a timely manner.
- Possess a collaborative demeanor.
- Objective viewpoint about trial data.
- Work in an embargoed environment and maintain confidentiality.
- Abstain from new or additional RWI during the entire WC process.
- Participate actively in all in-person and telephone conference calls.
- Be a diligent member with respect to prompt attendance to all in-person and vi.
- Other attributes as per chair.

Writing Committee

The selection of WC members, and the overall composition of the guideline development group, is one of the most important factors in the guideline development process. When selecting the WC members, a group size of 18-22 members is ideal because it encourages diversity and efficiency yet remains small enough to avoid delays and redundancy. The group should consist of the following roles:

1. Chair
2. Vice chair(s)
3. Content experts
4. Stakeholders from relevant disciplines
5. Collaborating organizations
6. JC liaison(s)
7. JCPM liaison
8. Patient/lay stakeholder representatives (at least 1)

Guideline WC participants must meet the following ACC/AHA volunteer competencies and expectations:
Competencies:

- Broad-based association-wide experience and view
- Excellent interpersonal relationship skills
- Excellent oral and written communication skills
- Results orientation
- Accountability

Specific responsibilities of the guideline development WC include the following:

- Disclose fully any potential conflicts of interest and/or relationships with industry (RWI) and other entities.
- Participate in most conference calls and all in-person meetings.
- Attend all meetings with a commitment to teamwork and clear communication.
- Read all relevant materials and provide constructive comments and feedback during and between meetings.
- Respond to e-mails on a regular basis.
- Complete personal assignments to meet deadlines.
- Maintain confidentiality of embargoed guideline material.
- Confer with the WC Chair, Vice Chair, JC Liaison, or ACC/AHA staff when issues are unclear or problematic.
- Adhere to the guideline outline, scope, and format of the document.
- Respond to peer review comments.

Primary Author Role

- The primary author is responsible for searching the literature and selecting the articles that are best suited for their section. This author cannot have any relevant RWI related to the section.
- The primary author is also expected to construct the evidence tables and to develop the first draft of the section(s) and its original content, including any proposed figures or tables. Other reviewers may assist as needed.
- The primary author is responsible for the integrity of the data in the evidence tables and for performing quality checks on the tables before they are finalized.

Primary Reviewer/Secondary Author Role

- Responsible for reviewing, editing, and supplying additional content as requested. They will provide edits to the draft sent to them by the **primary author**, based on:
  - Syntax
  - Readability
  - Inclusion of articles
  - Complete reference inclusion
- The primary reviewer/secondary author *may* assist with the construction of the evidence tables, if approved by the WC leadership and the JC liaison; requests for assistance will be reviewed on a case-by-case basis.

Joint Committee on Clinical Practice Guidelines Liaison

The primary responsibilities of the JCCPG liaison include:

- Ensure consistency with previously ACC/AHA guideline documents.
- Monitor the guideline development progress and report back to JC at regular intervals (after the kick-off meeting, after the consensus conference, and at each in-person meeting of the JC).
- Provide process guidance to guideline leadership and the WC.
- Participate in manuscript development drafting and revising. Ensure that the document adheres to the current format, styles, and standards for joint guidelines.
- Participate in weekly calls with the guideline leadership and the staff.
- Attend WC conference calls and meetings.
- Develop the scope and outline in consultation with the guideline leadership, for approval by the JC.
- Guide the WC leadership through the peer review process.
- Work with the joint staff to prepare a written and oral report at each JC meeting.
- Work with the JC Chair and Chair-Elect to discuss WC requests, if presented, to deviate from the approved scope.
- The JC liaison serves as an author on the WC.

Joint Committee on Performance Measures Liaison

The primary responsibilities of the Joint Committee on Performance Measures (JCPM) liaison include:

- Serve as a member of the guideline WC.
- Ensure consistency with previous ACC/AHA documents.
- Serve as the primary conduit between the performance measures and guideline WCs to track guideline development issues as they relate to a performance measure update.
- Inform the JCPM of new developments that may directly or indirectly affect the development and implementation of existing performance measures, or that might warrant development of new performance measures.
- Work with JCPM staff to create an impact summary report once the JC staff provides the guidelines' ballot copy of the recommendation tables to JCPM staff. The summary report will include a review of the impact of the potential guideline recommendations on JCPM products.
- Work with the JCPM staff to provide the JCPM with recommendations, including whether to retire, update, add, or leave the PM unchanged.
- Review the impact summary report with the JCPM Chair and provide recommendations (eg, impact decision) to the JCPM.

Patient or Lay Stakeholder Representative

Patient or lay stakeholder representatives are defined as patients, former patients, members of patients' families, caregivers and laypeople with 'health literacy' including scientists, statisticians, engineers, science writers, patient advocates, and patient or consumer organization representatives.[1]

The process for obtaining patient or lay stakeholder representatives includes the following steps:

1. A request for patient or lay stakeholder representatives is sent to AHA staff, which includes a summary of what the guideline is about, the clinical competencies that will be represented on the guideline WC, and a link to the patient or lay stakeholder representative survey.
2. The survey results are compiled and interviews are scheduled with candidates.
3. Patient or lay stakeholder representatives are appointed to the guideline WC and PRC following the process used for WC formation.
4. At least one patient or lay stakeholder representative is appointed to the guideline WC.
5. At least one patient or lay stakeholder representative is appointed to the PRC.

Expectations for patient or lay stakeholder representative members include the following:

- Participate in topic selection and outline/PICO(TS) question development focusing on issues regarding patient preferences, values, and shared decision-making.
- Provide input on content regarding patient choices, values, preferences and issues surrounding quality of life in selecting diagnostic modalities, therapies, medications, and follow-up.
- Acknowledged as a WC member in the manuscript publication with complete summary of RWI including adjudication of intellectual perspectives.
- Sensitive to their role as impartial members and do not allow financial and nonfinancial conflicts, including personal, intellectual, or organizational relationships to influence their judgment.
- Adhere to the confidentiality and embargo policies of the ACC and AHA.
- Complete recorded training modules and associated pre and post learning assessments prior to the kick-off meeting.
- All nonprofessional members of a WC should avail themselves of the U.S. Cochrane Center and Consumers United for Evidence-Based Medicine's "Understanding Evidence-based Healthcare: A Foundation for Action" or an equivalent online learning module (https://consumersunited.org/uebhc).
- Patient or lay stakeholder representatives are encouraged to review the following Consumers United for Evidence-based Healthcare (CUE) educational resources to assist in their reviewer responsibilities: www.consumersunited.org/education&training.

Patient or Lay Stakeholder Representative References

1. Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice G. In: Graham R, Mancher M, Miller Wolman D, et al., eds. *Clinical Practice Guidelines We Can Trust*. National Academies Press (US). Copyright 2011 by the National Academy of Sciences. All rights reserved; 2011.

Peer Review Committee

Nominations are submitted by the ACC, AHA, collaborating organizations, and the JC. The JC approves the PRC, including any systematic reviews.

Peer Review Committee Composition

Co-Chairs: The Chairs have primary responsibility for the peer review process, including adjudication and summarization of the peer review comments and adherence to all policies and procedures. The Chairs are ultimately responsible for ensuring timely completion of the peer review process, keeping the PRC focused, task-oriented, and encouraging balanced participation of all PRC members. The Chairs are ACC or AHA designees and they do not represent a collaborating society.

Members: The members are specific individuals, designated for consideration by the JC, ACC, AHA, and collaborating organizations who review the document. Members are asked to identify any thematic gaps, issues with the guideline WCs interpretations of the evidence (grading of the class of recommendations, level of evidence, and actionable clinical practice recommendations), and to provide detailed feedback to improve the quality of the document.

Peer Review Committee Competencies

The expertise sought for the peer reviewers is the same as the expertise sought for the members of the WC. The following competencies will be sought for peer reviewers, regardless of guideline clinical content:

1. Recognized content expertise/leadership at organizational/society level.
2. Prior guideline experience (WC member [preferred], peer reviewer, JC member, previous Vice Chair).
3. Shows ability to work with staff and finish tasks in timely fashion.
4. Exhibits collegiality and ability to provide constructive criticism.
5. Maintains confidentiality.
6. Maintains up to date RWI disclosures.

Peer Review Committee Co-Chair Responsibilities

- Attend the guideline kick-off meeting, the guideline consensus conference, chair the PRC kick-off meeting, lead conference calls with the Joint Guideline staff and the PRC to address the following issues:
  - Discuss the roles and responsibilities of the PRC and the dialogue between the PRC and the GL WC.
  - Adhere to the guideline scope and outline.
  - Discuss the responsibilities of the peer reviewers.
- Manage RWI, intellectual bias, and consensus development process:
  - Maintains disclosure policy during conference calls.
    - Chair reads RWI statement/reviews RWI on each conference call.
    - Disclosure table distributed to each member for conference call or face-to-face meeting. Chair invites each member to confirm RWI or state new RWI not listed on table.
    - Require members with relevant RWI to recuse themselves, if applicable.
- Confer with JC Guideline Liaison and ACC/AHA staff when issues are unclear or problematic.
- Confer with JC Chair and Chair-Elect, as needed if issues remain unclear or problematic.
- Management of minority opinions and differing perspectives. Encouraging all members to contribute to discussions and activities of the group.
- Establishing a climate of trust and mutual respect among members while remaining sensitive to pre-existing interprofessional tensions and hierarchies.

- Facilitate conference calls, ensuring opportunity for all to participate/discussion is balanced.
- Facilitate the introductory meeting:
  - Guide process to define PRC scope of work and timing and expectations to review and comment on the document.
  - Support the ACC/AHA RWI policy.
  - Determine strategy for reviewing studies and data by members' expertise and clinical competencies.
- Manage and maintain the document/timeline and encourage PRC members to meet deadlines.
- Summarizing main points and themes of the document reviews. Prepare a report for the committee twice throughout the guideline development process; once prior to the guideline consensus conference (presented to the WC at the consensus conference) and another time prior to organization approvals.
- Present the key issues and summary of the initial peer review at the Guideline consensus conference.
- Remind the PRC throughout the process about the confidentiality and strict embargo policies.

Pre-requisites/Competencies for the PRC Co-Chairs

- Recognized content expertise/leadership at organizational/society level.
- Experience with guideline writing as well as an understanding of evidence-based medicine.
- Previous experience serving as a guideline vice chair, a guideline WC member, a peer reviewer, or in a leadership position on the ACC/AHA Joint Committee on Clinical Practice Guidelines or a leadership position within the American College of Cardiology or American Heart Association.
- Must be free of relevant RWI as specified in the ACC/AHA RWI Policy.
- Ability to manage groups in fair, balanced manner; establish expectations/schedules.
- Ability to work with staff.
- Complete assignments in a timely manner.
- Possess a collaborative demeanor and establish a climate of trust and mutual respect among PRC members.
- Objective viewpoint about trial data.
- Encourage constructive debate without forcing agreement.
- Work in an embargoed environment and maintain confidentiality.
- Abstain from new or additional RWI during the entire guideline WC process.
- Participate actively in all in-person and virtual meetings.
- Be a diligent member with respect to prompt attendance to all in-person and virtual meetings.

Specific responsibilities of all PRC members include the following:

- Disclose fully any potential conflicts of interest and/or RWI and other entities.
- Participate in all in-person or virtual meetings.
- Attend all meetings with a commitment to teamwork and clear communication.
- Read all relevant materials and provide constructive comments and feedback during and between meetings.
- Maintain complete confidentiality of embargoed guideline material in all formats (written, verbal, or others).
- Confer with the PRC Chair, PRC Vice Chair, the JC Liaison, or AHA/ACC staff when issues are unclear or problematic.
- Maintenance of confidentiality and nondisclosure throughout guideline development process up through publication.
- Performance of the following tasks during the 2, 2-week peer review periods:

  - Ensure the document content is clear, accurate, complete, and balanced.
  - Confirm the class of recommendations are appropriate, and levels of evidence are supported.
  - Ensure the tables, figures, algorithms, appendixes and data supplements complement the text.
  - Identify discrepancies with previously published guidelines.
  - Identify gaps in evidence review.
  - Avoidance of solely focusing on copy-editing criticisms.
- For a systematic review (ERC report) reviewers should ensure that:
  - The ERC report—fairly and without bias—reflects the evidence properly.
  - There are no recommendations in the ERC report, only summaries of the evidence.
  - There are no errors in the report.

Surveillance Committee

The group should consist of the following competencies:

- Chair or co-chairs
- Vice chair (if there are no co-chairs)
- Content experts
- Early career members
- Fellows-in-training
- JC liaison

Specific responsibilities of the surveillance committee include the following:

- Disclose fully any potential conflicts of interest and RWI and other entities.
- Participate in most of the conference calls and all meetings.
- Attend all meetings with a commitment to teamwork and clear communication.
- Read all relevant materials and providing constructive comments and feedback during and between meetings.
- Review published literature and populate the evidence tables with key information extracted from studies.
- Respond to e-mails regularly.
- Complete personal assignments to meet deadlines.
- Maintain confidentiality of embargoed guideline material.
- Confer with the chair, vice chair, JC liaison, or ACC/AHA staff when issues are unclear or problematic.
- Adhere to the guideline outline, scope, and format of the document.
- The surveillance committee member is expected to construct the evidence tables. Other members may assist as needed. The surveillance committee member is responsible for the integrity of the data in the evidence tables and for performing quality checks on the tables before they are finalized.

Appendix 1a. Writing Committee Composition, Roles, and Responsibilities

Writing Committee Roles and Responsibilities	Chair	Vice Chair	Primary Author	Primary Reviewer	Patient or Lay Stakeholder Representative	JCCPG Liaison	JCPM Liaison	Collaborator Representative	PRC Co-Chairs	PRC Member
Drafts manuscript content	**P**	**P**	**P**	I	I	I	I	I	N	N
Reviews manuscript content	**P**	**P**	I	**P**	I	I	I	I	N	N
Verifies completeness and accuracy of guideline content	**P**	**P**	**P**	I	I	I	I	I	I	A
Conducts literature searches	I	I	**P**	I	I	I	I	I	N	N
Determines LOE	**P**	**P**	**P**	I	I	I	I	I	A	A
Checks COR language	**P**	**P**	**P**	I	I	I	I	I	I	I
Provides references	**P**	**P**	**P**	I	I	I	I	I	I	I
Completes data tables	I	I	**P**	I	I	I	I	I	N	N
Develops tables, figures, and algorithms	I	I	**P**	I	I	I	I	I	N	N
Performs statistical assessments	I	I	**P**	I	I	I	I	I	N	N
Performs manuscript quality check	**P**	**P**	I	I	I	**P**	I	I	N	N
Arranges phone calls/meetings	I	I	I	I	I	I	N	N	N	N
Copyedits manuscript	I	I	A	A	A	A	A	A	N	N
Develops guideline slide set	A	A	N	N	N	A	N	N	N	N
Develops pocket guide	I	A	N	N	N	N	N	N	N	N
Reviews existing guidelines for concordance with recommendations	I	I	**P**	**P**	I	**P**	I	I	I	I
RWI assessment and determination of relevance	A	A	A	A	A	A	A	A	N	N
Meeting logistics (Face-to-Face, Kick-off and Consensus Meetings)	A	A	A	A	A	A	A	A	N	N

Reviews typeset manuscript/galley proofs	**P**	I	N	N	N	A	N	N	N	N
Coordinates project timeline	I	I	N	N	N	I	N	N	N	N
Communicates deadlines and reminders	I	I	N	N	N	I	N	N	N	N
Performs peer review of guideline	N	N	N	N	N	N	N	A	**P**	**P**

A indicates aware; COR, Class of Recommendation; I, involved; JCCPG, Joint Committee on Clinical Practice Guidelines; JCPM, Joint Committee on Performance Measures; LOE, Level of Evidence; N, not responsible; P, primary responsibility; PRC, Peer Review Committee; and RWI, relationships with industry.

Appendix 1b. Staff Roles and Responsibilities

Writing Committee Roles and Responsibilities	AHA	ACC	AHA/ACC Science & Health Advisor, Guidelines	Operations Analyst	AHA/ACC National Senior Director, Guidelines	AHA/ACC Director of Guideline Science & Methodology	Collaborator Staff	Medical Librarian	Science & Medicine Advisor	Compliance Operations Manager	Contract Copy Editor
Drafts manuscript content	N	N	I	N	A	I	N	N	N	N	N
Reviews manuscript content	A	A	I	N	I	I	N	A	A	N	N
Verifies completeness and accuracy of guideline content	N	N	I	N	I	I	N	N	A	N	I
Conducts literature searches	N	N	I	N	A	A	N	**P**	N	N	N
Determines LOE	N	N	I	N	A	**P**	N	N	N	N	N
Checks COR language	A	A	I	N	I	I	N	N	A	N	I
Provides references	N	N	I	N	N	I	N	A	N	N	N
Completes data tables	N	N	I	N	N	I	N	N	N	N	N

Develops tables, figures, and algorithms	N	N	I	N	N	I	N	N	N	N	N
Performs statistical assessments	N	N	N	N	N	I	N	N	N	N	N
Performs manuscript quality check	A	A	**P**	N	I	I	N	N	N	N	I
Arranges phone calls/meetings	N	N	**P**	A	A	N	N	N	N	N	N
Copyedits manuscript	A	A	I	A	I	N	N	N	N	N	**P**
Develops guideline slide set	A	A	I	**P**	A	N	N	N	I	N	N
Develops pocket guide	A	A	I	**P**	A	N	N	N	N	N	N
Reviews existing guidelines for concordance with recommendations	A	A	I	N	I	A	N	I	**P**	N	N
RWI assessment and determination of relevance	**P**	**P**	A	A	A	I	N	N	I	**P**	N
Meeting logistics (Face-to-Face, Kick-off and Consensus Meetings)	I	I	**P**	**P**	A	N	N	N	N	N	N
Reviews typeset manuscript/galley proofs	I	I	**P**	N	I	N	N	N	N	N	N
Coordinates project timeline	I	I	**P**	A	I	A	A	A	A	A	N

Communicates deadlines and reminders	N	N	**P**	**P**	I	A	N	N	N	N	N
Performs peer review of guideline	A	A	I	A	A	A	A	N	A	A	N

A indicates aware; ACC, American College of Cardiology; AHA, American Heart Association; COR, Class of Recommendation; I, involved; LOE, Level of Evidence; N, not responsible; P, primary responsibility; and RWI, relationships with industry.

Appendix 2. Evidence Review Committee and Protocol

Addition of Evidence Review Committees

The guideline creation process was expanded to include an Evidence Review Committee (ERC) in addition to the WC. The task of the ERC is to complete all phases of the Systematic Review (SR) process including the identification, abstraction, and quality assessment of clinical evidence, culminating in analysis of the extracted data to support the writing of recommendations.

ERC Protocol: Screening and Abstraction

1. Initial Screening–title and abstract screening to determine if a full paper evaluation is warranted

a. Specific form for this step will be developed for web-based program based on the PICO(TS) criteria.
b. Blinded screening performed in pairs.
c. Purpose is to determine if paper can be excluded based on review of title/abstract alone.
d. If both members of the pair reject the paper, it will be excluded from subsequent evaluations (so, no consensus for inclusion is needed here).

2. Second Stage Screening–full review of paper to determine if it meets inclusion criteria

a. Specific form for this step will be developed in web-based program.
b. Blinded screening performed in pairs.
c. Purpose is to determine if paper can be included based on full read of paper.
d. There must be consensus between both members of a pair for each question response. If not, these steps should be undertaken:
    i. Discussion between reviewers to determine if agreement can be reached.
    ii. If further clarification needed, the ERC Chair or a designated member of the other reviewer pair should review the paper for final adjudication.

3. Labelling of Studies

a. **Relevant**: Is used when the reviewer determines the study fits the systematic review question and study data are included in the systematic review.
b. **Maybe Relevant**: Is used when a reviewer is not certain of the relevance of the study and wishes to discuss with other member of pair. Is also used when the original data on other (secondary) outcomes from study authors may be relevant.
c. **Not Relevant**: Is used when the reviewer determines the study does not fit the systematic review question criteria and study data are NOT included in the systematic review.

4. Study Design Classification of Included Studies

a. Pool of included studies (screened from Steps 1 and 2) will be classified by pairs of reviewers as either:
    i. RCTs
    ii. Cohort studies with 100 or more participants

    These categories may be modified depending on the overall criteria for the specific ERC—for example, some ERCs may include case control studies or smaller cohort studies.
b. Guiding principles:

    Study selection is individualized for each topic based on availability and quality of evidence. If the exploration of the randomized controlled trials (RCTs) is generating a meaningful number of good quality studies, then observational studies (preferably high-quality cohort analyses) may not be required to be included in a systematic review. Joint Committee methodologists further recommend:
    i. Systematic review of the non-randomized studies is allowed for the diagnostic or prognostic questions as very few of these questions have relevant RCTs.

ii. RCTs and cohort studies should never be pooled together given methodological differences.
iii. ERCs should delineate the specific quality criteria for observational studies that can be included in a meta-analysis (eg, prospective studies, similar definitions for the variables and endpoints, similar duration of follow up, etc).

c. The pool of studies to abstract will then be divided into approximately one-half for each pair of reviewers.

5. Risk of Bias Assessment

a. The included RCTs and nonrandomized studies will be evaluated by a pair of reviewers with respect to *risk of bias*, using 2 different instruments based on the study design:
   i. RCTs: Cochrane Risk of Bias Tool (http://ohg.cochrane.org/sites/ohg.cochrane.org/files/uploads/Risk%20of%20bias%20assessment%20tool.pdf)
   ii. Nonrandomized studies: Newcastle-Ottawa Scale (http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp)
   iii. The Risk Of Bias In Non-randomized Studies - of Interventions (ROBINS-I tool) *(https://sites.google.com/site/riskofbiastool/welcome/home?authuser=0)*

b. There must be consensus between both members of a pair for each key question response (ie, not the comments field). If not, these steps should be undertaken:
   i. Discussion between reviewers to determine if agreement can be reached.
   ii. If further clarification needed, the ERC* Chair or a designated member of the other reviewer pair should review the paper for final adjudication.

*Assumption is that there are 2 pairs of reviewers working on this example ERC.

6. Abstraction of Results from Included Studies

a. Pairs of reviewers will abstract the results of the included RCTs and nonrandomized studies.
b. There must be agreement between both members of each pair to ensure that abstracted results are accurate.
   i. Since some of the results are abstracted in text fields, the specific wording of abstracted results may vary between members of a reviewer pair.
   ii. Members of each reviewer pair will assess each other's abstracted results to ensure that the documented results are consistent.

Data Retrieval Procedures for Systematic Reviews:

Background: When dealing with quantitative analytic approaches for the purposes of meta-analytic systematic reviews, certain scenarios might arise which require retrieval of raw data from the published/peer review studies for minimizing imprecision. These may include:

- The quantitative meta-analytic approach may require having an actual numerator and denominator that comprise the proportion/rate of events at the patient level rather than summary rates.
- Such raw data may be needed for certain time points that might not have been presented in a study.
- Raw data may also be desired for published sub-groups dealing with the defined systematic review question.

Standard Operating Procedures for Data Requests from Authors at Academic Institutions:

The ERC chair and GL chair (in some cases), have discretion to request this type of data (after due diligence that the data from the study in question is not housed with the industry itself) to the academic authors such that applicable embargo policies are followed, and no specifics are shared regarding the content of nascent ACC/AHA guidelines.

Policy Prohibits Requests from Authors Representing Industry Entities:
While ACC/AHA recognizes the potential benefit of such data and analyses, because any ERC analysis needs to be viewed as completely free of any potential industry involvement and beyond reproach or question, it must therefore be based on peer-reviewed, published data. The industry cannot be directly (or indirectly) queried. This includes requests made from academic partners on behalf of the ERC members.

ERC should use published information from such industry sponsored peer-reviewed papers for qualitative narration in their report to help inform WC deliberations as the WC is counting on the ERC's objective report on the data and their quality assessments for the studies retrieved based on the systematic review question.

Appendix 2a. Systematic Review Reports

Systematic reviews (SRs) form the basis for modern clinical guidelines. The SR may take the final form of an evidence report that is published separately from the guideline and makes no recommendations. Thus, a SR may be defined as a scientific investigation that focuses on a specific question and that uses explicit, planned scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may or may not include a quantitative synthesis, or meta-analysis, of the results from separate studies. The Joint Committee recommends using the PRISMA group standards as a guide to develop a SR publication style to ensure that the appropriate information is included in each SR report (Checklist 1); however, flexibility may be needed depending on the topic and outcome of the SR.

Checklist 1. Suggested Items to Include When Reporting a Systematic Review or Meta-Analysis

Title	**Explanation**
1. Title	Identify the report as a systematic review, meta-analysis, or both
Abstract	
2. Structured summary	Provide a structured summary including, as applicable, background, objectives, data sources, study eligibility criteria, participants, interventions, study appraisal and synthesis methods, results, limitations, and conclusions (no recommendation verbiage used)
Introduction	
3. Rationale	Describe the rationale for the review in the context of what is already known
4. Objectives	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS)
Methods	
5. Protocol	Indicate if a review protocol exists, as well as if and where it can be accessed (such as web address)
6. Eligibility criteria	Specify study characteristics (such as PICOS, length of follow-up) and report characteristics (such as years considered, language, publication status) used as criteria for eligibility, with associated rationale
7. Information sources	Describe all information sources (such as databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched
8. Search	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated
9. Study selection	State the process for selecting studies (that is, screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis)
10. Data collection process	Describe method of data extraction from reports (such as piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators
11. Data items	List and define all variables for which data were sought (such as PICOS, funding sources) and any assumptions and simplifications made

12. Risk of bias in individual studies	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis
13. Summary measures	State the principal summary measures (such as risk ratio, difference in means)
14. Synthesis of results	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (such as I^2) for each meta-analysis
15. Risk of bias across studies	Specify any assessment of risk of bias that may affect the cumulative evidence (such as publication bias, selective reporting within studies)
16. Additional analyses	Describe methods of additional analyses (such as sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified
Results	
17. Study selection	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram
18. Study characteristics	For each study, present characteristics for which data were extracted (such as study size, PICOS, follow-up period) and provide the citations
19. Risk of bias within studies	Present data on risk of bias of each study and, if available, any outcome-level assessment (see item 12)
20. Results of individual studies	For all outcomes considered (benefits or harms), present for each study (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot
21. Synthesis of results	Present results of each meta-analysis done, including confidence intervals and measures of consistency
22. Risk of bias across studies	Present results of any assessment of risk of bias across studies (see item 15)
23. Additional analysis	Give results of additional analyses, if done (such as sensitivity or subgroup analyses, meta-regression [see item 16])
Discussion	
24. Summary of evidence	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (such as health care providers, users, and policy makers). Discuss the relevance (i.e., *generalizability)* and fidelity of implementation (i.e., *whether tested interventions were actually implemented in practice within the study*)
25. Limitations	Discuss limitations at study and outcome level (such as risk of bias), and at review level (such as incomplete retrieval of identified research, reporting bias)
26. Conclusions	Provide a general interpretation of the results in the context of other evidence, and implications for future research. The report should comment on the data but not make recommendations for medical management moving forward.

Adapted from Liberati et al, 2009.[1]

Healthcare consumers and policy makers can employ SRs, which objectively summarize large number of studies, identify gaps in research, and highlight beneficial and harmful interventions, as decision-making instruments.[2] SRs when critical, have traditionally been accomplished by three separate processes:

1. Independent ACC/AHA ERC WCs similar to the GL WCs using ACC/AHA provided software platforms such as Indico.
2. Systematic reviews accomplished within WC authors that have expertise to do such quantitative analysis.
3. Vendors [such as Evidence-based Practice Centers like OHSU (Oregon Health Sciences University)].

Appendix 2a. References

1. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *PLoS Med*. 2009;6:e1000100.
2. Bero LA, Jadad AR. How consumers and policymakers can use systematic reviews for decision making. *Ann Intern Med*. 1997;127:37-42.

Appendix 3. Reference Guide for Writing Recommendations and Supportive Text

The following points are provided as a guide for authors:

- **Class (strength) of Recommendation (COR) reflects the magnitude of benefit over risk and corresponds to the strength of the recommendation.**
- **Level (quality) of Evidence (LOE) denotes the confidence in or certainty of the evidence supporting the recommendation, based on the type, size, quality, and consistency of research findings.**
- **LOE: A, LOE: B-R (randomized)/B-NR (nonrandomized), and C-LD (limited data) require supportive evidence. LOE: C-EO (expert opinion) does not require a reference.**
- Recommendations **should**:
    - Use the appropriate verb for the COR noted in Table 2 in the main document above.
    - Be actionable, NOT a statement of fact.
    - Be written as stand-alone full sentences which facilitate tagging of keywords to the recommendation.
    - Be written in the active/positive tense rather than passive/negative tense (Example: COR 1 recommendations are to perform a test/give a treatment that is useful/effective rather than a COR 3 recommendation not to perform a test/give a treatment).
    - Use clearly defined terms, ie, quantify benefit, harm, and/or time period.
    - Be consistent/concordant with previous ACC/AHA guidelines, unless new evidence is available or a change in practice has occurred. The new evidence and/or change in practice must be described in the text.
    - Be listed in order based on LOE for recommendations of the same COR (starting with LOE: A). However, some flexibility is permitted with COR/LOE order when a particular sequence is preferred for guiding patient care.
- In formulating recommendations, clarify the target population (prefer at the beginning of the recommendation to promote a patient-centric focus, but not necessary in every recommendation), intervention, comparator or alternative if any, objective or intended outcome, pertinent time span and/or setting. It may be appropriate to provide some of this information in the supporting text rather than the recommendation.
- Recommendation should avoid ambiguous, vague, and underspecified language whenever possible; avoid use of the term “consider”.
- When more than 1 drug, strategy, or therapy exists within the same COR and LOE and there are no comparative data, options are listed alphabetically.
- Recommendations for drugs may be written for off-label use; but drugs/devices must be FDA approved and currently available for clinical use in the United States.[1]
- The Joint Committee on Clinical Practice Guidelines (JC) has designated the term *guideline-directed medical therapy* (GDMT), which replaced OMT (optimal medical therapy). This term is used when referring mostly to Class 1 and 2a recommendations in other ACC/AHA guidelines.
- **Comparative-effectiveness** recommendations may be included only for COR 1 and COR 2a (LOE: A, B-R, and B-NR), using appropriate comparator verbs; direct comparative data must be available for the active treatments or strategies. *Note:* In establishing this policy, the intent of the JC was to base comparative-effectiveness recommendations on high-quality evidence.
- The methodology for updating, removing or adding recommendations published in previous guidelines focuses on pivotal new evidence that warrants incorporation into the full guideline.
- **Class 3: No Benefit or Harm** recommendations should almost always be supported by LOE A or LOE B data.

- If the WC and Chair feel a COR 3 recommendation with LOE C is essential, discussion between the WC Chair and the JC is required.
- LOE C-LD recs should have:
  - Sufficient data (even if not meeting LOE B criteria).
  - Unanimous or near-unanimous consensus among WC members.
  - WC agreement that the statement is important enough to qualify as a guideline recommendation, rather than discussed only in the text.
- LOE C-EO recommendations should have:
  - Unanimous or near-unanimous consensus among WC.
  - WC agreement that the recommendation is essential, rather than discussed only in the text.

Evidence Guidance (Part 1):

- Evidence used to support LOE A and B recommendations must be summarized in an evidence table except in unusual circumstances requiring specific approval by the Joint Committee leadership. The following guidance may help distinguish LOE B-NR from LOE C-LD:
  - Evidence of sufficient quality to consider collectively must be presented in an evidence table. If the evidence is concordant in support of a course of action, it may qualify as LOE B-NR.
  - Conflicting evidence is best presented in an evidence table, and may lower the strength (COR) of recommendation to the extent that it influences either the risk-benefit ratio or generalizability of the recommendation (proportion of patients to which it potentially applies), and depending upon the number and scope of the studies might lower the LOE to C-LD. The authors are then encouraged to present the supporting evidence in a table.
  - When poor- or low-quality evidence is supported by clinical experience, the data may be presented in the context of LOE C-LD, phrasing the recommendation to acknowledge the relatively low-quality evidence. In this situation, authors are required to cite the evidence as references but need not formulate an evidence table.
- ACC/AHA or other guidelines, as well as expert consensus documents, cannot be used solely to support a recommendation; the original evidence source(s) must be cited.
- Because of the possibility of systematic error or bias, a single trial, regardless of its size or scope, is not sufficient to justify LOE: A.
- If specific data or information is cited in supportive text (eg, percent of patients experiencing specific outcomes, revised dosages, etc, or when citing a specific trial), a reference is required at the end of the sentence (preferably, the PUBMED ID number).
- Additional references may be cited in the supporting text (other than those used in the recommendation), if desired.
- Abstracts may not be used to support a recommendation, although they are permitted in the text. Abstracts <2 years old may be cited in text, tables, or figures but should be denoted as preliminary data.
- Constructing evidence tables: If the literature review identifies a large number of studies, WC members should consider the following:
  - Contact the WC Chair to clarify the specific assignment.

  Consider restricting the search to a specific period (eg, past 10 years).
  - Discount observational studies when sufficient evidence is available from RCTs.
  - Include meta-analyses or systematic reviews to condense and summarize the available data.
  - Limit studies based on logical criteria (eg, studies with patient populations over a specified size).

Evidence Guidance (Part 2 – LOE B-NR vs LOE C-LD):

- LOE B-NR: Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, registry studies, or meta-analyses of such studies.

- LOE C-LD: 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.
- Examples of LOE B-NR:
    - A 30,000-patient national or international registry report comparing management strategy A to strategy B (or management strategy A to no such management strategy), with propensity matching analysis.
    - A 9,000-patient report comparing treatment A to treatment B from a prospectively collected academic organization database, with multivariate analysis.
- Examples of C-LD:
    - A single center *post hoc* report of outcomes in 139 patients undergoing catheter ablation for an arrhythmia in pregnant women.
    - A registry report of 231 patients treated with a combination of drug A and drug B without high-quality statistical analyses to correct for nonrandomized treatment allocation.

‘Modular Recommendation Format’ Text Guidance:

- The text supporting most recommendations should not exceed **200 words**.
- Text **should** include:
    - Nuances or details about the recommendation that may be important or beneficial to clinicians.
    - Discuss the benefits and harms of the intervention.
    - 1-2 sentences that summarize the body of evidence that supports the recommendation.
- Text **should not** include:
    - A restatement of the recommendation.
    - Use of standard recommendation phrases/verbs (eg, is recommended, may be reasonable) or verbs that are discordant with the verb used in the recommendation.
    - Evidence data statistics, since hyperlinks to the data supplement will be provided.

Sample ‘Modular Recommendation Format’ Table:

9.5.1. Treating Hypertension to Reduce the Incidence of Heart Failure

	Recommendations for Treating Hypertension to Reduce the Incidence of Heart Failure Referenced studies that support the recommendations are summarized in the evidence table.	
COR	**LOE**	**Recommendations**
1	**C-LD**	1. In patients at increased risk, stage A HF, the optimal blood pressure in those with hypertension should be less than 130/80 mm Hg.[1-5]

[100-200 word max]

Recommendation-Specific Supportive Text

A large RCT demonstrated that in those with increased cardiovascular risk (defined as age >75 years, established vascular disease, chronic renal disease, or a Framingham Risk Score >15%), control of blood pressure to a goal systolic pressure of <120 mm Hg, as determined by blood pressure assessment as per research protocol, was associated with a significant reduction in the incidence of HF and an overall decrease in cardiovascular death. Blood pressure measurements as generally taken in the office setting are typically 5 to 10 mm Hg higher than research measurements; thus, the goal of <130/80 mm Hg is an approximation of the target blood pressure in conventional practice. Targeting a significant reduction in systolic blood pressure in those at increased risk for cardiovascular disease is a novel strategy to prevent HF.

Template for creating recommendations

	Recommendations for [match the header text] Referenced studies that support the recommendations are summarized in the evidence table	
COR	**LOE**	**Recommendations**
		1. Text…..

Synopsis

Maximum of 200 words

Recommendation-Specific Supportive Text

1. Text…maximum of 200 words
2. Text…maximum of 200 words

References

1. Reference
2. Reference
3. Reference

Rules for Brevity

What are "Rules for Brevity"? JCCPG-approved formatting rules for ACC/AHA guidelines. These rules make up the Single Publication Format or "SPF" (a Guideline Optimization initiative) which is currently in development.[2]

Top Take-Home Messages: are key points based on recommendations that the WC deems most notable and mapped directly to those recommendations.

Specifications	• This section should be included in every guideline. • Each take-home should be numbered starting with 1. • There can be 10 take-homes or less in this section. • Ordered as topics appear in the guideline (chronological order).

Content Considerations and Criteria	• Biggest changes in clinical practice
	  o ie, introduction of cardiac myosin inhibitory (2024 HCM Guideline)
	• Highest population impact
	  o ie, new classification system for atrial fibrillation (2023 Afib Guideline)
	• Possible controversy
	  o ie, lowering of the SBP goal from 140 mmHg to 130 mmHg (2017 HBP Guideline)
	• CORs 1 and 3 that have moved up or down due to new evidence
	• Reinforcement of evidence-based practices that have not been fully adopted
	  o ie, selective use of perioperative bridging of OACs (2024 Periop CV Management for Noncardiac Surgery Guideline)

Exclusion Criteria	• Statements that apply to general CV care and are not specific to the topic
	  o ie, social determinants of health, team-based care, etc.
	• Reiteration of a recommendation
	  o ie, "For this specific patient population, the following drug can be useful to..."
	• Reiteration of the guideline title or scope
	• Summarizing evidence or clinical trial information referenced in the guideline
	  o ie, "This one trial showed that the following device may reduce morbidity and mortality by x%..."

Associated Publications Table

Definition	A table with a list of publications and statements deemed pertinent to the writing effort and is intended for use as a resource, thus obviating the need to repeat existing guideline recommendations

Specifications	• Table will only list ACC and AHA documents
	• Referencing or listing of outdated/previous versions of guidelines or statements is prohibited
	• The table will only pull from sources cited within that guideline
	• Table will be featured in the Introduction section of the guideline
	• Main title: Associated Publications
	• Subsections:
	  o Guidelines
	  o Other Publications
	• Publications will be listed in chronological order based on year of publication
	• Titles of publications may be the condensed version, ie, "Atrial Fibrillation" (vs "The Guideline for the Diagnosis and Management of Atrial Fibrillation")

	• Publications in list will be linked to their web version appropriately

****Add example of table here once one publishes****

Parts of Modular Recommendation Format ("Modular Rec Format"): The "Modular Rec Format" (MRF) – a key element of the SPF – is used to organize/structure the content of AHA/ACC Clinical Practice Guidelines (CPGs). The primary content block of the MRF, known as a module, *always* includes recommendation text, including class of recommendation and level of evidence (COR/LOE); synopsis; recommendation-specific supportive text; and reference(s). MRF modules may *sometimes* include one or more tables and/or figures. Word counts for each of the aforementioned module elements are 200 words max (per section and per rec). Word counts in text sections exclude references and symbols.

Recommendation Text

Specifications	• Recs must stand alone (PICOT format + complete sentence + clearly actionable = stand-alone rec) • COR/LOE are independent of each other, but COR3:Harm recs must have an LOE higher than C.
Double-recs	• Each rec must stand alone and be matched with its own COR/LOE. **Double, triple, etc. recs are not permitted** (ie, more than one rec per number) • Example of a Double Rec: Aortic Disease 2022 Section 3.0 Imaging and Measurements 2a C-EO 6. In patients with known or suspected aortic disease, when performing echocardiography, it is reasonable to measure the aorta from leading-edge to leading-edge, perpendicular to the axis of blood flow. 2b C-EO Using inner-edge to inner-edge measurements may also be considered, particularly on short-axis imaging.
Recommendation tables organized by subtopic	• Recommendation tables may be organized by section subtopics • All recommendations should be numbered starting with 1 • Each subtopic recommendation should be organized by COR, starting with COR 1 and ending with COR3: Harm • Example: Section 6.1.2.2. Marfan Syndrome of 2022 ACC/AHA Aortic Disease Guideline Recommendations for Diagnostic and Surveillance Aortic Imaging in Marfan Syndrome Referenced studies that support the recommendations are summarized in the Online Data Supplement. COR / LOE / RECOMMENDATIONS Initial Diagnosis and Surveillance Imaging 1 C-EO 1. In patients with Marfan syndrome, a TTE is recommended at the time of initial diagnosis, to determine the diameters of the aortic root and ascending aorta, and 6 months thereafter, to determine the rate of aortic growth; if the aortic diameters are stable, an annual surveillance TTE is recommended.[1] If the aortic root, ascending aorta, or both are not adequately visualized on TTE, a CT or MRI of the thoracic aorta is recommended.[2] 2a C-EO 2. In adults with Marfan syndrome, after the initial TTE, a CT or MRI of the thoracic aorta is reasonable to confirm the aortic diameters and assess the remainder of the thoracic aorta. Imaging After Aortic Root Replacement 1 C-LD 3. In patients with Marfan syndrome who have undergone aortic root replacement, surveillance imaging of the thoracic aorta by MRI (or CT) is recommended to evaluate for distal TAD, initially annually and then, if normal in diameter and unchanged after 2 years, every other year.[3-6] 2a C-LD 4. In patients with Marfan syndrome who have undergone aortic root replacement, surveillance imaging every 3 to 5 years for potential AAA is reasonable.[2,6]
Unacceptable References	Scientific Statements by ACC, AHA or ESC cannot be used to support a rec's LOE. However, they may be cited in synopses and supportive text.

Synopsis: In 200 words or less (excluding references and symbols), the synopsis summarizes evidence cited in the rec-supportive text and/or summarizes clinical context specific to that (sub)section. Each MRF module must include only one synopsis. Format is free text. May include evidence not used in supportive text. Does NOT use rec language ("is recommended", "may be reasonable").

Recommendation-Specific Supportive Text

Definition	Additional text to summarize the evidence used to support a single rec.
Specifications	• Format is free text in paragraphs. • Each paragraph of supportive text is numbered starting with 1.

	• The number of the paragraph of supportive text is the same number as the rec it supports.
	• Supportive text may include additional references to those used to support a rec.
	• Supportive text does not:
	  o Restate the rec
	  o Reuse rec text (eg, "is recommended," "may be reasonable")
	  o Use verbs that are discordant with the verb used in the rec (eg, does not improve, does not reflect, is important to reduce, is preferred)
	  o Include evidence data statistics if hyperlinks to the data supplement are provided

Placeholder section: Placeholder sections are free text, do not have recs, and are not an element of the MRF module. This section is a necessary section of text in the guideline that acts as a placeholder for a future section with related recs. Placeholder sections should be limited and rarely used as sections should generally include recs and follow the MRF. Placeholder text does NOT include elements of the Preamble or Introduction (ie, RWI, Methodology, etc.) but strictly pertains to clinical content.

Structure of a Guideline

All CPGs should include these pre-introduction sections:

- Abstract
- Top Take-Home Messages
- Preamble

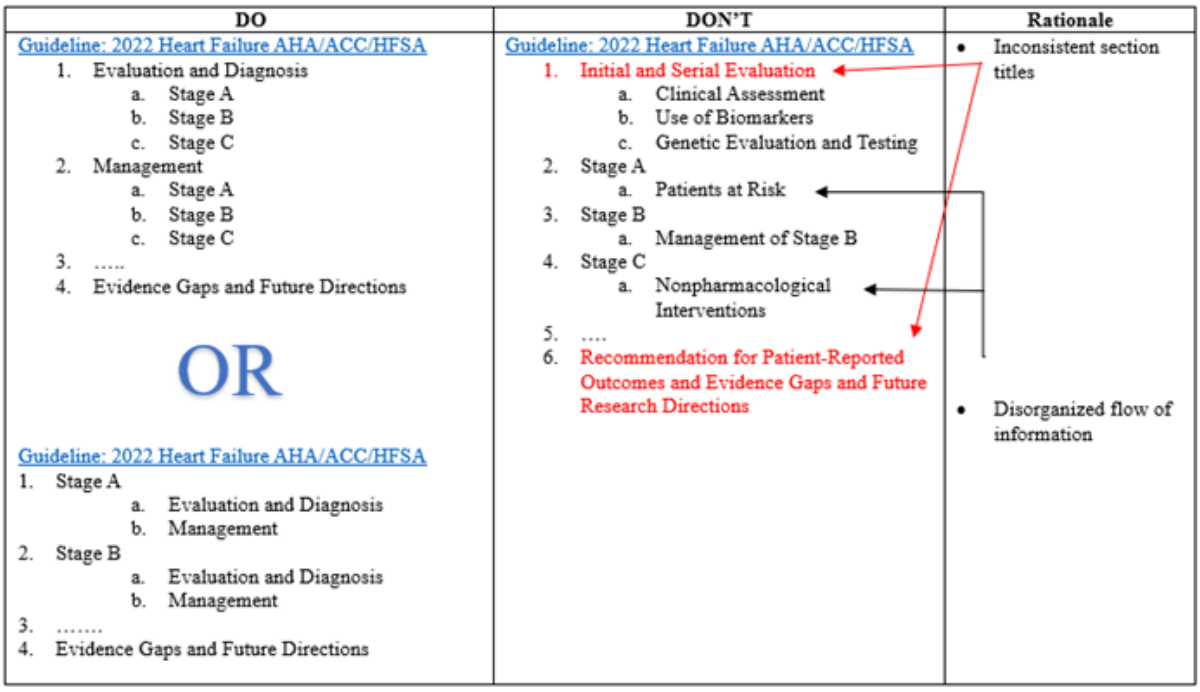
All CPGs should include a Chapter 1/Introduction and the following Chapter 1 sub-sections:

- 1.1. Methodology and Evidence Review
- 1.2. Composition of the WC
- 1.3. Guideline Review and Approval
- 1.4. Scope of the Guideline
- 1.5. Class of Recommendations and Level of Evidence

All CPGs should follow a standardized content outline. The following are required sections and section titles of the standardized content outline for disease-focused guidelines:

- 1. Definitions and Classifications
  - 1.1 Definitions
  - 1.2 Abbreviations
- 2. Evaluation and Diagnosis
  - 2.1 Risk Assessment
  - 2.2 Comorbidities
- 3. Prevention
- 4. Management
  - 4.1 Lifestyle
  - 4.2 Medical
  - 4.3 Surgical/Interventional
  - 4.4 Monitoring and Follow-Up
- 5. Complications of Management
- 6. Evidence Gaps and Future Directions

*Subsections should not exceed two levels, ie, Sections 1.1 and 1.1.1 *



Section Title	Definitions
Definitions and Classifications	Key terms discussed throughout the guideline
Abbreviations	Shortened versions of terms/phrases used throughout the guideline
Risk Assessment	All content relating to a patient's risk, including assessment, identification, stratification and management
Evaluation and Diagnosis	Any means of assessment or diagnostics, including H&P, imaging and labs
Management	Nonpharmacological, pharmacological, surgical and lifestyle interventions, etc.
Monitoring and Follow-Up	Short or long term follow up and monitoring of patients as they progress through the disease-state
Comorbidities	• Coexisting disease states that must be evaluated and discussed in relation to the guideline topic (ie, heart failure and diabetes, aortic disease and CKD) • Comorbidities are not considered "Specific Populations" • Management of comorbidities will be discussed in the "Management" section
Prevention	• Application of any healthcare measure to prevent disease • Includes primary, secondary, tertiary, etc. prevention
Complications of Management	Any unfavorable result or consequence of a disease, health condition or therapy
Evidence Gaps and Future Directions	• Evidence Gaps: Descriptions of gaps in currently available and documented evidence pertaining to a topic/disease/condition • Future Directions: Recommendations about how future research should be conducted

After a CPG kickoff, sections and subsections should not be added to the content outline. If an additional section or subsection is wanted, a change request must be submitted.

Appendix 3. References

1. Jneid H, Abdullah A, Ferrari V, et al. Guidance for incorporating FDA processes into the AHA/ACC methodology: a report of the American College of Cardiology/American Heart Association

Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. Published online September 25, 2025. https://doi.org/10.1016/j.jacc.2025.05.006.

2. Otto CM, Abdullah AR, Davis LL, et al. 2025 ACC/AHA guideline core principles and development process: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2025;https://doi.org/10.1016/j.jacc.2025.06.013.

Appendix 4. When is a Systematic Review Warranted?

1. Question Selection Criteria

Systematic review questions are selected because they affect the greatest number of people or patients (ie, should not be too esoteric), involve divergent data, or have large impact on patient care, including mortality, technologies with high cost or value, or quality improvement initiatives with broad implications to the public. They need to be focused questions with a sufficient amount and diversity of evidence to warrant a systematic review so the results can be translated into clear, actionable, and relevant recommendations. The questions must also be executable in a reasonable amount of time using a reasonable amount of resources. In areas where evidence is clear or widely accepted, a systematic review is not generally needed.

2. Data Criteria to Warrant Systematic Review Analysis

a. Variation of opinion regarding the literature or topic.
b. Conflicting data from more than a few individual studies.
    i. Once a systematic review has been completed, it may not need to be redone in the next iteration of the guideline (especially if there has been no significant interval change in the underlying literature) but rather a different topic may be selected.
c. Systematic review questions should <u>not</u> be posed if:
    i. There is strong existing consensus on the topic with adequate supporting literature.
    ii. There is minimal to no relevant data based on a preliminary literature search (with supplementation as needed based on expert opinion).
    iii. There are recent high-quality systematic reviews (in which case an ERC will simply be repeating work already done). When available, high-quality systematic reviews from reputable organizations (eg, the Cochrane Collaboration and Agency for Healthcare Research and Quality Evidence-based Practice Center) should be used.
d. The ERC is encouraged to run a meta-analysis (ie, quantitative systematic review where data are pooled across several studies) when at least 3 studies reported the same outcomes. Meta-analyses should not combine data from RCTs and cohort studies given methodological differences and other sources of heterogeneity in those types of studies.

Appendix 5. ACC/AHA Joint Committee on Clinical Practice Guidelines Charter

ACC/AHA[1] Joint Committee on Clinical Practice Guidelines

AHA Mission: The mission of the American Heart Association is to be a relentless force for a world of longer, healthier lives.

AHA Strategic Value Proposition: The AHA is a catalyst to achieving maximum impact in equitable health and well- being.

ACC Mission: The mission of the American College of Cardiology is to transform cardiovascular care and improve heart health.

ACC Vision: A world where innovation and knowledge optimize cardiovascular care and outcomes.

Roles and Responsibilities: The AHA/ACC Joint Committee on Clinical Practice Guidelines (Joint Committee, or JC) is responsible for:

[1] The name of the Committee will rotate every two years with the change of the Chair of the Committee. For clarity, when the Chair is an ACC appointee, the Committee will be referred to as the ACC/AHA Joint Committee on Clinical Practice Guidelines. When the Chair is an AHA appointee, the Committee will be referred to as the AHA/ACC Joint Committee on Clinical Practice Guidelines.

- Aligning strategically with the missions, values, and goals of the AHA and the ACC.
- Oversight and development of clinical practice guidelines (GLs) for the American Heart Association (AHA) and the American College of Cardiology (ACC).
- Operational oversight of timely GL maintenance and revisions as new practice changing science becomes available and following appropriate WC review and consensus.
- Prioritizing a GL development plan that will be updated at least every 3-5 years.
- Establishing policies, operating standards, and procedures to produce trustworthy, timely, and easily accessible evidence-based GLs.
- Establishing methodologies to be used for GL development including those related not only to defining Class of Recommendation and Level of Evidence, but also to considerations regarding the development and peer review of PICOT questions and the need for convening a formal Evidence Review Committee (ERC).
- Delegating to individual Writing Committees (WCs) the task of constructing GLs to promote the optimal evaluation, management, and prevention of cardiovascular disease with emphasis on patient wellness and shared decision-making where appropriate. For policies and process related to WC structure and composition, see Addendum A.
- Formal approval of all GL drafts and responses to reviewers before the documents are forwarded for AHA and ACC for organizational approval.
- The JC Chair (or designee) shall maintain a reciprocal communication relationship with the JCPM and JCDS to ensure coordination of clinical documents, policies, and guidance.

Composition and Terms: The JC consists of a core of 16 members. (Chair, Chair-Elect, 14 voting members: 7 members appointed by AHA, 7 members appointed by ACC).

- At least 1 of the 14 voting members will be a Fellow-in-Training (FIT) or an Early Career (EC). Appointment shall rotate between the two organizations.
- Processes for nomination and approval of JC member candidates will be determined by existing AHA and ACC policies, including those pertaining to RWI.
- From time to time, it will be necessary for an additional member(s) to be added when, in the opinion of the Chair and Chair-Elect, the JCCPG is lacking a competency that is required more urgently than the normal nominating cycle allows. Under these circumstances, the committee may appoint no more than two additional individuals to fill the lacking competencies.[2] JCCPG membership will not exceed 18 total members.

[2] The ACC Governance Committee will be notified of ad hoc appointment requests prior to invitations being issued.

Chair & Chair-Elect Terms and Requirements

- The Chair will serve one, non-renewable, two-year term.
- The Chair-Elect will be appointed to serve a two-year term prior to the expiration of the current Chair's term.
- The Chair and Chair-Elect will be appointed in the same year and will serve parallel terms.
- The Chair-Elect will automatically become Chair at the end of the current Chair's term.
- To be considered for Chair-Elect, the individual must have served as a member of the JC for at least one term (two years) within the last five years.
- Appointment of the Chair-Elect will alternate between AHA and ACC and be determined by existing AHA and ACC nomination policies, including those pertaining to RWI.
- Chair and Chair-Elect terms run from January–December.
- To ensure coordination of clinical documents, policies, and guidance, the Performance Measure Chair (or designee), and Clinical Data Standards Chair (or designee) shall be invited to serve ex officio as Joint Committee on Clinical Practice Guideline members to maintain the reciprocal relationships with their respective Joint Committees.

Member Terms and Requirements

- The JCCPG members will represent AHA's and ACC's diverse membership groups and professional specialties.
- Appointment of JCCPG members will reflect AHA and ACC principles for inclusion, diversity, and equity.
- All JCCPG members are voting members.
- All members except FIT and EC will serve two-year terms, with the opportunity for reappointment, for a maximum of four consecutive years, as determined by the appointing organization.
- FIT and EC appointees will serve one, non-renewable, two-year term.
- An individual participating as a FIT is not eligible to later be appointed as an EC.
- An individual participating as an EC or FIT is eligible to later be appointed as a regular JC member.
- Members should have experience as a previous GL author (or peer reviewer at a minimum).
- Members will serve terms consistent with their respective organization's appointment cycle as follows:
    - ACC appointees serve April–March terms.
    - AHA appointees serve July–June terms.

Competency Requirements: The Committee as a whole should encompass these competencies; individual members need not demonstrate all.

- Proficiency in providing GL oversight.
- Expertise in clinical cardiovascular medicine, as well as across several, sub-specialty areas including, but not limited to, prevention, coronary disease, electrophysiology, vascular medicine, heart failure, interventional cardiology, cardiac surgery, arrhythmia, etc.
- Experience as author, reviewer, and communicator.
- Exceptions will be made to accommodate early career individuals, fellows-in-training (FIT) without such prior experience, in accordance with AHA and ACC strategic priorities.

Regular reporting and communication mechanisms: Final guideline drafts are sent to the ACC Clinical Policy Approval Committee and AHA Science Advisory Coordinating Committee for approval; all comments must be adjudicated and discussed during a leadership call. Lastly, all other partnering organizations and collaborators are sent the guideline for approval and/or endorsement.

AHA reporting structure: The JC reports to the AHA Science Advisory Coordinating Committee.

ACC reporting structure: The JC reports to the ACC Science and Quality Committee.

Meeting Schedule:

- JC members are expected to attend two meetings per year (typically held in-person at AHA Scientific Sessions and ACC Scientific Sessions in accordance with each organization's travel policies) and participate in periodic conference calls as deemed necessary by the Chair and Chair- Elect.
- Monthly calls between the JC Chair, Chair-Elect, and Staff will be held to oversee current activities.

AHA Attendance Policy: AHA appointees of the Committee will adhere to AHA's attendance policy.

ACC Attendance Policy: Members of the Committee will adhere to the College's Attendance Policy. Any Committee member who fails to attend two (2) consecutive regular meetings without valid reason shall be required to step down from the Committee.

AHA Staff Liaison: Senior Vice President, Science and Medicine

ACC Staff Liaison: Team Leader, Guidelines & Toolkits, Digital & Organizational Strategy

Addendum A

The ACC/AHA Joint Committee on Clinical Practice Guidelines is responsible for delegating individual Writing Committees (WCs) to construct GLs to promote the optimal evaluation, management, and prevention of cardiovascular disease with emphasis on patient wellness and shared decision-making where appropriate. The WC leadership and its members will be appointed with input from AHA and ACC science leadership and in accordance with the following process:

1. The JC will select and appoint the Chair and Co- or Vice-Chair(s) for specific GLs.
2. Processes for appointment of Chair and Co- or Vice-Chair candidates for specific GL WCs will be determined by existing AHA and ACC policies that govern such activities, including those polices that pertain to relationships with industry (RWI).
3. Delegating to the GL WC Chair and Co- or Vice-Chair primary responsibility for responding to the reviewer comments.
4. The JC will select and appoint individual GL WC members in consultation with the Chairs and Co- or Vice-Chairs.
    - The JC will modify WC membership as needed in consultation with the Chair and Co- or Vice Chair of the WC.
    - At least one JC member will be selected to serve as formal liaison to an individual GL WC.
    - A separate JC member will be appointed as the JC's lead reviewer for the GL.
    - The liaison(s) appointed by the JC to the WC will oversee the multi-step process and ensure appropriate adjudication of all peer reviewer and organizational comments, consulting with the JC Chair and Chair- Elect as needed. In the event of a disagreement between the WC and the JC, the JC's decision will be binding.
    - WC Members will be required to periodically review and approve all guidelines and other clinical documents.
    - Individual members are selected to serve a liaison role between the JC and each writing committee.
    - All JC Members are invited to participate in the peer review process for an individual GL, especially when the guideline topic is relevant to their area of expertise. Final review and approval are required on all guidelines prior to formal AHA and ACC organizational approval.
5. The JC, in consultation with the WC Chair and Vice-Chair, will designate WC positions for partnering professional societies according to AHA and ACC organizational policies that govern this designation.
6. The JC, in collaboration with partnering societies when appropriate, will appoint GL peer reviewers.
7. The JC Chair and Chair-Elect will seek input from the AHA and ACC Science Leadership, the WC Chair/Co- or Vice Chair, and collaborating societies
8. Any requests for changes to recommendations or text after organizational review will be discussed among the JC Chair, Chair-Elect and the WC Chair/Co- or Vice-Chair and written responses (and any accompanying GL revisions) submitted to the organizations for final adjudication.

Appendix 6. ACC/AHA Guideline Topic Selection

When a new guideline topic is proposed, the ACC/AHA staff will work with the Joint Committee leadership to assign the proposal to a Joint Committee member with expertise in the content area. The Joint Committee member will complete the form below and present their recommendation to the Joint Committee.

ACC/AHA Guideline Topic Suggestion Form Submitted by: Presented to JCCPG on: Approved by JCCPG on:	
1. Core topic Where does this suggestion fit into the ACC/AHA Guideline core topic list? Core topic list: Coronary artery disease, valvular heart disease, arrythmia, myopericardial disease, non-coronary vascular disease, prevention, other.	
2. Topic title/impact What is the importance/impact on public health? What is the timeliness of the topic? Where does this topic fall? o Evaluation o Diagnosis o Management/treatment	
3. Magnitude of anticipated change to practice What is the magnitude of anticipated change to current clinical practice? o Expected to reduce major adverse cardiac events o Expected to change practice significantly o Expected to result in modest practice change o Expected to clarify uncertainty in practice o Other Describe a use case scenario for this topic suggestion.	
4. Availability of new evidence What new evidence is available since the last relevant ACC/AHA Guideline publication? If this is a new topic, how timely is the available evidence? Are there any upcoming topically relevant trials?	
5. Quality of evidence What is the quality of the new and available evidence? o High quality evidence (RCTs, meta-analyses) o Good evidence (retrospective studies, cohort studies) o Expert opinion (single case reports)	
6. Relevant publications List the relevant ACC/AHA guidelines and relevant guidelines from other societies (include publication year).	
7. Suggested organizations for involvement List possible organizations that may be invited to participate at various levels (partner, collaborator).	

Appendix 7. Literature Search Request Form

Literature Search Form:
ACC/AHA Guidelines Research

* Required field

Name * Click or tap here to enter text.	Today's Date (mm/dd/yyyy) * Click or tap here to enter text.
Phone number * Click or tap here to enter text.	Email address * Click or tap here to enter text.
Guideline * Click or tap here to enter text.	Section Number(s)/Title(s) * Click or tap here to enter text.

1. **Date needed by** *(Please allow at least 7-10 business days for search to be completed.)* *
   Click or tap to enter a date.

2. **Please write a brief statement describing your research.** *
   If you are using PICO(TS) format (population, intervention, comparator, outcomes, timing, and setting), include your PICO(TS) question here.
   Click or tap here to enter text.

3. **What databases and resources should be searched?** *

☐ PubMed ☐ Cochrane ☐ EMBASE
☐ CINAHL ☐ Other (Please specify. NOTE: Some databases may not be available for this search): Click or tap here to enter text.

4. **What types of studies/articles should be included in the search?** *

☐ RCTs ☐ Reviews
☐ Clinical Trials ☐ Meta-analyses
☐ Observational studies ☐ Systematic Reviews
☐ Comparative studies ☐ Guidelines
☐ Case Studies
☐ Other (please specify): Click or tap here to enter text.

5. **Are you looking for information specific to one or more ethnic groups? If so, please provide information regarding which ethnic group/s you are interested in.**
   Click or tap here to enter text.

6. **By default, searches will be run with a focus on human subjects. Additionally, searches will be run for English language articles only.** *

Please select an answer below to acknowledge that you accept these terms OR to indicate that additional discussions are needed.

☐ I understand that my search will focus on human subjects and will include references for English language articles only.

☐ My search needs may require animal studies and/or non-English language articles. Please contact me to discuss this further.

7. **Sex**

☐ Female ☐ Male ☐ Both

8. **Age group**

☐ Infant (1-23 months) ☐ Adult (19+ years)

☐ Child (6-12 years) ☐ Aged (65+ years)

☐ Adolescent (13-18 years) ☐ Other (please specify): Click or tap here to enter text.

9. **Publication dates to include in search** *

If you select "Other," indicate the specific time period covered by the search including the beginning date (month/year) and end date (month/year): [e.g., 05/1980 to 08/1999]

☐ All ☐ 2 years

☐ 5 years ☐ 10 years

☐ Other (please specify): Click or tap here to enter text.

10. **If you have already found an article that closely matches your research, please provide sample citations. If you know of authors who are experts in this topic, please provide their names.**

Click or tap here to enter text.

11. **How would you like to receive the results of the search?**

☐ Citations only ☐ Citations and abstracts

☐ Compressed EndNote library ☐ Text file

☐ XML file ☐ Other (please specify): Click or tap here to enter text.

Appendix 8. Generating Clinical Questions

ACC/AHA guidelines are based on thorough evidence reviews and each recommendation or section should be based on a carefully formulated and well vetted research process to address major clinical issues. Framing a research question offers a common, accessible language for specialists, clinicians in general, and researchers. Consistent with this idea, ACC/AHA adopts the Centre for Evidence Based Medicine (CEBM) approach. Clinical practice guidelines are systematically developed statements designed to assist health care professionals and patients make decisions about appropriate health care for specific clinical circumstances.[1] In addition, therapeutic area expertise is required for the development of a well-framed research question. ACC/AHA tend to classify research questions into two broad categories: Foreground questions and Background questions.

Foreground Questions:
Foreground questions ask for specific knowledge to inform clinical judgments for major clinical issues. These should be PICO(TS)-based questions. A study evaluating 89 randomized controlled trials has shown that PICO(TS) format is linked to better reporting of the quality of such trials.[2] The answers to such questions inform clinicians with "what works" and "how much"; the impact of a specific intervention has on benefits, harms, and resources. The Joint Committee further categorizes the foreground questions into questions addressed by the WC and questions addressed by a systematic review.

Question/s for Systematic Review Addressed by an ERC to Form the Basis for Recommendations to be Developed by the WC
WCs and ERCs formulate and prioritize candidate PICOTS questions, which are then thoroughly vetted by the leadership, partners and other parties, as appropriate. Practical considerations, including time and resource constraints, limit the ERCs to addressing clinical questions for which the evidence relevant to the guideline topic lends itself to systematic review and analysis, and when the systematic review could impact the sense or strength of related recommendations. If there are existing high-quality SRs, an ERC-based SR may not be needed. The SR criteria is described in Appendix 4.

The approved questions or keywords are then subjected to a comprehensive literature review based on carefully formulated search protocols. ERC members first perform dual title and abstract screening of the literature returned by the search. The ERC then performs full-text screening for further refining the inclusion or exclusion of the relevant articles based on the protocol criteria. The ERC then extracts the data and digitizes the relevant studies. Next, the quality of the studies is assessed by the ERC through analysis by a pair of reviewers using the appropriate tools. The ERC then conducts the data analysis and statistical meta-analyses where appropriate. The systematic review report is written and supplied to the WC to be utilized for the recommendation development. The WC develops recommendations on the basis of the systematic review and denotes them with superscripted "SR" (ie, ^{SR}) to denote support was derived from the formal systematic review. An example of a systematic review-based recommendation is:

COR	LOE	Recommendation
1	**B-R^{SR}**	**1. For patients with (disease for specific GL/condition), beta blockers should be continued in patients who have been on chronic beta blockers (due to outcome based on trials). (references)**

Background Questions:
The ACC/AHA methodology also includes recommendations based on background questions in order to give comprehensive guidance to clinicians at the point of care. There may not be sufficient existent research concerning certain background questions. These questions mainly address the who, what, how, where, when and why about a disorder, test, or a treatment.[3] An example of a background question-based recommendation is:

COR	LOE	Recommendations
1	C-LD	**1. In patients with clinically suspected moderate or greater degrees of valvular stenosis who have not undergone preoperative echo within 1 year, echo should be performed/is recommended if there has been a significant change in clinical status or physical examination since the last patient exam. (references)**

Types of Studies Suggested for Clinical Questions:
The categories of studies included for a review are determined by the types of carefully chosen critically relevant questions for a specific therapeutic area (see Appendix 8a). A well thought out question helps identify the kinds of studies that meet the criteria to be included in an evidence review.[4] A systematic review should explicitly state a standardized and rigorous procedure for selection of the studies included.[5] To minimize random error and bias, as many relevant studies as resources allow are a requisite.[4]

The explicit strategy for analyzing the quality of included studies should also be well-defined within the document and the studies should be of good quality. While not limited to specific topics or cases, the ACC/AHA guidelines do incorporate expert experience and opinion for consensus-based recommendations; especially to supplement areas where available evidence is not sufficient but the clinical issue is important.[6]

Appendix 8. References

1. Law K, Howick J. Centre for Evidence-Based Medicine. CEBM glossary. Accessed June 2, 2025. https://www.cebm.ox.ac.uk/resources/ebm-tools/glossary
2. Rios LP, Ye C, Thabane L. Association between framing of the research question using the PICOT format and reporting quality of randomized controlled trials. *BMC Med Res Methodol*. 2010;10:11.
3. Georgetown University Dahlgren Memorial Library. Evidence-based medicine resource guide. Types of clinical questions. Accessed June 2, 2025. https://guides.dml.georgetown.edu/ebm/ebmclinicalquestions
4. Counsell C. Formulating questions and locating primary studies for inclusion in systematic reviews. *Ann Intern Med*. 1997;127:380-387.
5. Varandas T, Carneiro AV. Types of clinical studies. Systematic reviews. *Rev Port Cardiol*. 2006;25:233-246.
6. Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice G. In: Graham R, Mancher M, Miller Wolman D, et al., eds. *Clinical Practice Guidelines We Can Trust*. National Academies Press (US). Copyright 2011 by the National Academy of Sciences. All rights reserved; 2011.

Appendix 8a. Types of Studies Suggested for Recommendation Development

The categories of studies included for a review are determined by the types of carefully chosen critically relevant questions for a specific therapeutic area. A well thought out question helps identify the kinds of studies that meet the criteria to be included in an evidence review. A systematic review should explicitly state a standardized and rigorous procedure for selection of the studies included.[1] To minimize random error and bias, as many relevant studies as resources allow are a requisite.[2]

The explicit strategy for analyzing the quality of included studies should also be well-defined within the document and the studies should be of good quality. The Institute of Medicine (IOM) recommends using a comprehensive search process for including the published and unpublished data to minimize publication bias.[3] In addition to evidence (published and unpublished), the guidelines also incorporate expert experience/opinion—especially to supplement areas where available evidence is not sufficient but the clinical issue is important.

The following is a list adapted from an existing methodology manual.[4]

Study Types Considered for Therapeutic Questions:

1. Randomized controlled trials in a representative population/sub-analysis.
2. Prospective cohort studies.
3. Controlled studies (including well defined natural history controls or patients serving as their own controls).
4. Registries and national databases such as NHANES
5. Case series/reports

Categories for Causation/Prognostic Questions:

1. Prospective cohort study.
2. Retrospective cohort study or case control study.
3. Registries.
4. Case series/reports.

Categories for Diagnostic Accuracy:

2. Prospective cohort study.
3. Study of cohort patients at risk for the outcome from a defined geographic area (ie, population based).
4. Case-control study.
5. Registries.
6. Case series/reports.

Categories for Population Screening:

1. Study of cohort of patients at risk for the outcome from a defined geographic area (ie, population based).
2. A non-population based non-clinical cohort (eg, mailing list, volunteer panel).
3. A referral cohort from a center with a potential specialized interest in the outcome.
4. Registries.
5. Case series/reports.

Existing systematic and non-systematic reviews are also helpful. Information sources that contain gray literature, particularly trial data and other unpublished reports should also be incorporated.

Appendix 8a. References

1. Varandas T, Carneiro AV. Types of clinical studies. Systematic reviews. *Rev Port Cardiol*. 2006;25:233-246.
2. Counsell C. Formulating questions and locating primary studies for inclusion in systematic reviews. *Ann Intern Med*. 1997;127:380-387.
3. Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice G. In: Graham R, Mancher M, Miller Wolman D, et al., eds. *Clinical Practice Guidelines We Can Trust*. National Academies Press (US). Copyright 2011 by the National Academy of Sciences. All rights reserved; 2011.
4. AAN (American Academy of Neurology). 2011. Clinical practice guideline process manual, 2011 Ed. St. Paul, MN: The American Academy of Neurology.

Appendix 9. Collaborator Relationships on ACC/AHA Clinical Practice Guidelines

Collaborator Role on ACC/AHA Guidelines	
General Principle	Collaborating organizations are determined by ACC and AHA. The organizations invited are those whose constituencies have a vested interest in treating patients specific to the disease or procedure under development. To maintain rigor and credibility organizations should be ACGME accredited.
Funding	Collaborating organizations pay for their representatives' travel to any in-person meetings for the document. ALL other direct and indirect guideline expenses are funded by ACC and AHA.
Shared Marquee	Collaborator organization acronyms are listed in the guideline title and collaborators are listed in the second line of the title page.
Committee Representation	One official representative for each collaborator organization is appointed to the writing committee.
Relationships with Industry and Other Entities (RWI)	The ACC/AHA policy is followed (see Relationships with Industry Policy - American College of Cardiology).
Content Approval	N/A
Policy Decisions/ Methodology	ACC/AHA methods and policies are mandated.
Peer Review	Writing Committee Chairs are not required to provide responses to comments provided by collaborator peer reviewers during the peer review comment period.
Copyright Ownership	ACC/AHA retains copyright ownership
Publication	Collaborators have the opportunity to reprint the document in their journal after publication in *Circulation* and *JACC*.
Endorsement	Endorsement is sought from each collaborator after ACC and AHA have approved the guideline. Collaborators that endorse the guideline are listed on the title page of the document.
Derivative Products	Collaborators may develop derivative products from the guideline that are concurrent with the publication, but they must sign a nondisclosure agreement.
Concordance	Collaborating organizations agree not to publish a competing document in any manner for at least 30 days postpublication.
Updating a Guideline	ACC/AHA will notify collaborating organizations when an update is initiated to ascertain interest in continued participation.

MEMORANDUM OF UNDERSTANDING ("MOU") AMONG THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION, THE AMERICAN HEART ASSOCIATION, AND _____

I. **IN GENERAL**

WHEREAS, the American College of Cardiology Foundation ("ACCF') is a District of Columbia nonprofit corporation located at 2400 N Street NW, Washington, DC 20037; and

WHEREAS, the American Heart Association, Inc. ("AHA") is a nonprofit corporation located at 7272 Greenville Avenue, Dallas, TX 75231; and

WHEREAS, both ACCF and AHA through the Joint Committee on Clinical Practice Guidelines ("ACCF/AHA") develop certain documents, and wish to have the _____, a non-profit organization located at _____("Collaborator") serve as a collaborator in connection with the development of a guideline _____ ("Document"). For the purpose of this MOU, AHA, ACCF, and Collaborator agree that a clinical practice guideline, as defined by the National Academy of Medicine, is a statement that includes 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.

NOW, therefore, based on mutual consideration, the receipt and adequacy of which are mutually acknowledged, ACCF and AHA and Collaborator agree on the following terms and conditions.

II. **PURPOSE.** This MOU delineates the roles, rights, and responsibilities of ACCF, AHA, and the Collaborator in the development of the Document.

III. COLLABORATOR PRIVILEGES & OBLIGATIONS

1. Collaborator shall serve as an organizational collaborator for the Document and will be listed as such on the title page of the published Document, unless the Collaborator expresses in writing that the Collaborator wishes to withdraw from being a listed collaborator.
2. If Collaborator agrees in writing to endorse the Document, then Collaborator shall have the Collaborator's organizational acronym listed alphabetically in the title of the Document after AHA and ACCF, or on the title page. If the Collaborator does not express in writing that the Collaborator will endorse the Document, then the Collaborator's organizational acronym and name will not be listed in the title or in the second line on the title page as a collaborator.
3. If Collaborator chooses to not endorse the Document or chooses to not be identified as a collaborator on the Document, then Collaborator, AHA and ACCF shall agree to language describing Collaborator's participation on the Document, with the agreed upon language to be included in Document when published. This language will accurately reflect the extent of Collaborator involvement, including appointed members of the Collaborator on the writing committee tasked with drafting the Document, peer review, organizational review and/or other activities of the Collaborator, as appropriate.
4. Collaborator acknowledges that the writing committee tasked with drafting the Document (the "Writing Committee") is responsible for the review and synthesis of available evidence, and the application of AHA/ACCF Guideline Methodology to the Document. Collaborator acknowledges

that the Writing Committee, while subject to AHA/ACCF methodology, policies and procedures, otherwise operates autonomously and does not necessarily represent the organizational views of the AHA, ACCF, and collaborating organizations participating in the Document.

5. Collaborator shall have at least one (1) individual who will serve as the official appointee of Collaborator on the general Writing Committee. Collaborator shall provide at least three (3) nominees for consideration by the ACCF and AHA for the Writing Committee Chair(s). to choose from. The Writing Committee Chair(s) may appoint additional individuals who were nominated by the Collaborator to the Writing Committee, but those individuals would not participate as an official appointee of the Collaborator to the Writing Committee. In the event that Collaborator nominees are not appointed to the Writing Committee, then the Collaborator shall propose additional names for consideration.
6. Collaborator shall require its appointee(s) to adhere to the requirements of service on the Writing Committee, including but not limited to the assignment of all rights in any materials contributed by the appointed individual(s) in connection with service on the Writing Committee to ACCF and AHA. Collaborator understands that ACCF and AHA shall appoint nominees in a manner consistent with AHA's and ACCF's principles for diversity, equity, and inclusion. ACCF and AHA will also consider whether the nominees have relationships relevant to the Document content with industry, as defined in the AHA/ACCF Relationships with Industry ("RWI") Policy.
7. If Collaborator chooses to not endorse the Document, then the Collaborator appointee(s) to the Writing Committee may choose to: withdraw from the Writing Committee and not have their name(s) listed as author(s) when the Document is published, or remain on the Writing Committee and have their name(s) listed as an ACCF/AHA representative. Collaborator appointee(s) to the Writing Committee will be listed in the comprehensive RWI tables of the Document regardless of Collaborator's decision to endorse.
8. ACCF and AHA may request that Collaborator nominate at least three (3) individuals, of which at least one (1) will be appointed by ACCF and AHA to serve as the organizational reviewer participating in the peer review process of the Document. The Writing Committee Chair(s) may appoint additional individuals who were nominated by the Collaborator to participate in peer review, but they would not be participating as an official appointee of the Collaborator to the peer review process. Collaborator's nominees shall be provided to ACCF and AHA within two (2) weeks of ACCF and AHA's request. Collaborator shall require any appointed peer reviewer to assign any and all necessary rights and licenses to any contributions made by such peer reviewer to the Document to ACCF and AHA in order to allow ACCF and AHA to maintain all ownership rights and title to the Document, including but not limited to copyright and all rights subsumed thereunder. In the event that none of the proposed nominees are suitable to serve as an organizational reviewer, ACCF and AHA will communicate in writing to the Collaborator a request for additional nominees, requesting specific attributes or expertise required to serve as an organizational reviewer.
9. If Collaborator decides to engage in peer review, then Collaborator acknowledges that the peer reviewer(s) shall have a maximum of four (4) total weeks to submit comments as requested by ACCF and AHA. Collaborator acknowledges that the Writing Committee chair(s) is not required to provide responses to each comment provided by the Collaborator peer reviewer(s) during the peer review comment period.
10. In the event Collaborator's appointee on the Writing Committee and/or Collaborator's appointed peer reviewer(s) identify a concern with the Document content, such Collaborator appointee and/or peer reviewer(s) may engage in a confidential conversation with the Collaborator's executive

leadership in an attempt to resolve issues related to the Document content in a timeframe that does not delay publication.

11. Collaborator acknowledges that the Collaborator's executive leadership may submit a written request for a confidential conversation with the AHA/ACCF Joint Committee on Clinical Practice Guidelines Chair and Chair-elect to the AHA/ACCF National Senior Director of Guidelines to address Collaborator's concerns. Collaborator acknowledges that internal conversations between the Collaborator's appointee(s), peer reviewer(s), and executive leadership must be confidential and Collaborator shall be responsible for maintaining confidentiality among them. A non-disclosure agreement, using the form provided by ACCF and AHA, must be executed by each individual from Collaborator before such individual may participate in confidential conversations as appropriate.
12. Collaborator shall have a maximum of three (3) weeks to decide whether to endorse the final version of the Document after the ACCF Clinical Policy Approval Committee and AHA Scientific Advisory Coordinating Committee approve the final version of the Document. Collaborator acknowledges that the Writing Committee is not obligated to make changes to the Document during the Collaborator's approval period. Collaborator acknowledges that Collaborator is sufficiently engaged in the development of the Document through the participation of its appointed member and peer reviewer(s) such that the Collaborator's decision on whether or not to endorse the Document is well-informed. Collaborator further acknowledges that comments submitted by Collaborator during this approval period do not require response by the Writing Committee.
13. Collaborator may link, at its own discretion and cost, to the Document on its organizational website after the Document has been published by AHA and ACCF, and as early as the date and time that the Document embargo is lifted. ACCF and AHA shall provide Collaborator with the URL address that the Collaborator will use for this purpose.
14. Collaborator's only financial responsibility associated with the development of the Document will be the expenses associated with the Writing Committee appointee's(s') travel to any in-person meetings (kick-off meeting and consensus conference) for the Document. Total cost is not expected to exceed seven thousand five hundred US Dollars (USD$7,500.00) per appointee. Travel expenses associated with participation in the development of the Document will not be reimbursed regardless of Collaborator's decision to endorse or not endorse the Document.
15. Collaborator's Writing Committee appointee(s) must attend the kick-off Writing Committee meeting, consensus conference, and the presentation of the appointee's assigned section(s). The Collaborator Writing Committee appointee(s) must attend greater than fifty percent (50%) of all other Writing Committee teleconferences/virtual meetings.
16. Collaborator shall not hold a copyright interest, nor any other rights, title, or interest in the Document, and nothing in this MOU is intended to assign any such rights to Collaborator.
17. Collaborator may communicate and promote the Document to its members and provide the link to the published Document in a manner approved in advance by ACCF and AHA.
18. Collaborator acknowledges that the publication of a guideline or clinical document by the Collaborator in the areas of clinical practice covered by the Document, that makes recommendations for clinical practice using similar grading to the ACCF/AHA Class of Recommendation/Level of Evidence methodology, or the GRADE approach (Grading of Recommendations Assessment, Development, and Evaluation)during the development period of the Document and thirty (30) days post-publication of the Document, may be perceived by the AHA and ACCF as competitive and contradictory to the Document.
19. Collaborator acknowledges ACCF and AHA have joint copyright ownership of the Document and agrees to comply with policies that govern use and distribution of the Document.

20. Collaborator may seek permission to reprint the Document in its journal after publication of the Document by ACCF and AHA, by entering into a separate publisher reprint agreement upon Collaborator's request. Collaborator acknowledges that reprinting the Document cannot delay publication of the Document by ACCF and AHA. In no event will Collaborator reprint the Document in its journal sooner than sixty (60) days following the publication of the Document by ACCF and AHA.
21. Collaborator may develop derivative works from the Document for release as early as concurrent with the publication of the Document with appropriate citation to ACCF and AHA. In the event that Collaborator wishes to develop derivative works from the Document, the Collaborator must execute a non-disclosure agreement in the form provided by ACCF and AHA. Collaborator acknowledges and agrees that the release of a derivative work by the Collaborator before publication of the Document would constitute a violation of embargo. . Examples of "derivative works" include Document summaries, pocket guides, applications, and patient education materials.
22. Collaborator agrees that ACCF and AHA are not granting any rights to use or display the service marks of ACCF or AHA in any manner without the prior review and written consent of ACCF and AHA.

IV. ACCF AND AHA PRIVILEGES & OBLIGATIONS

1. ACCF and AHA are joint owners of the Document and shall be responsible for oversight of the Writing Committee in the development of the Document. This includes scheduling conference calls, establishing and enforcing requirements for service on the Writing Committee, developing drafts of the Document, and securing peer review comments.
2. ACCF and AHA shall contact the individual designated by Collaborator to serve on the Writing Committee, and shall provide the information needed to participate in the Writing Committee.
3. In the event the Collaborator designates an organizational peer reviewer, ACCF and AHA shall provide the information needed to participate in the peer review process (the "Peer Review Committee").
4. ACCF and AHA shall be responsible for coordinating peer review comment periods of the Document.
5. ACCF and AHA shall ensure publication of the Document in the ACCF and AHA journals.
6. ACCF and AHA shall be responsible for maintaining future versions of the Document.
7. ACCF and AHA shall lead media and communication initiatives when publishing the Document.
8. ACCF and AHA shall maintain joint copyright ownership of, and shall jointly own all rights, title, and interest in and to, the Document.

V. CONFIDENTIALITY AND EMBARGO

1. Collaborator will not disclose any Confidential Information, as defined herein, of ACCF or AHA to any third party, or permit any third party to examine and/or make copies of any Confidential Information.
2. For the purpose of this MOU, "Confidential Information" means any software, material, data, or business, financial, operational, customer, vendor and other information disclosed by one party to the other party(ies) (the "receiving party") and not generally known by or disclosed to the public or known to the receiving party solely by reason of the negotiation or performance of this MOU, and shall include, without limitation, the terms of this MOU. Confidential Information shall include the names of the members of the Writing Committee of the Document, the organizations involved in the development, peer review participation, all Document content, including but not limited to

written text, tables, algorithms, or figures, and the exact date and time of publication ("embargo") of the Document.

3. Each receiving party shall maintain all of the other parties' Confidential Information in strict confidence and will protect such information with the same degree of care that such receiving party exercises with its own Confidential Information, but in no event less than a reasonable degree of care. Except as provided in this MOU, a receiving party shall not use or disclose any Confidential Information of the other parties in any manner without the express prior written consent of the disclosing party. Access to and use of any Confidential Information shall be restricted to those employees and persons within a receiving party's organization with known discretion, and with a need to use the information to perform such receiving party's obligations under this MOU. A receiving party's consultants and subcontractors may be included within the meaning of "persons within a receiving party's organization," provided that such consultants and subcontractors have executed a non- disclosure or confidentiality agreement with provisions no less stringent than those applicable to such receiving party under this MOU, and such receiving party shall make such signed agreements available to the other parties upon request.
4. Notwithstanding anything herein to the contrary, Confidential Information shall not include information that is: (a) already known to or otherwise in the possession of a party at the time of receipt from the other party and that was not known or received as the result of violation of any obligation of confidentiality; (b) publicly available or otherwise in the public domain prior to disclosure by a party; (c) rightfully obtained by a party from any third party having a right to disclose such information without restriction and without breach of any confidentiality obligation by such third party; (d) developed by a party independent of any disclosure hereunder, as evidenced by written records; or (e) disclosed pursuant to the order of a court or administrative body of competent jurisdiction or a government agency, provided that the party receiving such order shall notify the other prior to such disclosure and shall cooperate with the other party in the event such party elects to legally contest, request confidential treatment, or otherwise avoid such disclosure.

VI. **INTELLECTUAL PROPERTY WARRANTY AND INDEMNIFICATION.** Collaborator represents and warrants that any and all information, content and materials shared by Collaborator, including appointee(s) of Collaborator, with ACCF and AHA during the development of the Document does not and will not infringe upon, and is free from any claim by any third party of infringement of, any patent, trademark, copyright, trade secret or any other proprietary right of any third party. Collaborator agrees to indemnify, defend and hold harmless ACCF and AHA, their respective officers, directors, employees, agents and representatives from and against all costs, damages, expenses, and liabilities, including reasonable attorneys' fees, arising out of all claims of any nature or kind brought against ACCF and/or AHA, or ACCF and/or AHA customers or members, based on any claim that the information shared by Collaborator, including appointee(s) of Collaborator, or any portion thereof, or any use by ACCF and AHA or its customers or members of the information or portion thereof, infringes or misappropriates any patent, copyright, trademark or other proprietary right of any third party.

VII. **FUNDING.** Nothing in this MOU shall be deemed to be a commitment or obligation of ACCF and AHA funds for Collaborator's activities under this MOU.

VIII. TERMS, TERMINATION, MODIFICATIONS, AND CHOICE OF LAW

1. This MOU constitutes the entire agreement between the parties with respect to the subject matter hereof.

2. There are no representations, warranties, agreements, or understandings, express or implied written or oral between the parties hereto relating to the subject matter of this MOU that are not fully expressed herein.
3. Any supplements, amendments, or modifications to this MOU will be executed in writing within thirty (30) days of advance notice and will become final by mutual written consent of the parties.
4. This MOU shall be governed exclusively by the laws of the State of New York.
5. This MOU, when accepted by the parties, will have an effective date from the date of the last to sign and will remain effective through publication of the Document. Sections III. 13, III.16, III.18, III.22, IV.7, IV.8, V, VI, VII, VIII and IX shall survive the expiration of this MOU. In the event of a breach of any term of this MOU by a party, the non- breaching party may terminate this MOU upon thirty (30) days' written notice to the breaching party if the breaching party does not cure its breach in such thirty (30) day period.

IX. CONTACT INFORMATION. Collaborator acknowledges that communication regarding this MOU shall occur with ACCF and AHA representatives as listed or with representatives acknowledged by all parties.

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X. SIGNATORIES

AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION	**AMERICAN HEART ASSOCIATION, INC.**
Signature: _ Name: Cathleen C. Gates Title: Chief Executive Officer Date: _	Signature: _ Name: Mariell Jessup, MD, FAHA Title: Chief Science and Medical Officer Date: _
COLLABORATOR	

Signature: Name Title: Date:	

Appendix 10. How to Analyze Evidence Based on Study Subgroups

First and foremost, evidence from subgroups should be approached with caution.[1] In order to be credible, all evidence should come from high-quality studies, with the results replicated in follow-up studies. Replicability pertains to replicating subgroup findings in trial focused on subgroup–this is important where feasible.

1. Subgroup Evidence, Review Criteria:

Positive, prespecified secondary endpoints in the setting of a positive primary endpoint generally represent the highest quality evidence and are generally recognized as such in FDA evaluations.

Next in strength of evidence would be prespecified subgroup analyses in the setting of a positive primary endpoint; The appropriate steps are:

a. Prespecify biologically plausible subgroups
b. First test for interaction between subgroup and treatment.
    i. If not statistically significant, you can extrapolate overall treatment effect to all subgroups.
    ii. If there is a significant interaction, then there may be differences of treatment effects across subgroups. Before any statistically significant subgroup treatment effects are regarded valid, quantitative and qualitative differences between overall and subgroup effects should be considered. If in the same direction, then this is reasonably plausible. Qualitative differences are much less common than quantitative differences but there may be some instances that qualitatively different treatment effects are biologically plausible.

2. Subgroup Evidence, Possible Applications:

As with other types of evidence, the strength/level/quality of subgroup evidence primarily should affect Level of Evidence (LOE), whereas Class of Recommendation (COR) is an estimate of effect size and/or strength of recommendation.

Examples of subgroup data application to LOE:

a. LOE A might require randomized study subgroups to be prespecified and whether there is significant interaction as described above and be noted in at least 2 and preferably more high quality studies.
b. LOE B-R might involve the same but from 1 moderate-quality randomized study or 2 or more studies of lesser quality or with less definitive results for the substudy.
c. LOE B-NR might involve moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized, observational studies, or registry studies following the ACC/AHA COR/LOE schema. Given the limitations of nonrandomized studies, even more cautious approach with interpreting subgroup effects should be adopted.
d. LOE C-LD might involve evidence from lower quality studies or when the primary endpoint in negative following the COR/LOE schema.

These potential distinctions could be the focus for discussion and might need to be individualized based on the circumstance, additional supporting evidence (Bayesian approach), and general principles.

Appendix 10. References

1. Rothwell PM. Subgroup analysis in randomised controlled trials: importance, indications, and interpretation. *The Lancet*. 2005;365:176-186.

Appendix 11. Evidence Table Instructions and Examples

(For WC Members)

General Instruction:

- Begin by submitting the *Literature Search Request Form*. Review abstracts to determine the most important references to support the recommendations.
- Tables should include pivotal evidence that you have selected to support your section recommendations; they do not need to capture the universe of evidence available for the topic.
- Use the **Master Table Templates** below for all evidence tables; one table for RCTs and one table for observational studies. Please do not modify column headings without contacting staff as table column changes need to be approved by the Chair after consultation with the Joint Committee.
- Evidence used to support LOE A and B recommendations must be summarized in an evidence table except in unusual circumstances requiring specific approval by the JOINT COMMITTEE leadership. The following guidance may help distinguish LOE B-NR from LOE C-LD and when an evidence table is needed or not:
    - Evidence of sufficient quality to consider collectively must be presented in an evidence table. If the evidence is concordant in support of a course of action, it may qualify as LOE B-NR.
    - Conflicting evidence is best presented in an evidence table, and may lower the strength (COR) of recommendation to the extent that it influences either the risk-benefit ratio or generalizability of the recommendation (proportion of patients to which it potentially applies), and depending upon the number and scope of the studies might lower the LOE to C-LD. The authors are then encouraged to present the supporting evidence in a table.
    - When poor- or low-quality evidence is supported by clinical experience, the data may be presented in the context of LOE C-LD, phrasing the recommendation to acknowledge the relatively low quality of evidence. In this situation, authors are required to cite the evidence as references but need not formulate an evidence table.
- Meta-analyses may be included in tables, as may the original studies if deemed appropriate by the author and/or Chair. Guidelines and/or scientific statements should not be added to evidence tables.
- Do not leave any cells empty; use 'N/A' to show that data are not available so that staff knows the information was not left out as an oversight.
- Indicate the specific type of statistic, eg, CI, HR, OR, not just the number within the column. When providing confidence intervals (CIs), provide the percent associated with the CI (eg, 95% CI: 0.74 to 1.11).
- When copying and pasting data directly from articles, please *clear formatting* of the text and confirm that symbols have not become corrupt. If copying and pasting information from a pdf, ensure all math operators are inserted correctly. Frequently they appear as blanks or nonmathematical symbols. *Note*: You must paraphrase text from the study; exact duplication is considered plagiarism.

Studies Included in Evidence Tables*:*

- All references supporting a recommendation must be in the evidence table. The only

deviation from this policy is if another guideline is cited, which is permissible, but it does not count towards support for the LOE.

- Additional references (not cited with the recommendation) may be included in the evidence table to show the body of evidence the author compiled, however, it may have been deemed inconclusive, low quality, or perhaps it did not support the specificity of the recommendation.
- Additional references may be included in the text of the knowledge but not listed in the evidence table.

Style:

- *Note*: Staff will modify or correct all style issues but we would appreciate you trying to use this information when developing your tables.
- Use numerals (eg, "2") rather than spelling out numbers (eg, "two").
- Explain all abbreviations in a list below the table.
- Please provide enough information for staff to find the reference (ie, name, title, publication date, page numbers, journal name). If we only have partial information (eg, just the author and year), we may have to contact you for more information. FYI, in addition to the citation, we will include a hyperlink to the abstract if available.

- A sample evidence table from a published guideline can be found in the "2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients with Acute Coronary Syndromes" (2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients With Acute Coronary Syndromes: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines | Circulation.[1]

Appendix 11. References

1. Rao SV, O'Donoghue ML, Ruel M, et al. 2025 ACC/AHA/ACEP/NAEMSP/SCAI guideline for the management of patients with acute coronary syndromes: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Col Cardiol*. 2025;85:2135-2237.

Appendix 12. Mendelian Randomization

Summary and Consensus Points

1. Mendelian Randomization (MR) techniques provide supportive evidence for causality of the studied trait.
2. MR studies, if of high quality, provide important observational data regarding impact of studied traits on health.
3. MR studies are increasingly common, and of increasing sophistication. Sometimes multiple outcomes can be tested in a single analysis (e.g. assessment for intended effects and also unanticipated associations or likelihood of co-morbidities). Expert opinion from leadership in the field has led to the development of measures for quality, although formal guidelines do not yet exist.
4. The proliferation of MR studies and important successes of the method suggest an imminent need to include MR studies in evidence evaluation schema.
5. MR studies do not fit neatly into the current ACC/AHA evidence categories. Most readers of guidelines expect evidence to come from traditional controlled clinical trials and will be unfamiliar with MR technique.
6. Evidence review and guideline panels will likely need support in assessing the quality of MR studies.
7. MR studies, by themselves, are not sufficient to justify treatment recommendations for pharmacologic interventions. MR studies can provide supportive evidence for the efficacy of life-style interventions that alter the trait of interest.
8. MR studies have limitations that must be recognized.

Most Common Limitations of Mendelian Randomization Analyses

- Linkage disequilibrum: a set of highly correlated genetic variants in a region including the genetic instrument influence the expression/function of multiple genes nearby which affect the outcome directly or through other risk factors. This situation can result in a major violation of the instrumental variable assumptions of MR studies.
- Pleiotropy: the gene under the control of the genetic instrument has effects on multiple traits that are linked to the outcome of interest. Once again, this situation can lead to a major violation of the instrumental variable assumptions. Canalization/Developmental Compensation: during development, impact of trait is ameliorated by other biologic processes.
- Complexity of Associations: biology insufficiently understood.
- Populations not Homogeneous/Population Stratification: genetic variants that have higher frequency in specific sub-populations can introduce a bias into the analysis.
- Reverse Causation: genetic trait directly causes outcome which in turn impacts intermediary (MR is designed to reduce the likelihood of this).
- Low Statistical Power.

What Level of Evidence Do MR Studies Provide?

a. MR studies do not fit neatly into the current ACC/AHA evidence categories as they are not true clinical trials, do rely on observational data but by virtue of using instrumental variable techniques modify the interpretation of the observational data.
b. MRs studies, depending on quality and robustness, can provide evidence that could be equivalent to B-R if of high quality but also similar to C-LD if of poorer quality.
c. MR studies may provide high quality evidence for non-pharmacologic or lifestyle interventions, perhaps approaching A if interventions considered can be assumed to have limited unintended consequences (eg, alcohol cessation, certain diet interventions).

d. MR studies cannot replicate pharmacologic intervention trials in assessing safety, unintended consequences, costs, etc, of the intervention.
e. MR studies can provide evidence about whether a specific therapeutic has a causal relationship with important clinical outcomes. Negative findings from MR studies may suggest that interventions aimed at a specific target are unlikely to be effective. MR analyses can assess multiple outcomes simultaneously, this may allow for assessment of possible unintended consequences of interventions.

How can expert panels or evidence review committees evaluate Mendelian Randomization studies for quality?

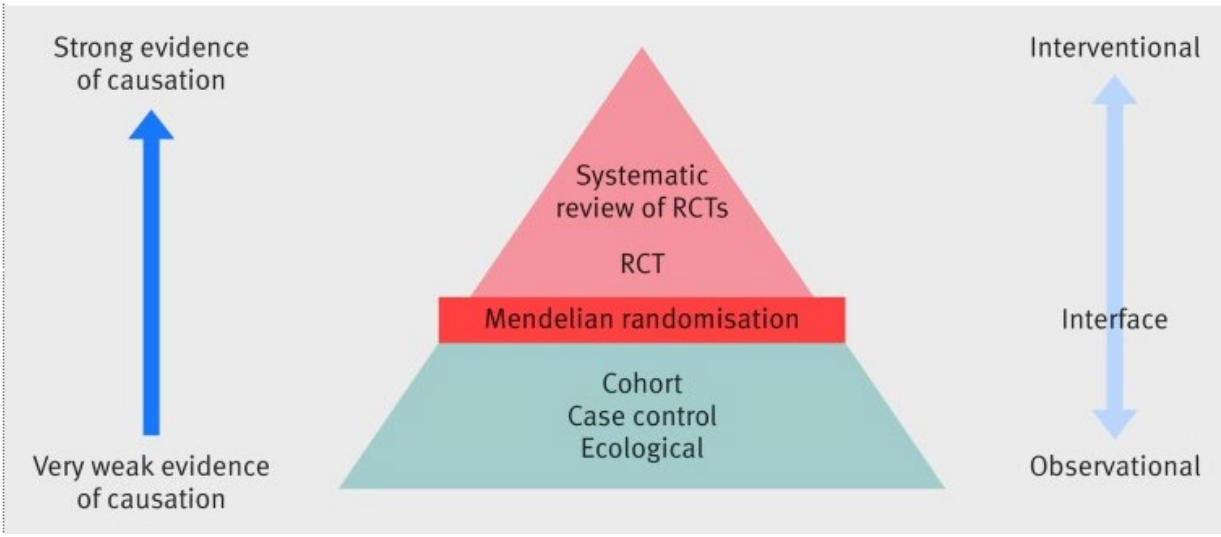
f. Genotypes chosen for MR studies must fulfill criteria as instrumental variables.
    i. The genotype is associated with the exposure.
    ii. The genotype is associated with the outcome only through the studied exposure.
    iii. The genotype is independent of other factors which effect the outcome.
g. Published papers of high quality will assess and report the validity of the above assumptions.
h. Genotypes chosen should be evaluated for criteria in the limitations table (prior page) as these impact the validity of the above assumptions.
i. The current literature has studies of widely varying quality.
j. Independent markers of usefulness.
    i. Strong phenotype/genotype correlation.
    ii. MR replicable across cohorts and populations.

Recommendations

1. MR studies may be used to support and strengthen a recommendation of B-NR or C-LD based on their quality, consistency, and adherence to principles of instrumental variable analysis. When used for this purpose the phrase “additional support provided by mendelian randomization studies” should be added to the evidence grade.
2. The role of MR studies in the evidence evaluation schema should be revisited in 2-3 years as the field matures. In particular, the B-NR label, in the future, may need to be reconsidered because of the confusing terminology.

Summary of Current Search: (references from the literature search are included below[1-25]; the search included studies from 2015 to 2019)

- “Mendelian randomization still sits at the interface of experimental and observational studies. Their findings can be used to provide more reliable evidence to guide interventional research and provide information about potential public health interventions when a randomized controlled trial may not be feasible”.



https://www.ncbi.nlm.nih.gov/core/lw/2.0/html/tileshop_pmc/tileshop_pmc_inline.html?title=Click%20on%20image%20to%20zoom&p=PMC3&id=6041728_davn040667.f4.jpg

"A well conducted Mendelian randomization study that reasonably satisfies the above assumptions often provides more reliable evidence than a conventional observational study. But the findings should be interpreted in the context of existing evidence from other sources, using different study designs, and clinical guidelines should not be rewritten solely based on Mendelian randomization results."

The findings could still help prioritize clinical trials or drug development and inform clinical or public health decision making.

- Various methodological checklists have been developed for the clinicians to interpret evidence from MR studies. The limitations for the quality of such studies have been enumerated.

In the summary that was done in 2016 by ACC/AHA.

- Scientifically, MR is still considered an epidemiological study design and minimizes many of major biases of conventional epidemiologic observational studies.
- Almost all the studies point to the fact that these MR techniques enable to identify causal effects in non-experimental data or in other words observational data.
- In one of the research studies, high quality MR studies on ASCVD were chosen, causal relationship of a series of biomarkers with ASCVD was gauged, and the role of MR in validating biomarkers as a therapeutic target was examined by comparing the results from MR studies and randomized clinical trials (RCTs) for the treatment of ASCVD. There was good concordance and the authors concluded MR could be performed as a screening process prior to novel drug development.

Proposal:
"Although new methodologic strategies will help to strengthen the validity of MR studies, the fact remains that these are epidemiologic study techniques that strengthen the evidence for observational studies and could form basis of designing high quality RCTs.
ACC/AHA guidance on the LOE supports the hierarchy of evidence and has place to rate these MR studies within the current methods."

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Appendix 13. Patient-Reported Outcomes

Background:
Available information on the rates of assessment of patient-reported outcomes (PRO) in cardiovascular clinical trials suggests that between 16% and 30% of trials collect any PRO data.[1-4] A systematic review of trials published in 10 major medical journals between 2005 and 2008 revealed 16% reported some PRO information.[1] It's unclear that the situation has improved more recently. For example, in a review of 1709 studies of atrial fibrillation recorded in clinicaltrials.gov between 1999 and 2018, 238 (14%) included at least one PRO.[5] In the subset of Phase III studies, the rate was 11%. The majority of instruments used were generic, not specific to the condition or therapy under study. While the use of PROs in clinical trials remains low, acknowledgement of the importance of such data seems to be increasing in more recent years.[6] Three reasons for that can be postulated: 1) growing consensus on the importance of capturing the "patient's perspective" regarding treatment strategies being tested in the trial, 2) expectations for demonstrating outcome benefits that might have clinical and potentially regulatory implications, including labeling, and 3) providing a more comprehensive, balanced assessment of all relevant dimensions of treatment outcomes, including both benefits and harms. Reasons why trials often do not include PRO measures include: 1) lack of expectation that the strategy or therapy in question will cause important incremental effects that cannot be assessed other than with a PRO, 2) funding and operational complexity of the trial, both of which are increased with the inclusion of PROs. In particular, unless the collection rate of PRO data is very high, missing data will reduce the impact of the findings by raising unresolvable questions about unmeasured biases. In addition, the common practice of including a short generic instrument, such as the EuroQol, and representing it as sufficient to assess all relevant PROs may actually mislead, particularly if the analysis fails to show differences that a more sensitive disease specific instrument might reveal.

Thus, from the guideline perspective, incorporation of PRO data is desirable but faces several important challenges, including the quality of the trial data (including completeness and how collected), the appropriateness of the measures reported, and the challenges in interpretation of mean treatment group differences in the context of treatment response heterogeneity.

With regard to the quality of instruments used, regulatory agencies have developed methodologic standards for the use of PROs in clinical trials.[7,8] However, from the standpoint of regulatory approval, the FDA has only identified a small number of cardiovascular PROs as allowable thus far. In order to determine whether particular clinical trial PRO results should be included in guideline recommendations, the regulatory viewpoint on admissible PRO metrics is currently probably too limited. Thus, at present, the regulatory perspective on acceptable PRO measures is likely too narrow to use in deciding whether specific clinical trial PRO results should be included in guideline recommendations. In addition, the common belief that a PRO measure once "validated", performs equally well independent of circumstances is not well founded. Instrument performance varies across time and circumstance and particularly as the composition of tested populations vary. Thus, a case for "fitness for purpose" needs to be established in each trial, even for "validated" instruments.

The Consolidated Standards of Reporting Trials (CONSORT) statement[9] provides guidance to improve reporting of randomized controlled trials (RCTs) and has developed a CONSORT-PRO extension[10] that identifies 5 items to report when PROs are categorized as primary or secondary outcomes of RCTs. Their recommendations are: "1) that the PROs be identified as a primary or secondary outcome in the abstract, 2) that a description of the hypothesis and relevant domains be provided (if a multidimensional PRO tool has been used), 3) that evidence of instrument validity and reliability be provided or cited, 4) that the statistical approaches for dealing with missing data be explicitly stated, and 5)

that PRO-specific limitations of study findings and generalizability of results to other populations and clinical practice be discussed".[10] GL groups should use the latter criteria when determining if appropriate to include PRO/PROMS in the guideline statements.

To summarize, the reporting of PRO data with the primary trial findings can be useful in formulating recommendations in the context of benefit versus risk. A growing body of evidence is available on not only the selection of PROM tools but also the methodology for assessing the quality of these tools. For example, the simple rating criteria developed by the Oxford University PRO measurement group[11] can be used to assess the methodological quality of such tools. See Appendix A (table i, ii) from the Patient-Reported Outcome Measurement Group (Oxford) Report.[11]

Appendix A

Appraisal of the methodological quality of PROMs

A simple rating scale (Table i) was used to rate the sum total of evidence available for each dimension or criterion against which PROMs were assessed. The dimensions or criteria are summarised in Table ii.

Table i: Psychometric and operational criteria

0	*not reported (no evaluation completed)*
—	*Evaluation evidence available indicating poor performance of instrument*
+	*Some limited evidence in favour*
++	*Good evidence in favour*
+++	*Excellent evidence in favour*

Table ii: Appraisal criteria

Appraisal component	Definition/test	Criteria for acceptability
Reliability		
Test-retest reliability	The stability of a measuring instrument over time; assessed by administering the instrument to respondents on two different occasions and examining the correlation between test and re-test scores	Test-retest reliability correlations for summary scores 0.70 for group comparisons
Internal consistency	The extent to which items comprising a scale measure the same construct (e.g. homogeneity of items in a scale); assessed by Cronbach's alpha's and item-total correlations	Cronbach's alphas for summary scores ≥0.70 for group comparisons Item-total correlations ≥ 0.20
Validity		
Content validity	The extent to which the content of a scale is representative of the conceptual domain it is intended to cover; assessed qualitatively during the questionnaire development phase through pre-testing with patients. Expert opinion and literature review	Qualitative evidence from pre-testing with patients, expert opinion and literature review that items in the scale represent the construct being measured Patients involved in the development stage and item generation
Construct validity	Evidence that the scale is correlated with other measures of the same or similar constructs in the hypothesised direction; assessed on the basis of correlations between the measure and other similar measures	High correlations between the scale and relevant constructs preferably based on a priori hypothesis with predicted strength of correlation
	The ability of the scale to differentiate known-groups; assessed by comparing scores for sub-groups who are expected to differ on the construct being measured (e.g a clinical group and control group)	Statistically significant differences between known groups and/or a difference of expected magnitude
Responsiveness	The ability of a scale to detect significant change over time; assessed by comparing scores before and after an intervention of known efficacy (on the basis of various methods including t-tests, effect sizes (ES), standardised response means (SRM) or responsiveness statistics	Statistically significant changes on scores from pre to post-treatment and/or difference of expected magnitude
Floor/ceiling effects	The ability of an instrument to measure accurately across full spectrum of a construct	Floor/ceiling effects for summary scores <15%
Practical properties		
Acceptability	Acceptability of an instrument reflects respondents' willingness to complete it and impacts on quality of data	Low levels of incomplete data or non-response
Feasibility/burden	The time, energy, financial resources, personnel or other resources required of respondents or those administering the instrument	Reasonable time and resources to collect, process and analyse the data

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Appendix 14. Shared Decision-Making

What Is Shared Decision-Making?

Shared decision-making is a process in which clinicians and patients come together to make healthcare decisions that align with the best available options for diagnosis and management, coupled with patients' preferences, values and goals.

There is a lack of consistency about what constitutes shared decision-making. For many of the recommendations, the use of a certified decision aid, a written or audio/video tool which summarizes the options, including the risks, benefits, and tradeoffs/practical issues of each option, and prompt patients to develop informed preferences, is recommended. However, there are communication models which also support shared decision-making such as the SHARE approach recommended by the Agency for Healthcare Research and Quality (AHRQ).[1] Shared decision-making may also be facilitated by other types of informational materials, group sessions and clinical support staff such as trained nurses and community health workers.

The SHARE Approach
Step 1: Seek your patient's participation.
Step 2: Help your patient explore and compare treatment options.
Step 3: Assess your patient's values and preferences.
Step 4: Reach a decision with your patient.
Step 5: Evaluate your patient's decision.

The evidence shows that the process of shared decision-making results in: a) patients being more informed about the reasonable available options for diagnosis and treatment, including the option of no intervention; b) more realistic expectations about the magnitude of benefits and risks associated with each diagnostic or treatment option; c) patients feeling more included in their healthcare decisions; and, d) greater alignment with the goals of care. Randomized controlled studies also demonstrate increased uptake of guideline-directed medical therapy and greater achievement of guideline-directed targets; however, evidence for medication adherence is mixed.[2-8]

Examples From the Current Guidelines

Several ACC/AHA guidelines name shared decision-making to enhance the implementation of recommendations, and to support decision making when more than one option is reasonable.

Class of Recommendation/Level of Evidence Guidance

- Class of Recommendation (COR) will be guided by net benefit based on expert consensus that signifies meaningful benefit represented by the patients in conjunction with the available evidence.
- Level of Evidence (LOE) will be guided by positive, pre-specified primary and secondary endpoints generally representing the highest quality evidence and are generally recognized as such in FDA evaluations.
    - LOE A might require at least 2 randomized controlled trials studying the effectiveness of SDM (or SDM tools eg, ISDM-P [Informed Shared Decision-Making Program for people with type 2 diabetes]) in achieving pre-specified outcomes, which may include clinical outcomes as well as patient-reported outcomes.

- LOE B-R might involve the same but from 1 high or moderate-quality randomized study or 2 or more studies of lesser quality or with less definitive results for the sub-study (looking at the test for interaction between subgroups and treatment).
- LOE B-NR might involve moderate-quality evidence from 1 or more well designed, well executed nonrandomized, observational studies, or registry studies following the ACC/AHA COR/LOE schema. Valid, sensitive, and disease-specific health status measure studies can be rated as B-NR. Given the limitations of nonrandomized studies, an even more cautious approach with interpreting subgroup effects should be adopted.
- LOE C-LD might involve evidence from lower-quality studies, or when the effectiveness of SDM in achieving primary endpoints is conflicting for various studies or the SDM tools are of lower quality and the authors would still like to formulate a recommendation.
- LOE C-EO will not apply as the SDM incorporation in guidelines is based on collaborative interactions with patients, not only the interpretation of expert experience.

The rigor of studies supporting these recommendations varies. For example, there are high-quality randomized controlled trials and implementation science studies of shared decision-making to inform decisions to prevent ASCVD.[9-15] Such trials have evaluated the use of shared decision-making to improve control of hypertension, diabetes, and hypercholesterolemia, and to reduce overall cardiovascular risk. These trials were mainly conducted in primary care populations, with both underserved and elderly groups, and demonstrate improved patient involvement and satisfaction with care. Other areas for which there are high-quality randomized controlled trial to inform recommendations include acute chest pain evaluation in the Emergency Department, primary prevention implantable cardiac defibrillators for patients with heart failure and left ventricular assist devices in advanced heart failure. There are also high-quality studies to support decisions about anticoagulation for the prevention of thromboembolic events in patients with atrial fibrillation. The recommendations for shared decision-making in patients with heart failure were summarized in this Scientific Statement.[16]

Other Examples in Support of Shared Decision-Making

Outside of the guidelines, several AHA Scientific Statements encourage shared decision-making models of care, despite not having high-quality evidence for the role of shared decision-making, including decisions about valvular replacement (eg, TAVR vs SAVR) for aortic stenosis and return to play in athletes.[17-19] Additionally, the ACC has several free decision aids related to atrial fibrillation, aortic stenosis, and the management of heart failure on the CardioSmart website for download; additionally, on CardioSmart there are educational videos demonstrating best practices.[20]

Finally, the Centers for Medicare and Medicaid Services has mandated that coverage for primary prevention AICDs and left atrial appendage closure be conditional on a shared decision-making discussion having taken place prior to the procedure. However, measures that this has occurred, and with what quality, are lacking.

Clinical Implications and Future Directions

In summary, shared decision-making has been used as an overall approach to guide decisions for which there is more than one reasonable treatment option and for which the optimal treatment approach is unclear (or there is equipoise). In some areas, rigorous science has emerged to support the development of decision aids, and to test their effectiveness through randomized clinical trials and implementation studies. In areas without evidence, shared decision-making is largely accepted as being best practice and often appears in the guidelines, although not as an evidence-based recommendation.

Still, challenges exist around uptake and quality. There are no structures in place to determine whether guideline recommendations for shared decision-making were followed. In clinical practice,

evidence-based decision aids are not commonly used, and if they are used, it is not documented. There are some patient-reported measures of shared decision-making, however, they are also not widely used in clinical practice.

Second, prior research has identified clinician, patient, and system-level barriers to implementing shared decision-making. In recognition of the evidence-utilization gap, the Centers for Medicare and Medicaid Services has tied shared decision-making to reimbursement coverage for the following procedures: a primary prevention defibrillator in patients with advanced heart failure and left atrial appendage closure to prevent thromboembolic events in patients with atrial fibrillation. Although even with these stipulations, there is scant guidance for what qualifies as shared decision-making and how to evaluate whether it has occurred.

Given the variable evidence for recommending shared decision-making for certain decisions, the guideline committees could include:

1. Specific guidance on how to implement shared decision-making in clinical practice, reinforcing accepted and key principles in shared decision-making. Consider partnership with AHRQ or CardioSmart or Decision Aid developers to develop tools to support clinicians in using SDM in their practice.
2. Examples of decision aids or other tools (eg, talking points) that would facilitate SDM.
3. Specific guidance on how to document that a shared decision-making process was used to arrive at a decision (eg, smart phrases that reference use of a decision aid or a communication approach; patient surveys; use of informed consent documents that incorporate SDM principles).

List of current guidelines that include passages or recommendations re: SDM

1. Brook RD, Rajagopalan S. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Soc Hypertens. 2018;12:238.
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9. 2021 AHA/ACC/ASE/ASNC/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines
10. 2021 ACC/AHA/AATS/STS/SCAI Guideline for Coronary Artery Revascularization A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

Full text of SDM recommendations from current ACC/AHA guidelines*

Guideline	Recommendation/s related to:	COR/LOE
2019 ACC/AHA Primary Prevention of ASCVD	**EXAMPLE 1:** Consideration of risk-reductive medication (for BP and cholesterol) when risk is sufficiently high to support more than just lifestyle interventions ***2.1. Patient-Centered Approaches to Comprehensive ASCVD Prevention*** *COR I, LOE B-R* *2. Shared decision-making should guide discussions about the best strategies to reduce ASCVD risk.* [S2.1-15–S2.1-18] **EXAMPLE 2:** Integration of calcium score to reclassify patients with a baseline intermediate risk score should be used in conjunction with shared decision-making to make decisions about statin and aspirin preventative therapy ***2.2. Assessment of Cardiovascular Risk*** *COR 2a, LOE B-NR* *4. In adults at intermediate risk (≥7.5% to <20% 10-year ASCVD risk) or selected adults at borderline risk (5% to <7.5% 10-year ASCVD risk), if risk-based decisions for preventive interventions (e.g., statin therapy) remain uncertain, it is reasonable to measure a coronary artery calcium score to guide clinician–patient risk discussion.* [S2.2-15–S2.2-31]	COR 1, LOE B-R COR 2a, LOE B-NR
2018 ACC/AHA Management of Cholesterol	**EXAMPLE 1:** Clinician-patient risk discussion should include shared decision-making ***4.4.2. Primary Prevention Adults 40 to 75 Years of Age With LDL-C Levels 70 to 189 mg/dL (1.7 to 4.8 mmol/L)*** *COR 1, LOE B-NR* *4. Clinicians and patients should engage in a risk discussion that considers risk factors, adherence to healthy lifestyle, the potential for ASCVD risk-reduction benefits, and the potential for adverse effects and*	COR 1, LOE B-NR

	drug–drug interactions, as well as patient preferences, for an individualized treatment decision. [S4.4.2-12–S4.4.2-14] **EXAMPLE 2:** Statin therapy in children 8 years and older with FH should be based on a shared decision-making discussion with the family ***4.4.4.3. Children and Adolescents*** *COR 2a, LOE B-R* *3. In children and adolescents 10 years of age or older with an LDL-C level persistently 190 mg/dL or higher (≥4.9 mmol/L) or 160 mg/dL or higher (4.1 mmol/L) with a clinical presentation consistent with FH (see Section 4.2.) and who do not respond adequately with 3 to 6 months of lifestyle therapy, it is reasonable to initiate statin therapy.* [S4.4.4.3-13–S4.4.4.3-16] **EXAMPLE 3:** Specific guidance is given for shared decision-making: • Encourage patient to verbalize what was heard • Invite patient to ask questions, express values and preferences, and state ability to adhere to lifestyle and medication interventions • Refer patients to trustworthy materials to learn more about the decision and associated risks and benefits of different options • Collaborate with the patient to determine therapy and follow-up ***6. IMPLEMENTATION*** *COR 1, LOE B-NR* *3. Before therapy is prescribed, a patient clinician discussion should take place to promote shared decision-making and should include the potential for ASCVD risk reduction benefit, adverse effects, drug-drug interactions, and patient preferences.* [S6-7,S6-8] **EXAMPLE 4:** Shared decision-making should be conducted regularly given dynamics in health ***4.4.4.1. Older Adults*** *COR 2b, LOE B-R* *2. In adults 75 years of age or older, it may be reasonable to stop statin therapy when functional decline (physical or cognitive), multimorbidity, frailty, or reduced life expectancy limits the potential benefits of statin therapy.* [S4.4.4.1-9]	COR 2a, LOE B-R COR 1, LOE B-NR COR 2b, LOE B-R
2018 ACC/AHA Evaluation and Management of Bradycardia and Conduction Delay	**EXAMPLE 1:** Shared decision-making should be used to decide on pacemaker implantation in patients with bradycardia and a clinical indication for a PPM ***11. Shared Decision-Making*** *COR 1, LOE C-LD* *1. In patients with symptomatic bradycardia or conduction disorder, clinicians and patients should engage in a shared decision-making approach in which treatment decisions are based not only on the best available evidence, but also on the patient's goals of care, preferences, and values.* [S11-1—S11-6]	COR 1, LOE C-LD

	EXAMPLE 2: Device choice should be based on a shared decision-making discussion ***11. Shared Decision-Making*** *COR 1, LOE C-LD* *2. Patients considering implantation of a pacemaker or with a pacemaker that requires lead revision or generator change should be informed of procedural benefits and risks, including the potential short- and long-term complications and possible alternative therapy, if any, in light of their goals of care, preferences, and values.* [S11-1–S11-6] **EXAMPLE 3:** Lead revision and generator changes should be based on a SDM discussion ***11. Shared Decision-Making*** *COR 1, LOE C-LD* *2. Patients considering implantation of a pacemaker or with a pacemaker that requires lead revision or generator change should be informed of procedural benefits and risks, including the potential short- and long-term complications and possible alternative therapy, if any, in light of their goals of care, preferences, and values.* [S11-1–S11-6]	COR 1, LOE C-LD COR 1, LOE C-LD
2020 ACC/AHA Diagnosis and Treatment of HCM	**EXAMPLE 1:** Shared decision-making regarding rigorous/competitive sports participation ***9.1. Sports and Activity*** *COR 1, LOE C-EO* 2. For athletes with HCM, a comprehensive evaluation and shared discussion of potential risks of sports participation by an expert provider is recommended. ***9.1. Sports and Activity*** *COR 2b, LOE C-LD* 5. For patients with HCM, participation in high-intensity recreational activities or moderate- to high-intensity competitive sports activities may be considered after a comprehensive evaluation and shared discussion, repeated annually with an expert provider who conveys that the risk of sudden death and ICD shocks may be increased, and with the understanding that eligibility decisions for competitive sports participation often involve third parties (e.g., team physicians, consultants, and other institutional leadership) acting on behalf of the schools or teams. **EXAMPLE 2:** Shared decision-making to support decisions related to but not limited to genetic evaluation, activity, lifestyle, and therapy. ***4. Shared Decision-Making*** *COR 1, LOE B-NR* *1. For patients with HCM or at risk for HCM, shared decision-making is recommended in developing a plan of care (including but not limited to decisions regarding genetic evaluation, activity, lifestyle, and therapy choices) that include a full disclosure of the risks, benefits, and*	COR 1, LOE C-EO COR 2b, LOE-CLD COR 1, LOE B-NR

	anticipated outcomes of all options, as well the opportunity for the patient to express their goals and concerns.[1-4] **EXAMPLE 3:** Shared decision-making regarding genetic testing and counseling ***6.8. Genetics and Family Screening*** *COR 1, LOE B-NR* *4. In patients with HCM who choose to undergo genetic testing, pre- and post-test genetic counseling by an expert in the genetics of cardiovascular disease is recommended so that risks, benefits, results, and their clinical significance can be reviewed and discussed with the patient in a shared decision-making process.* [1-3, 16] **EXAMPLE 4:** Shared decision-making regarding AICD preventative therapy in patients 16 years and older with elevated 5-year risk of sudden cardiac death ***7.1. SCD Risk Assessment*** *COR 2a, LOE B-NR* *3. For patients who are ≥ 16 years of age with HCM, it is reasonable to obtain echocardiography-derived left atrial diameter and maximal LVOT gradient to aid in calculating an estimated 5-year sudden death risk that may be useful during shared decision-making for ICD placement*[2,22] *(Table 7).* **EXAMPLE 5:** Shared decision-making regarding ICD device selection (transvenous vs subcutaneous) ***7.3. Device Selection Considerations*** *COR I, LOE B-NR* *1. In patients with HCM who are receiving an ICD, either a single chamber transvenous ICD or a subcutaneous ICD is recommended after a shared decision-making discussion that takes into consideration patient preferences, lifestyle, and expected potential need for pacing for bradycardia or VT termination.* [1–16] **EXAMPLE 6:** Shared decision-making regarding septal reduction therapy in patients who fail BB and CCB ***8.1.2. Invasive Treatment of Symptomatic Patients With Obstructive HCM*** *COR I, LOE B-R* *5. For severely symptomatic patients with obstructive HCM, SRT in eligible patients, performed at experienced centers (Table 3 and Table 4), may be considered as an alternative to escalation of medical therapy after shared decision-making including risks and benefits of all treatment options.* [1, 10, 23-25]	COR 1, LOE B-NR COR 2a, LOE B-NR COR 1, LOE B-NR COR 1, LOE B-R
2021 Evaluation and Diagnosis of Chest Pain	**EXAMPLE 1:** Shared decision-making for diagnostic test choice in clinically stable patients ***4.1.7. Shared Decision-Making in Patients With Acute Chest Pain***	COR 1, LOE B-R

	COR I, LOE B-R *2. For patients with acute chest pain and suspected ACS who are deemed intermediate risk by a CDP, shared decision-making between the clinician and patient regarding the need for admission, for observation, discharge, or further evaluation in an outpatient setting is recommended for improving patient understanding and reducing low-value testing.* [1,2] **EXAMPLE 2:** Shared decision-making to enhance patient understanding and reducing low-value testing. ***4.1.7. Shared Decision-Making in Patients With Acute Chest Pain*** *COR I, LOE B-R* *2. For patients with acute chest pain and suspected ACS who are deemed intermediate risk by a CDP, shared decision-making between the clinician and patient regarding the need for admission, for observation, discharge, or further evaluation in an outpatient setting is recommended for improving patient understanding and reducing low-value testing.* [1,2] **EXAMPLE 3:** Patient decision aids are beneficial to improve understanding and effectively facilitate risk communication ***4.1.7. Shared Decision-Making in Patients With Acute Chest Pain*** *COR I, LOE B-R* *1. For patients with acute chest pain and suspected ACS who are deemed low risk by a CDP, patient decision aids are beneficial to improve understanding and effectively facilitate risk communication.* [1,2] **EXAMPLE 4:** Acute chest pain and suspected ACS in low-risk patients, SDM for need for admission, observation, discharge, or further evaluation to improve understanding and reduce low-value testing ***4.1.7. Shared Decision-Making in Patients With Acute Chest Pain*** *COR I, LOE B-R* *2. For patients with acute chest pain and suspected ACS who are deemed intermediate risk by a CDP, shared decision-making between the clinician and patient regarding the need for admission, for observation, discharge, or further evaluation in an outpatient setting is recommended for improving patient understanding and reducing low-value testing.* [1,2]	COR 1, LOE B-R COR 1, LOE B-R COR 1, LOE B-R

*For the references indicated in the table above, refer to the individual ACC/AHA guideline documents.

Appendix 14. References

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