

ACC/AHA CLINICAL PRACTICE GUIDELINES METHODOLOGY

Recent Innovations, Modifications, and Evolution of ACC/AHA Clinical Practice Guidelines: An Update for Our Constituencies



A Report of the American College of Cardiology/American Heart Association
Task Force on Clinical Practice Guidelines

Glenn N. Levine, MD, FACC, FAHA,
Immediate Past Chair
Patrick T. O’Gara, MD, MACC, FAHA,
Chair
Joshua A. Beckman, MD, MS, FAHA,
Chair-Elect
Sana M. Al-Khatib, MD, MHS, FACC,
FAHA

Kim K. Birtcher, PHARM D, MS, AACC
Joaquin E. Cigarroa, MD, FACC
Lisa de las Fuentes, MD, MS
Anita Deswal, MD, MPH, FACC,
FAHA
Lee A. Fleisher, MD, FACC, FAHA
Federico Gentile, MD, FACC

Zachary D. Goldberger, MD, MS,
FACC, FAHA
Mark A. Hlatky, MD, FACC, FAHA
José A. Joglar, MD, FACC, FAHA
Mariann R. Piano, RN, PhD, FAHA
Duminda N. Wijeyesundera, MD, PhD

Since 1980, the American College of Cardiology (ACC) and American Heart Association (AHA) have translated scientific evidence into clinical practice guidelines with recommendations to improve cardiovascular health (1). These guidelines, based on systematic methods to evaluate and classify evidence, provide a foundation for the delivery of quality cardiovascular care. Practice guidelines provide recommendations applicable to patients with or at risk of developing cardiovascular disease.

Over the past 3 decades (1-3), there has been a continued evolution of clinical practice guidelines.

Beginning in 2017, numerous innovations and modifications to the guidelines were implemented. The purposes of these changes are: 1) to make published guidelines shorter and more “user friendly” (and hence more readable for busy practitioners); 2) to focus guidelines more on actual recommendations and patient management flow diagrams and less on extensive text and background information; 3) to format guidelines in a manner that allows for more facile and seamless updating of the guideline through the incorporation of guideline focused updates; and 4) to format “chunks” of information in a manner that

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facilitates integration of discrete modules of information into electronic media, fostering easier implementation at the point of care. This communication updates our constituencies and all healthcare providers on these changes that are being implemented.

MODULAR KNOWLEDGE CHUNK

The format of clinical practice guidelines has continued to evolve over the past 3 decades. In 2017, the *modular knowledge chunk* format was introduced. This knowledge chunk format allows guideline information to be grouped into discrete packages (or modules) of information on a disease-specific topic or management issue (e.g. treatment of hypertension for secondary stroke prevention). The modular knowledge chunk of information consists of: 1) a table of related recommendations; 2) a brief synopsis; 3) more detailed recommendation-specific supportive text for each recommendation in the section; 4) a flow diagram (when appropriate); 5) an additional informational table (when appropriate); and 6) hyperlinked references specific for that knowledge chunk.

The modular chunk format has numerous advantages over prior formats. In contrast to the prior “knowledge byte” guideline format, this new format bundles all related recommendations together in one table, which enables better conceptualization of when a test treatment or intervention *is recommended*, when it *may be recommended* or *is considered reasonable*, and when it *is not recommended*. It allows for easier and seamless updating of this information in future guideline focused updates, because future guideline focused updates will update an entire modular knowledge chunk, with all its related recommendations and text. The format allows busy practitioners with limited time to view and read the table of recommendations, a brief text synopsis, and any relevant flow diagrams, while also providing a section titled “recommendation-specific supportive text” for readers interested in a more detailed discussion of the background and rationale for each recommendation.

By bundling related recommendations, text, flow diagrams, and references in what can be transformed into a freestanding entity of information, the modular knowledge chunk may in the future facilitate the ability to search for guideline information on a specific clinical management issue via search engines or smartphone apps.

Several guidelines (high blood pressure, ventricular arrhythmias/sudden cardiac death, adult congenital heart disease) were already in the later stages of writing and review when this modular chunk format was initiated and were retrofitted into this format as best as could be done.

TABLE 1 The Modular Knowledge Chunk

Table of related recommendations with class of recommendation and level of evidence

Synopsis
Brief summary, which may include important background information, overarching management or treatment concepts, and key recommendation messages
Recommendation-specific supportive text
Text explaining the rationale for and study data supporting each specific recommendation
Flow diagram (when appropriate)
Adjunctive table (when appropriate)
Helpful information best presented in table format relevant to implementing recommendations (e.g. factors that increase the risk of bleeding)
References
Readily viewable, hyperlinked references specific to the individual modular knowledge chunk
Allows readers to view in one list all relevant references (rather than scrolling through references scattered among 1000 references)

Guidelines on bradycardia and cardiac conduction delay (4) and blood cholesterol management (5) were the first to be written de novo in this format. Elements of the modular knowledge chunk are shown in **Table 1**; an example of the general appearance of the modular knowledge chunk is given in **Figure 1**.

STANDARDIZED GUIDELINE FORMATS

In conjunction with the implementation of the modular knowledge chunk, standardized guideline formats and a target maximum number of words have been implemented. The intentions of this format are; 1) to make a guideline more recommendation-centric; and 2) to limit text (and thus the overall size of the guideline), making the guideline more relevant and readable for the busy practitioner. Detailed and extensive background information, which can readily be found in book chapters, on websites, or via search engines, is deemphasized. Rather, the focus of the guideline is on the recommendations themselves, presented in the modular knowledge chunk format.

So as to decrease the total text (and length) of guidelines, for each aspect of the guideline and each section of the modular chunk, maximum word targets (goals) have been established. Text at the beginning of each major section of the guideline that presents recommendations, the synopsis text for each modular chunk, and recommendation-specific supplemental text all have a target maximum number of 200 words.

The goal for Section 1 of the guideline (methodology, organization of the writing committee, document review and approval, abbreviations and acronyms) and section 2

FIGURE 1 Example of the general appearance of a modular knowledge chunk**3.7. Mental Health and Neurodevelopmental Issues**

Recommendations for Mental Health and Neurodevelopmental Issues
Referenced studies that support recommendations are summarized in Online Data Supplement 14.

COR	LOE	RECOMMENDATIONS
I	B-NR	1. Patients with ACHD should be evaluated for depression and anxiety (S3.7-1-S3.7-3).
IIa	B-NR	2. Referral for mental health evaluation and treatment is reasonable in patients with ACHD (S3.7-1-S3.7-4).
IIb	B-NR	3. Neurodevelopmental or neuropsychological testing may be considered in some patients with ACHD to guide therapies that enhance academic, behavioral, psychosocial, and adaptive functioning (S3.7-5-S3.7-9).

Synopsis

Mental health and neurodevelopmental issues are common in patients with ACHD and may significantly affect QoL. Neurodevelopmental abnormalities are more frequently seen in children who have complex disease, complex surgical repairs, and other characteristics (S3.7-10-S3.7-12). There is extensive literature in the pediatric population on the frequency and importance of neurodevelopmental abnormalities. However, many adults may not have been evaluated as children in accordance with current diagnostic and treatment strategies (S3.7-13, S3.7-14). Neurodevelopmental disorders, such as impairment of cognition, social skills and communication, and attention disorders, are often under-recognized even though appropriate diagnosis, treatment, and rehabilitation may be beneficial in optimizing function and QoL. An AHA scientific statement describes the common neurodevelopmental disorders affecting children with CHD and may inform neurodevelopmental issues related to adults with CHD (S3.7-13).

Recommendation-Specific Supportive Text

1. Anxiety and depression are underrecognized in the ACHD population. Point-of-care assessment with simple questions about anxiety and depression should be included in the symptom review.
2. Anxiety and depression are prevalent among patients with ACHD. Self-reported symptoms are incomplete to identify the existence of mood disorders. Structured professional psychological evaluation can identify up to 50% more patients with mood disorders (S3.7-1).
3. Although there is limited evidence on neurodevelopmental and neuropsychological issues in patients with ACHD, there is increasing evidence of the neurodevelopmental impact of CHD and surgery in childhood (S3.7-6, S3.7-8, S3.7-9). It is likely that this impact will persist into adulthood and may manifest in lower educational and occupational achievement. This is particularly evident in patients with genetic conditions such as 22q11 deletion and trisomy 21.

COR indicates class of recommendation; LD, limited data; LOE, level of evidence; and NR, nonrandomized. Reprinted from Stout et al. (5a) Copyright © 2018, the American College of Cardiology Foundation, and the American Heart Association, Inc.

(general concepts, brief background information, overarching principles) is a maximum of 2,000 words and 5 journal-formatted pages for each section. This standardized guideline format is a process-in-evolution that will bring a more standardized layout, and more limited text, to guidelines, although it will still allow guideline writing committee chairs some discretion in how to best construct each specific guideline. The current iteration of this standardized guideline format is shown in [Table 2](#).

WEB GUIDELINE SUPPLEMENT

In accordance with the goal of shortening the length and size of the core guideline document, a web guideline supplement has been created. Tables and figures contained in prior guidelines that provide the reader with additional or supplemental information but are not critical to understanding and executing guideline recommendations have been moved from the primary guideline document to this web guideline supplement. This change

TABLE 2 Recommendation-Centric Standardized Guideline Format

Top 10 Take-Home Messages
Abbreviated Preamble
Section 1. Introduction (e.g., methodology and evidence review, organization of the writing committee, document review and approval, table of abbreviations and acronyms)
Section 2. General concepts (e.g., brief background information, overriding concepts and principles)
Section 3. Recommendations-centric section on topic A (e.g., initial patient evaluation)
Knowledge chunk subsection 3.1 of recommendations
Knowledge chunk subsection 3.2 of recommendations
Section 4. Recommendations-centric section on topic B
Knowledge chunk subsection 4.1 of recommendations
Knowledge chunk subsection 4.2 of recommendations
Section 5. Recommendations-centric section on topic C
Knowledge chunk subsection 5.1 of recommendations
Knowledge chunk subsection 5.2 of recommendations
Section 6. Recommendations-centric section on topic D (e.g., long-term management)
Knowledge chunk subsection 4.1 of recommendations
Knowledge chunk subsection 4.2 of recommendations
Knowledge gaps and future research

This is the recommendations-centric standardized guideline format, incorporating the modular knowledge chunk format and target maximum number of words. The actual number of sections depends on the number of topics covered.

reduces the size of the core guideline document, while affording the interested reader access to additional information that may be useful to his or her practice.

The web guideline supplement is a separate PDF file that is hyperlinked to the primary guideline document and downloadable via organizational and journal (*Circulation* and *Journal of the American College of Cardiology*) websites. The first implementation of this web guideline supplement was in bradycardia and cardiac conduction delay (4) and blood cholesterol management (5) guidelines.

TOP 10 TAKE-HOME MESSAGES

It is well recognized that many busy practitioners do not have the time to read a lengthy guideline cover to cover, and that key recommendations and messages in the guideline may thus not be fully appreciated. Therefore, a Top 10 Take-Home Messages list is now being included in all guidelines. This top 10 list may contain information alerting and reminding the reader of new recommendations, important changes to old recommendations (e.g., change in the class of recommendation), key overarching principles, and other critical take-home patient

management messages of which readers and practitioners should be aware.

This list is at the beginning of the guideline, immediately after the table of contents. The list of top 10 messages serves as a form of abstract, highlighting for the busy practitioner the key take-home messages of the guideline. These top 10 lists could also likely serve as slide presentation bullet points for educational talks on guidelines, be used in articles and websites that summarize guidelines, and be incorporated into electronic media and apps, further disseminating the key practice points of emphasis for a specific topic to practitioners.

PREAMBLE

Guideline writing committees are asked to limit text whenever possible. The task force chair’s preamble should similarly be as concise as possible. Therefore, the task force chair’s preamble at the beginning of each guideline has now been shortened by >50%. This abbreviated preamble contains only the key information that guideline readers should be aware of regarding the guideline process and appropriate use of guidelines. This abbreviated preamble appears in the guidelines for bradycardia and conduction abnormalities (4) and the blood cholesterol management guidelines (5) and will be used in subsequent guidelines. The full preamble will be available in each guideline’s web guideline supplement.

ADDRESSING AREAS OF PERCEIVED NEED (“GAPS”) IN OUR GUIDELINES

Current ACC/AHA guidelines cover 8 broad topics and consist of >20 guidelines (Table 3). Two areas of perceived need for dedicated guidelines to fill gaps in the portfolio of guidelines are currently being addressed. The first area being addressed is that of chest pain, a condition that requires evaluation in >7 million people each year (6). Although the stable ischemic heart disease and non-ST-elevation myocardial infarction guidelines contain small sections on chest pain, the focus of those guidelines is on the downstream management of patients who are already diagnosed with those conditions. Given the importance of this topic and the multidisciplinary approach to evaluation of patients presenting with chest pain, which includes not only cardiologists but also emergency physicians, primary care providers, and radiologists, a dedicated guideline on the evaluation of chest pain, both in the office/clinic setting and in the emergency department, was commissioned. This guideline includes writing committee members from numerous medical stakeholders.

The second area of perceived need is a comprehensive guideline on the approach to cardiovascular disease

TABLE 3 AHA/ACC Guidelines by Topic

Arrhythmia/electrophysiology
Bradycardia and cardiac conduction delay
Supraventricular tachycardia
Atrial fibrillation
Ventricular arrhythmias and sudden cardiac death
Syncope
Coronary artery disease
Evaluation of chest pain
Stable ischemic heart disease
Non-ST-elevation myocardial infarction
ST-elevation myocardial infarction
Percutaneous coronary intervention
Coronary artery bypass grafting
Myocardial
Heart failure
Hypertrophic cardiomyopathy
Valvular
Valvular heart disease
Vascular
Lower-extremity peripheral arterial disease
Extracranial carotid and vertebral artery disease
Thoracic aortic disease
Prevention
High blood pressure
Blood cholesterol
Prevention of cardiovascular disease
Secondary prevention
Congenital heart disease
Adult congenital heart disease
Perioperative
Perioperative cardiovascular evaluation and management

The 2 new guidelines, which fill gaps in the portfolio of guidelines, are indicated in red.

prevention. Although there are dedicated guidelines on high blood pressure, blood cholesterol, and secondary prevention, as well as numerous scientific statements, expert consensus documents, and other authoritative publications on aspects of cardiovascular risk reduction and prevention of cardiovascular disease, there is a need for a comprehensive guideline specifically on the approach to cardiovascular disease prevention. Such a guideline was thus commissioned, with the specific charge of being concise enough to be readable in one sitting by busy practitioners. This guideline will consolidate for busy practitioners the key recommendations on assessment of cardiovascular risk, smoking cessation, exercise and physical activity, diet and nutrition, obesity and weight loss, diabetes mellitus management, and aspirin use, as well as the key primary prevention recommendations on high blood pressure and blood

cholesterol. This guideline on the prevention of cardiovascular disease, in addition to filling a gap in current guidelines, affirms the AHA's and the ACC's commitment to not only treating established cardiovascular disease but preventing it as well.

ABBREVIATIONS

To make the guideline document more user friendly, the abbreviation table placed in each guideline has been moved. The table defining the meanings of abbreviations and acronyms used in the guideline, which gave what the abbreviation/acronym meant or stood for, had previously been located at the end of the guideline, in the [appendix](#). This table is now at the beginning of each guideline (in the introduction section).

OTHER ONGOING IMPROVEMENTS AND REFINEMENTS OF GUIDELINES

Several additional improvements and refinements of guidelines and of the guideline development process, instituted over the past decade, merit discussion. The first of these are data supplement tables, which summarize the studies and study findings that were considered when Level of Evidence: A or B recommendations were formulated for a specific topic. The data supplement tables include, for key studies relevant to these recommendations, the study aim and design, the study control and intervention groups, and the primary and relevant secondary endpoint findings, both numerically and statistically. These data supplement tables serve 3 purposes.

First and foremost, they facilitate the process by which guideline section authors and the entire guideline writing committee can first thoroughly review the most relevant study data on a specific topic, and then discuss potential recommendations and their designated class of evidence in an optimally informed, evidence-based manner. Second, they allow detailed discussions of study results to be moved from the guideline itself to the data supplement. Guideline text can now simply summarize the data on a topic in broad statements, with more granular details given in the data supplement tables. Third, interested readers can themselves review and scrutinize key aspects and findings of relevant studies. These data supplement tables are published in separate PDF files, are hyperlinked to the guideline itself, and can be downloaded from the websites of both organizations and journals.

The second refinement to the guideline development process was the institution of evidence review committees (ERCs) (1,2). ERCs were established to provide an expert, independent, systematic review and analysis of study data relevant to one or more key patient evaluation or management question. ERCs and systematic reviews

are developed by criteria consistent with established methodology practices and are aligned with recommendations promulgated by the Institute of Medicine in 2011 (7,8). All members of the ERC must be free of any relevant relationships with industry and other entities. The first such ERC report, published in 2014, was on the use of perioperative beta blockade in noncardiac surgery (9). Subsequent ERC reports have addressed topics including duration of dual antiplatelet therapy in patients with coronary artery disease (10), pacing as a treatment for reflex-mediated syncope (11), management of patients with asymptomatic preexcitation (12), targets for blood pressure lowering during antihypertensive therapy (13), and the impact of the use of implantable cardioverter-defibrillators for primary prevention in older patients and patients with significant comorbidities (14), physiologic versus right ventricular pacing among patients with left ventricular ejection fraction >35%, (15) management of secundum atrial septal defects (16), and the magnitude of benefit of adding a second lipid-modifying agent to statin therapy alone (17). The criteria for commissioning a formal ERC have evolved over the past decade and now include: 1) absence of a recent authoritative systematic review on the same topic (e.g., Cochrane analysis); 2) relevance to a substantial number (e.g., at least tens or hundreds of thousands) of patients; and 3) high likelihood that the findings of the systematic review can be translated into actionable recommendations.

Over the past decade, the focus of guidelines has changed from procedure-centric to condition-centric. Thus, procedures such as pacemakers and defibrillators, which were previously addressed in a guideline on device-based therapies (18), are now addressed in guidelines on bradycardia and cardiac conduction delays (4), ventricular arrhythmias and sudden cardiac death (19), and syncope (20). Similarly, indications for cardiac resynchronization therapy are covered in the guideline on heart failure (21). By being disease- or condition-centric, the focus is now on the indications for such interventions, and how these interventions fit within the overall management of the specific condition, rather than on the devices themselves and nuances of device implantation (such as pacing or defibrillation thresholds). Current guidelines on percutaneous coronary intervention (22) and coronary artery bypass grafting (23), which contain sections on topics such as bifurcation stenting and bypass graft anastomotic techniques, will be consolidated into one guideline on myocardial revascularization. The consolidated guideline will focus on coronary artery disease-related conditions and clinical settings in which revascularization is indicated, and where one revascularization procedure may or may not be preferred. This new guideline on revascularization will have its kickoff meeting in March 2019.

CONTINUING CHALLENGES AND FUTURE DIRECTIONS

Physicians and all healthcare providers face increasing demands on their time, because in addition to the long hours devoted to actual direct patient care, there are increasing administrative and clerical demands (e.g., electronic health records, coding), as well as time required for continuing educational and academic activities. These requirements and activities in aggregate often leave little time for reading lengthy guidelines. Thus, there is an increasing need to format guidelines and deliver practice-relevant information and guidance in actually readable, searchable, and electronically accessible formats. The modular chunk format and standardized guideline format are in their early stages, and the Task Force will continuously evaluate how recommendations and information are presented and made available to busy practitioners. At the organizational level, the AHA and ACC continue to develop and refine electronic platforms and applications to facilitate ready access to and dissemination of guidelines and guideline recommendations.

The formatting, development, and presentation of guidelines is a continuing process in evolution. It is hoped and believed that these recent innovations and modifications will serve to improve guidelines and their dissemination to point-of-care practitioners devoted to improving cardiovascular health. As always, we will continue to highly value our constituencies' and practitioners' feedback.

ACC AND AHA GUIDELINE ORGANIZATIONAL AND JOINT STAFF LEADERSHIP

Thomas S.D. Getchius, AHA/ACC Director, Guideline Strategy and Operations

Katherine A. Sheehan, PhD, Immediate Past AHA/ACC Director, Guideline Strategy and Operations

Mariell Jessup, MD, FAHA, AHA Chief Science and Medicine Officer

Rose Marie Robertson, MD, FAHA, AHA Deputy Chief Science and Medicine Officer

William J. Oetgen, MD, MBA, FACC, ACC Executive Vice President, Science, Education, Quality, and Publishing

Gayle R. Whitman, PhD, RN, FAHA, FAAN, AHA Senior Vice President, Office of Science Operations

MaryAnne Elma, MPH, ACC Senior Director, Science, Education, Quality, and Publishing

Abdul R. Abdullah, MD, AHA/ACC Senior Manager, Guideline Science

Heather Goodell, AHA Vice President Scientific Publishing, Office of Science Operations

Radhika Rajgopal Singh, PhD, AHA Director, Science and Medicine, Office of Science Operations

Morgane Cibotti-Sun, MPH, ACC Associate, Guidelines and QI Solutions

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APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—RECENT INNOVATIONS, MODIFICATIONS, AND EVOLUTION OF ACC/AHA CLINICAL PRACTICE GUIDELINES: AN UPDATE FOR OUR CONSTITUENCIES

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section
Glenn N. Levine	Baylor College of Medicine—Professor of Medicine; Michael E. DeBakey Medical Center—Director, Cardiac Care Unit	None	None	None	None	None	None	None
Patrick T. O’Gara	Harvard Medical School—Professor of Medicine; Brigham and Women’s Hospital—Director, Strategic Planning	None	None	None	None	None	None	None
Joshua A. Beckman	Vanderbilt University Medical Center— Director, Section of Vascular Medicine	None	None	None	None	None	None	None
Sana M. Al-Khatib	Duke Clinical Research Institute—Professor of Medicine	None	None	None	None	None	None	None
Kim K. Birtcher	University of Houston College of Pharmacy—Clinical Professor	None	None	None	None	None	None	None
Joaquin E. Cigarroa	Oregon Health and Science University—Clinical Professor of Medicine	None	None	None	None	None	None	None
Lisa de las Fuentes	Associate Professor of Medicine and Biostatistics, Co-Director of the Cardiovascular Imaging and Clinical Research Core Laboratory, Washington University School of Medicine	None	None	None	None	None	None	None
Anita Deswal	Michael E. DeBakey VA Medical Center—Chief, Cardiology; Baylor College of Medicine—Professor of Medicine	None	None	None	None	None	None	None
Lee A. Fleisher	University of Pennsylvania Health System—Chair, Department of Anesthesiology & Critical Care	None	None	None	None	None	None	None
Federico Gentile	Centro Cardiologico Gentile	None	None	None	None	None	None	None
Zachary D. Goldberg	University of Washington School of Medicine—Assistant Professor of Medicine; Division of Cardiology, Harborview Medical Center	None	None	None	None	None	None	None
Mark A. Hlatky	Stanford University, School of Medicine—Professor of Health Research Policy, Professor of Cardiovascular Medicine	None	None	None	None	None	None	None

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APPENDIX 1. CONTINUED

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section
José A. Joglar	UT Southwestern Medical Center University—Professor of Medicine	None	None	None	None	None	None	None
Mariann R. Piano	Vanderbilt University School of Nursing—Nancy and Hilliard Travis Professor of Nursing; Senior Associate Dean for Research	None	None	None	None	None	None	None
Duminda N. Wijeyesundera	Department of Anesthesia and Pain Management, Toronto General Hospital	None	None	None	None	None	None	None

This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of $\geq 5\%$ of the voting stock or share of the business entity, or ownership of $\geq \$5,000$ of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. According to the ACC/AHA, a person has a *relevant* relationship if: a) the *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document*; or b) the *company/entity* (with whom the relationship exists) makes a drug, drug class, or device addressed in the *document* or makes a competing drug or device addressed in the *document*; or c) the *person or a member of the person's household*, has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the *document*.

ACC indicates American College of Cardiology; AHA, American Heart Association; UT, University of Texas; and VA, Veterans Affairs.