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TASK FORCE STATEMENT

The Evolution and Future of ACC/AHA Clinical Practice Guidelines: A 30-Year Journey

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

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In 2014, we mark the 30th anniversary of the first publication of an American College of Cardiology (ACC) and American Heart Association (AHA) clinical practice guideline (CPG). This joint effort was undertaken in response to the U.S. government's request to review the evidence concerning cardiac pacemakers and develop CPGs to mitigate potential overuse. Since then, fueled by a shared sense of responsibility to translate available evidence into clinical practice to guide cardiovascular clinicians, the ACC and AHA have developed 23 CPGs across the spectrum of cardiovascular diseases and procedures.

The "why" and "how" of CPGs continue to evolve. Although the "why" is based on the directive to develop evidence-based recommendations for selection of diagnostic tests, procedures, and treatments to improve quality of care and outcomes for patients with cardiovascular disease, it is precisely where evidence is lacking or is controversial that clinicians need the most guidance. A 2012 survey of ACC and AHA members provides important insight into the way clinicians and other healthcare professionals apply CPGs; further details are provided below. The results highlight a natural tension

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between the needs of clinicians for comprehensive clinical advice from seasoned experts and for a clear delineation of diagnostic and therapeutic measures for which strong scientific evidence exists.

Notably, there has been an increased focus on the "how" of CPGs and changes in the methodology used to collect and evaluate the evidence. In 2011, the Institute of Medicine (IOM) published 2 reports, *Clinical Practice Guidelines We Can Trust* (1) and *Finding What Works in Health Care: Standards for Systematic Reviews* (2). In response to these reports and our own mandate to continually improve processes and methods while evaluating the continuous stream of new knowledge and maintaining relevance at the point of care, the ACC/AHA Task Force on Practice Guidelines (Task Force) held a Methodology Summit in December 2011. The Methodology Summit focused on the standards for systematic reviews and process improvements. The response to the 21 standards and 82 supporting elements proposed by the IOM was published in the "ACCF/AHA Clinical Practice Guideline Methodology Summit Report" (3). However, many of the IOM recommendations and standards are themselves based more on consensus than data, and there is little evidence on the extent to which their implementation may have a favorable impact on clinical outcomes. Hence, the effectiveness of the IOM report recommendations must be assessed over time as organizations similar to the ACC and AHA begin the complex process of applying the proposed standards in CPG development.

During the past few years, several process improvement initiatives have been implemented to limit the narrative text in CPGs by substituting increased use of summary and evidence tables (with references linked to abstracts in PubMed). Consensus conferences at which members of guideline writing committees (GWCs) reach agreement and concordance on overlapping recommendations are now held routinely. Methodological enhancements include development and future validation of a scoring tool to consistently assess the quality of randomized trials that inform recommendations in the domains of bias, relevance, and fidelity. In addition, an analysis of Bayesian approaches to evidence synthesis was undertaken (4). Other enhancements include separation of the Class III recommendations to delineate whether the recommendation is determined to be of "no benefit" or associated with "harm" to the patient, as well as inclusion of comparative-effectiveness recommendations based on comparative-effectiveness studies to indicate when one treatment/strategy is preferred to another. Lastly, to harmonize with other CPG classification schema, we now more precisely indicate the strength of the recommendation associated with the Class of Recommendation (COR).

RATIONALE FOR CPGS

In the IOM report (1), CPGs were redefined as follows:

> *Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of the evidence and an assessment of the benefits and harms of alternative care options.*

CPGs that are rigorously developed have the potential to improve the quality of cardiovascular care, lead to better patient outcomes, improve cost-effectiveness by targeting resources to the most effective therapies, enhance the appropriateness of clinical practice, and identify critical gaps in evidence and areas needing additional research. In fact, when patients are treated according to ACC/AHA Class I recommendations, outcomes are improved. Specifically, data from the quality of care CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes With Early Implementation of the ACC/AHA Guidelines) Registry demonstrate that in patients with acute coronary syndromes, there is a 10% reduction in in-hospital mortality for every 10% increase in adherence to ACC/AHA Class I guideline-directed medical therapies (5). Similarly, data from ADHERE (Acute Decompensated Heart Failure National Registry) demonstrate that patients treated according to heart failure performance indicators have a significant reduction in in-hospital mortality and length of stay (6).

DEVELOPMENT PROCESS

The Task Force, which is composed of a broad constituency with varying content expertise, oversees and directs the CPG development process and methodology that are the foundation of the documents and the underpinning of their broad recognition. The process begins with selection of a topic for a new, revised, or updated CPG by the Task Force with the input of GWCs and ACC and AHA council and committee members. In view of the overarching goal of inclusivity and collaboration, selected organizations and professional societies with similar interests and expertise are invited to participate as partners or collaborators. Next, a GWC chair is selected by the Task Force, and, with input from the leadership of participating organizations, potential members of the GWC are identified, based on a detailed and specific policy on relationships with industry and other entities (RWI) and a desire to balance intellectual and practice perspectives in addition to sex, race, geographic location, and ethnicity. In view of the AHA's focus on the patient and the public it serves and its lay membership, the ACC's initiative on patient-centered care, and the recommendations of the Methodology Summit, the

Task Force now invites lay representatives (i.e., patients, patient advocates, or consumer organization representatives) to participate as members of GWCs and may include them on the Task Force. Methods to identify, select, train, and manage RWI and the intellectual perspectives of lay representatives are in development. Lay representatives may participate in topic selection; delineation of diagnostic and therapeutic options, values, preferences, and patient-oriented outcomes; and shared decision making.

The GWC outlines the document content, performs a detailed and specific evidence acquisition and review, and drafts recommendations based on the strength and quality of evidence with limited preliminary text. On the basis of the Methodology Summit recommendations, the process has started to involve an Evidence Review Committee (ERC) that is separate from the GWC. The ERC includes methodologists, epidemiologists, clinicians, and biostatisticians tasked with formal systematic review of available evidence and responsibility for identification, abstraction, and quality assessment of the evidence. Given practical considerations, including limited resources and time constraints, the role of ERCs will be limited to addressing critical questions where the evidence lends itself to a systematic review and that are most clinically relevant to the CPG topic. The role of the ERC in selected CPGs may be fulfilled by a partnership with other highly regarded organizations that perform systematic reviews, such as the National Institutes of Health, the Cochrane Collaborative, and Kaiser Permanente. When appropriate, other stakeholders may be invited. In 2013, the Task Force successfully piloted a focused ERC approach to a confined topic using a PICOTS (Population, Intervention, Comparator, Outcomes, Timing, and Setting) format to develop critical questions for the systematic review. The PICOTS format specifically identifies the target population (**P**) for whom the intervention is intended; defines the intervention (**I**) and whether the comparator (**C**) is placebo, no intervention, or some alternative strategy; designates the outcome (**O**) as a clinical event (e.g., mortality, nonfatal myocardial infarction) or a patient-oriented endpoint (e.g., symptoms, functional capacity, quality of life, diagnosis, or prognosis); and specifies the timing (**T**) of measurement for the intended outcome and the setting (**S**) in which the outcome is measured. Developing appropriate questions is a collaborative process, with input from the GWC chair and members, the Task Force, partner organizations involved with the CPG, and the ERC. The questions may also be reviewed more broadly by organizational leadership and the public. It is then the responsibility of the GWC to develop recommendations using the evidence reviewed by the ERC.

Once recommendations and limited text are drafted, the vetting process begins. In the absence of new evidence, prior recommendations in ACC/AHA CPGs do not change. Because recommendations often overlap across multiple documents (Figure 1), reconciliation can be complex and time consuming. The first consensus conference was held in 2009 and attended by members of the GWCs of the percutaneous coronary intervention,

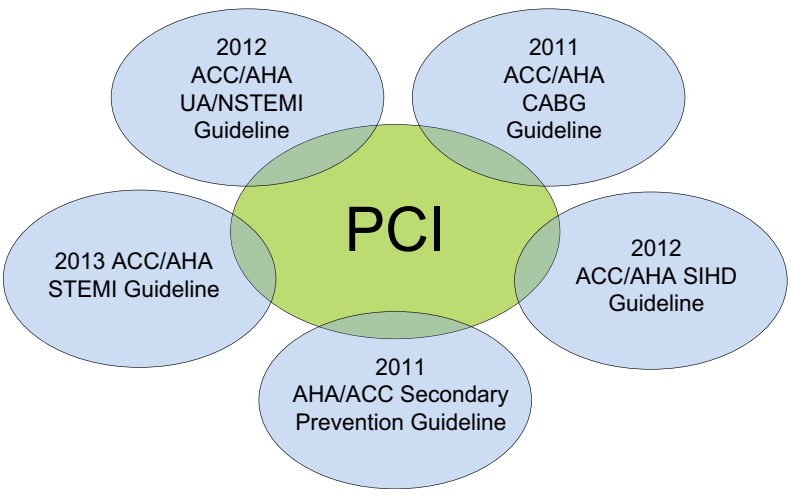

FIGURE 1 Concordance Among Existing Guideline Recommendations and Those From the 2011 ACC/AHA/SCAI PCI Guideline

ACC indicates American College of Cardiology; AHA, American Heart Association; CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; SIHD, stable ischemic heart disease; STEMI, ST-elevation myocardial infarction; and UA/NSTEMI, unstable angina/non-ST-elevation myocardial infarction.

coronary artery bypass surgery, and ST-elevation myocardial infarction CPGs all of which were under revision. With input from the stable ischemic heart disease GWC, the attendees crafted a combined section on coronary revascularization for inclusion in all 3 CPGs. The consensus conference approach broadens input on related recommendations, facilitates consensus, enhances implementation at the point of care, expedites the CPG development process, and promises to be useful in similar future applications.

Although usually approved by consensus, every recommendation is ratified by a majority of votes by the members of the GWC; those members with relevant RWI are required to recuse themselves from voting on sections to which their specific RWI applies. The finished document then undergoes peer review by ACC and AHA official reviewers, content experts (many of whom serve on ACC and AHA councils and committees), participating organizations, and the Task Force (Figure 2). The peer review process has been expanded to encompass a broad spectrum of relevant stakeholders, including lay representatives and constituencies and governmental agencies when appropriate (e.g., the Agency for Healthcare Research and Quality and the U.S. Food and Drug Administration).

Each peer reviewer's comment is reviewed by the chair and members of the GWC, and a response is generated; it is not unusual to receive >1,000 comments from peer reviewers. A lead reviewer from the Task Force ensures appropriate reconciliation of all peer reviewer comments. Changes in recommendations require approval by a formal vote of the members of the GWC according to the voting policy. The document then requires ratification by the ACC Board of Trustees, the AHA Science Advisory and Coordinating Committee, and partnering or collaborating organizations. After thorough vetting within the academic and clinical communities and the leadership of the ACC and AHA, the CPG is jointly published in the *Journal of the American College of Cardiology*, *Circulation,* and the flagship journals of partnering and collaborating organizations as appropriate. Once published, CPG recommendations become the official policy of both the ACC and AHA, informing strategic initiatives, advocacy, education programs, and services. To accelerate access to

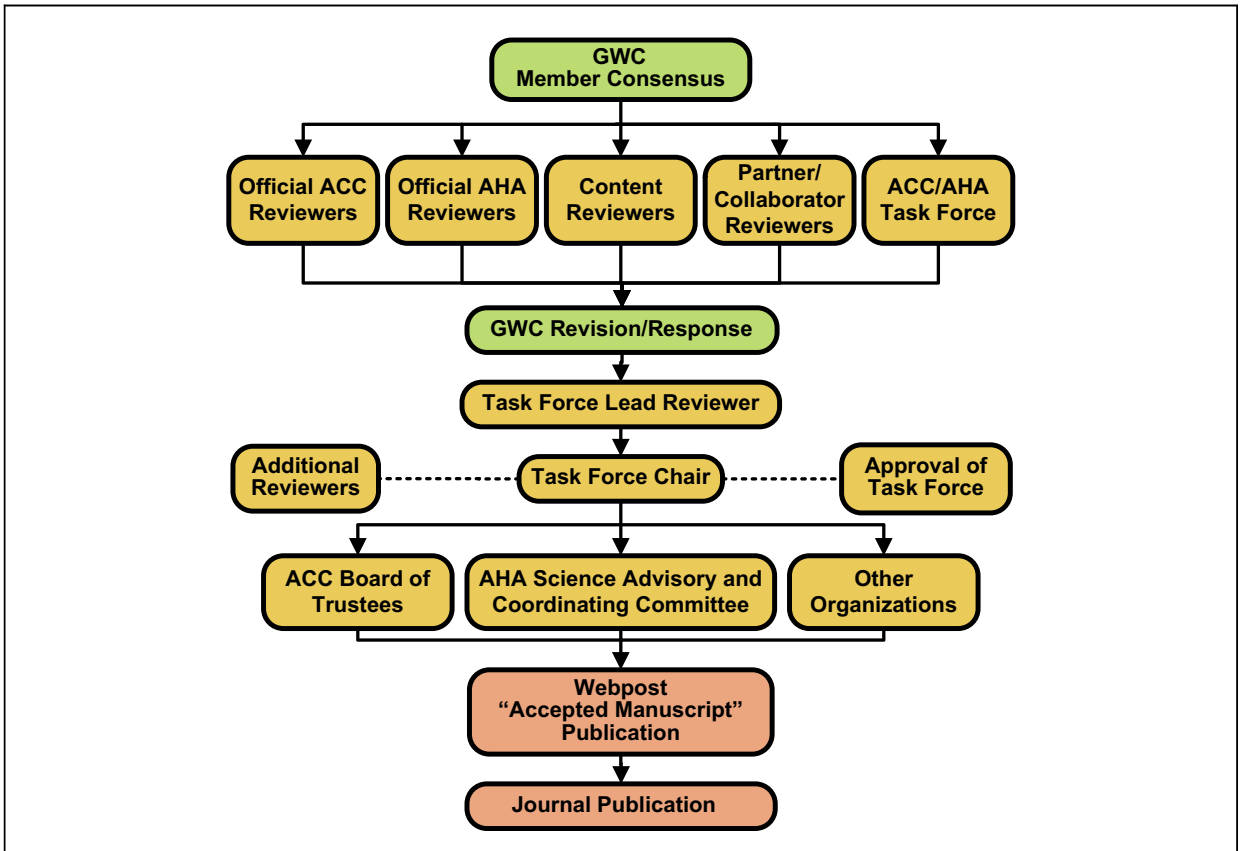

FIGURE 2 ACC/AHA CPG Peer Review Process

ACC indicates American College of Cardiology; AHA, American Heart Association; CPG, clinical practice guideline; and GWC, guideline writing committee.

CPGs that have received final approval, the ACC and AHA release the manuscripts before typesetting, allowing the documents to be available nearly 2 months ahead of formal publication in the journals.

RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES

The validity and reliability of CPGs have been questioned, based on concerns that the CPGs are composed by individuals with perceived conflicts of interest (COI), primarily due to RWI engaged in the development or marketing of medical technology or pharmaceutical agents. The perception that all RWI imply COI is not inherently accurate (7,8). There is no evidence to confirm or deny that RWI lead to a bias in writing recommendations, and the quantitative impact of RWI is unknown. Bias may also exist without RWI, and individuals with RWI often have the greatest expertise in the subject.

Even so, strict policies are in place to prevent undue influence of commercial or other special interests on the CPG development process (9). In late 2009, well in advance of the IOM report, policies were updated to require more rigorous management of RWI. The ACC and AHA believe that, when transparent and properly managed, including experts with RWI on GWCs strengthens the writing effort and results in improved documents by ensuring the availability of necessary expertise. The 2011 Methodology Summit participants supported this view, noting that the "absence of experts (perhaps with relevant RWI) on the GWC would undermine the credibility of the review and CPG as much or more than the presence of committee members with RWI" (3). Moreover, the term "RWI" is preferred over "COI" because the former does not imply ethically conflicting interests or objectives.

In addition to managing RWI, the ACC and AHA monitor and manage other potential biases that may be relevant to the writing effort, including academic settings, race, sex, geography, intellectual stance, or scope of clinical practice. On the basis of the Methodology Summit recommendations, the intellectual (referring to prior published opinion or research) and practice (applying when an individual's income is enhanced by or derived from reimbursement for performing specific tests or procedures) perspectives relevant to the guideline topic are recognized, defined, disclosed, and managed. As with the choice of the term "RWI" rather than "COI," the ACC and AHA have chosen the terms "intellectual perspective" and "clinical practice perspective" (rather than *bias*) to denote intellectual and practice-related opinions and expertise based on knowledge or experience.

To address these issues, the ACC and AHA rely on the principles of *define, disclose,* and *manage*. The relevance, scope, and level of RWI are clearly defined. For the purpose of identifying a chair and/or member of a GWC, the following criteria are used to determine if a *relevant* relationship with a company or other entity exists:

- The *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document*; or
- 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
- The *person or a member of the person's family or 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*.

In terms of scope, the ACC and AHA require disclosure of all RWI (comprehensive for the previous 12 months) involved in the production, marketing, distribution, or reselling of healthcare goods, services, advice, or information consumed by patients, investors, or physicians. This may include relationships with government entities as well as not-for-profit institutions and organizations, which differs from and is more comprehensive than the IOM standards. In addition, authors are strongly discouraged from engaging in new RWI until the document has been approved by the organizations and published.

The amount or level of RWI is defined as:

- None—If the individual has no conflicts or relationships to disclose, he or she must indicate *none*.
- Modest (<$10,000)—A relationship is considered *modest* if it is less than *significant*. (In the fall of 2014, this will change to <$5,000 to align with U.S. Public Health Service regulations.)
- Significant (≥$10,000)—A person is deemed to have a *significant* interest in a business if it represents ownership of ≥5% of the voting stock or share of the entity, ownership of ≥$10,000 of the fair market value of the entity, or if funds received from the entity exceeded 5% of the individual's gross income during the prior year. (In the fall of 2014, this will change to ≥$5,000 to align with U.S. Public Health Service regulations.)

Disclosure of relationships of members of the GWC is performed as follows:

- In advance—RWI are reviewed and vetted during initiation of the GWC to ensure fair balance on the GWC.
- On an ongoing basis—verbally and in writing at the start of every meeting and conference call.
- Published—in print and online using a tabular format to highlight type and level of relationship; publication of all relevant relationships for authors and peer reviewers with each guideline, including documentation

of sections from which authors recused themselves from writing or voting; and online posting of comprehensive RWI for each author and oversight Task Force member.

Reporting categories include consultancies, speakers bureaus, ownership, partnerships, principal roles, research support, salary, institutional and organizational relationships, and expert witness activities.

Management of RWI involves selection of a balanced GWC and requires that both the chair and a majority of members have no relevant RWI. Authors are restricted with respect to writing or voting on sections to which RWI apply. Although they are permitted to participate in discussion and comment on the draft, the chair is responsible for ensuring that this does not result in undue or unfair influence. All CPG recommendations require approval by a majority of the members of the GWC without relevant RWI through confidential balloting. Members recused from voting are listed in the RWI table. Members of the final approving bodies of the ACC Board of Trustees and AHA Science Advisory and Coordinating Committee also recuse themselves from voting if they have relevant RWI. The RWI of GWC members and peer reviewers pertinent to the CPG are located in the Appendix. In addition, to ensure complete transparency, comprehensive disclosure information—including RWI not pertinent to the document—is available online for all members of the GWC, as is disclosure information for the entire Task Force. The creation of CPGs and the work of the GWC are supported exclusively by the ACC, AHA, and partnering organizations without commercial support. Members of the GWC and Task Force volunteer for this activity without compensation. The ACC and AHA are fully committed to transparency in the development of CPGs, have aligned RWI policies with respect to CPG documents, and continuously evaluate these policies.

RECOMMENDATION CLASSIFICATION SYSTEM

In analyzing evidence and developing recommendations, GWCs use benchmarks developed by the Task Force (9). The COR is a statement of the strength of the recommendation and continues to serve as the primary guide for clinicians. The choice of the COR may involve consideration of an estimate of the size and strength of the effect of the intervention (diagnostic test or therapeutic strategy, medication, device, procedure, or other intervention) and the magnitude of benefit in relation to risk. The Level of Evidence (LOE) describes the certainty or precision of the information supporting the recommendation based on the type and quality of the evidence. Class I and III recommendations are considered strong recommendations and are based on size, strength, and positive or negative benefit-risk estimate of the effect and generalizability of benefit over risk. Class IIa recommendations carry intermediate strength and correspond to less benefit in proportion to risk. Class IIb recommendations, the weakest, address measures associated with marginal benefit-risk ratios or uncertain outcome advantages and suggest that additional evidence is needed to clarify the relative benefit-risk of the intervention.

Class III recommendations are unique in that they have 2 qualifiers. Class III: Harm is a strong recommendation usually derived from 1 or more trials in which outcomes were worse with the intervention than with the control. Class III: No Benefit is a moderate recommendation that is applied infrequently when evidence suggests that a strategy is no better than the control. Class III: No Benefit recommendations should not be associated with weak evidence or expert opinion—LOE C or E—because it is virtually impossible to ascertain lack of benefit without randomized trials or carefully conducted observational studies when safety is not the primary concern. Class III: No Benefit recommendations should be supported by moderate or high-quality evidence. The adequacy of the supporting data, including sample size and event rates, needs careful consideration based upon objective criteria (i.e., validated grading tools).

The LOE rates the precision and quality of the scientific evidence supporting the effect of an intervention based on the type, quantity, consistency, and quality of clinical trials and other relevant evidence. The ERC or GWC grades the evidence supporting each recommendation, depending on whether this includes randomized, observational, prospective, or retrospective studies, and their quality, including objectively defined criteria for assessment of potential bias in addition to their relevance and fidelity. When published scientific evidence is lacking, a consensus of expert opinion is sought to gauge standards of care based on clinical experience and ranked as Level E.

To accommodate the more quantitative, graded approach to evidence assessment, the Task Force has cautiously modified the COR/LOE schema (**Table 1**) to provide additional categories that offer greater granularity with separate categories for randomized and nonrandomized/observational evidence to define the level and quality of evidence. The COR/LOE schema continues to evolve as we refine tools to assess the quality of evidence and collaborate with other organizations such as the European Society of Cardiology to enhance the clarity, accuracy and utility of guideline recommendations. Suggested phrases for writing recommendations are provided in the interest of consistency. The revised grading schema consists of the following categories, with studies assessed by the GWC or (selectively) the ERC, increasingly using standardized evidence

TABLE 1 **Applying Class of Recommendations and Level of Evidence to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care***

CLASS (STRENGTH) OF RECOMMENDATION

CLASS I (STRONG) — Benefit >>> Risk

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

CLASS IIa (MODERATE) — Benefit >> Risk

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

CLASS IIb (WEAK) — Benefit ≥ Risk

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

CLASS III: No Benefit (MODERATE) — Benefit = Risk

(Generally, LOE A or B use only)

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

CLASS III: Harm (STRONG) — Risk > Benefit

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

LEVEL (QUALITY) OF EVIDENCE‡

LEVEL A

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

LEVEL B-R (Randomized)

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

LEVEL B-NR (Nonrandomized)

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

LEVEL C

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

LEVEL E

Consensus of expert opinion based on clinical experience when evidence is insufficient, vague, or conflicting

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

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

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

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

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

COR indicates Class of Recommendation; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.

grading tools where useful to facilitate consistent evaluation of the quality of evidence:

- Level A
  - High-quality evidence* from more than 1 randomized controlled trial (RCT)
  - Meta-analyses of high-quality RCTs
  - One or more RCTs corroborated by high-quality registry studies
- Level B-R (Randomized)
  - Moderate-quality evidence* from 1 or more RCTs
  - Meta-analyses of moderate-quality RCTs
- Level B-NR (Nonrandomized)
  - Moderate-quality evidence* from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
  - Meta-analyses of such studies
- Level C
  - Randomized or nonrandomized observational or registry studies with limitations of design or execution
  - Meta-analyses of such studies
  - Physiological or mechanistic studies in human subjects
- Level E
  - Consensus of expert opinion based on clinical experience when evidence is insufficient, vague, or conflicting

In view of the increasing number of studies involving active controls rather than placebos, recommendations addressing the relative effectiveness of one clinical strategy compared with another continue to be included with specific phraseology. These apply to COR I and IIa recommendations only and to LOE A or B-R/B-NR.

To address the concern about coupling the strong COR categories I and III with lower LOEs or expert opinion, specific new guidance from the Task Force is being given to GWCs as follows: Class I recommendations based only on LOE C/E should be minimized, and Class III: No Benefit recommendations should be avoided whenever possible if supported only by LOE C/E.

An analysis of the 3,271 recommendations across 19 CPGs published by 2013 showed that nearly 50% were Class I recommendations. In addition, 50% of recommendations were informed by LOE C and <10% were based on LOE A. Of the Class I recommendations, only 11% were based on LOE A, and 46% were informed by LOE C; even fewer were assigned LOE A within COR IIa, IIb, and III. Taken together, these results indicate an important gap in evidence suggesting a need for clinical trial evidence in the future. Across CPGs, the proportion of LOE C recommendations has prompted criticism and questions about whether CPGs should define the standard of care (8,10). Yet, when evidence is weak, conflicting, or absent, clinicians seek and need the most guidance. Moreover, it is recognized that certain LOE C recommendations that represent common sense and conventional wisdom are unlikely to be studied. However, a review of past LOE C recommendations suggested that many were, in fact, supported by lower levels of evidence as well as expert opinion. Overall, these observations and concerns highlight the need for evidence-based and practice-directed CPG recommendations and have prompted the revisions in evidence analysis and COR/LOE grading schema shown in **Table 1**.

2012 GUIDELINE SURVEY: SUMMARY OF RESULTS AND IMPLICATIONS

To better understand the views and requirements of the ACC/AHA CPG user, a survey was taken from September to October 2012. The survey was conducted via 2 online sources: 1) the ACC CardioSurve Panel, which is composed of U.S. cardiologists who are currently active Fellows of the ACC, and 2) an open, online survey emailed to representative members of the ACC Board of Trustees, AHA, Heart Rhythm Society, and Society for Cardiovascular Angiography and Interventions. The CardioSurve survey received a total of 166 responses from 450 CardioSurve panelists for a response rate of 37%. A total of 40 of 301 members of the organizations above completed the survey for an overall response rate of 13%. Thus, the final number of responses for this survey was 206.

The findings of the survey are summarized as follows:

- When members were asked to rate the relevance of weaker COR and LOE (Class IIa and IIb and LOE C) to their practice, more than two thirds of cardiologists indicated that the weaker class/levels were helpful or very helpful when making informed diagnostic and therapeutic decisions. This is an important observation, because it indicates that clinicians seek guidance on important topics even in situations where the evidence base is weak. It also suggests that focusing CPGs only on strong evidence is not adequate for clinicians to deliver comprehensive best practices. These observations highlight the natural tension between the value to clinicians of a comprehensive CPG and a more restricted CPG limited to a few recommendations informed by a strong scientific evidence base.
- More than 90% of cardiologists found the ACC/AHA CPGs routinely useful in clinical practice. In fact, >80% of cardiologists apply CPGs in managing patients in most circumstances. The CPG features found most useful are clinical applicability and authority, brevity and clarity, comprehensiveness, ease of access and use, and currency.

*The method of assessing quality is evolving, including the application of standardized, widely used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an ERC.

- For cardiovascular or multispecialty practice clinicians, the most frequent use of CPGs is to address a specific clinical question at the point of care, such as in the office, in the hospital, or on rounds. For cardiologists in medical schools and universities, CPGs are most commonly used as a teaching tool.
- Cardiologists are almost uniformly more interested in an electronic means to access CPGs compared with print access alone. However, they do not have a single preference for electronic means of accessing CPGs. They are nearly evenly split between ACC/AHA websites through topic listings, smartphone applications, search engines, or electronic tablet applications. The majority of cardiologists prefer a comprehensive CPG separated into different sections or chapters, with all sections published together as a single document.
- More than two thirds of cardiologists prefer a "dynamic" update of CPGs, either continuously as a "living" electronic document or as an update that occurs whenever new information requires changes to the content/recommendations.
- The majority of cardiologists are very or extremely satisfied with the current use of a color-coded recommendation table format. In addition, more than two thirds of cardiologists prefer limited text informing the recommendations, with links to an evidence table that provides pertinent details of each study that can be accessed as desired.
- Nearly three fourths of cardiologists believe that clinicians have a responsibility to help society provide optimal care for all patients and that CPGs should incorporate available information about cost/resource utilization to educate providers, payers, and patients about the value of various strategies.

The IOM recommendation to have CPGs informed by the highest-quality (i.e., RCT) evidence and meta-analyses, assessed by an independent ERC, may seem to be discordant with the views and needs of these CPG users, that is, to include not only strong evidence-based recommendations, but also those based on lesser evidence and expert opinion and to do so in a timely, concise, and accessible way. This dilemma presents an ongoing and major challenge to the Task Force in charting the future course for CPGs.

EVOLUTION IN CPG METHODS AND PROCESSES

To provide a balanced response to the IOM, clinicians, and CPG users and the concern that recommendations are not based only on the highest LOE, the following initiatives were undertaken in 2013 and 2014:

- An ERC was established to provide an independent systematic review of evidence related to key PICOTS questions generated by the GWC in collaboration with the ERC. To ensure transparency and consistency, the ERC uses a standardized quantitative tool for assessing RCT data and a separate standardized, quantitative tool for grading registry/observational data.
- The challenge to generate CPGs based on a more deliberative, independent, and transparent approach to evidence review while responding to the desire for more timely, responsive, "living" guidelines will be addressed by compiling CPGs from individual recommendations, each a concise knowledge "byte," accompanied by concise supporting text and linked to supporting references and evidence tables (as piloted in the 2014 AHA/ACC valvular heart disease guideline [11]) and stored in an electronic repository. The individual recommendations for each CPG will then be assembled together for the web-published and print versions. Not only will these be accessible through a variety of electronic search strategies, enabled by a standard taxonomy, but they will be capable of being shared among overlapping documents and individually updated or expanded in a "living" document fashion as new evidence becomes available. Accessing and updating individual modules from the electronic guideline content management system will be much less onerous and more efficient once the initial guideline has been developed. These documents may include revision history and can be accessed from mobile devices at the point of care and can eventually be integrated into electronic medical record systems and other patient management tools.

CPG UPDATES: CURRENT PROCESS

The process for initiating, revising, and updating CPGs continues to evolve under the direction of the Task Force. Keeping pace with new data is an ongoing challenge in the development of CPGs. In the early 1980s, the Task Force established policies and procedures for maintaining the relevancy of published recommendations. The process involved full revisions and shorter updates. Full revision occurred after 2 updates or when new evidence required revision of a significant portion of the recommendations. Each topic was reviewed a year after publication of a CPG document and annually thereafter. There was on average a 4- to 5-year span between revisions of each topic.

Recognizing the necessity to review new and rapidly changing evidence in an ongoing fashion and the time required to initiate, develop, review, and publish a CPG, the Task Force developed a new initiative in 2005 to integrate an accelerated focused update process. The GWC (whose membership often spans >1 document) and Task Force members review late-breaking clinical trials presented at major meetings and scan the literature pertaining to each guideline topic twice annually. The decision to initiate a focused update of a CPG is based

on specific criteria, including the publication of adequately powered RCTs or nonrandomized studies with safety or efficacy implications (see criteria below). They do not require comprehensive accounting for all literature published since the date of the previous CPG evidence review; the evidence review period is noted in the introduction of each CPG.

The criteria and considerations for new data include the following:

- Publication of the full report (rather than the abstract) in a peer-reviewed journal
- Adequately powered RCT(s)
- Important nonrandomized data that affect safety and efficacy assumptions
- Strengths/weaknesses of research methodology and findings
- The likelihood that additional studies will influence the findings or conclusions
- The impact on current performance measure(s) or the need to develop new measures
- Requests for review and update from the practice community, key stakeholders, and other sources free of bias or commercial relationships
- The number of previous studies with consistent results
- Consistency with other CPGs or CPG revisions
- Approval of new drugs, devices, or applications by the U.S. Food and Drug Administration that have an impact on cardiovascular care

Initiation of a focused update does not imply that a recommendation must change but rather that new evidence is critically reviewed by the GWC to reach a decision. With the exception of the recommendations modified in focused updates, the full CPG remains current. Recommendations in focused updates are current until superseded by another update or a full revision of the CPG. Since the publication of the first 2 focused updates in 2007 (12,13), they have been created as stand-alone documents with section numbers corresponding to the CPG and new and revised recommendations denoted in adjacent tabular columns. The focused updates are also incorporated into the full CPG, which is republished online in order to provide a complete, comprehensive CPG.

CPG DERIVATIVES

The recommendations in CPGs remain the primary source of guidance for clinicians. Access to CPGs will increasingly be through sources other than the full, written versions of the CPGs, including Web sites (such as those of the AHA and ACC), pocket guides, and electronic access such as smartphone applications. Performance measures operationalize CPG recommendations and are developed as derivatives of CPGs by a separate task force, the ACC/AHA Task Force on Performance Measures. Performance measures focus on critical recommendations carrying large benefit based on high-quality evidence to provide quantitative metrics for assessing the quality of patient care for specific cardiovascular conditions. Failure to deliver this care to an eligible patient suggests a quality lapse. Increasingly, performance measures are used as the basis for public reporting and pay-for-performance programs. Recommendations selected for performance measures must be measureable, valid, reliable, and actionable; address demonstrable gaps in care; and lead to improved patient outcomes (14,15). Currently, the number of measures, feasibility of data collection, exceptions, and correct attribution are under active consideration by the ACC/AHA Task Force on Performance Measures.

The ACC appropriate use criteria documents, another derivative of CPGs, supplement the recommendations by providing representative clinical scenarios that allow clinicians to document practice patterns for comparison against established benchmarks. In addition, they address scenarios for which evidence is lacking. The appropriate use criteria methodology is based on the RAND (Research And Development) Delphi model, which provides consensus judgments about the utility of interventions in specific clinical situations. Clinical scenarios are constructed by a committee using CPG recommendations and are then evaluated by a separate technical panel to translate and implement CPG recommendations in clinical practice. When CPGs and appropriate use criteria documents were directly mapped against each other for coronary revascularization indications in validation testing, all Class I recommendations were appropriate and all Class III recommendations mapped to inappropriate (16).

Whereas CPG recommendations are “should” or “should not” directives, performance measures represent “must do” and appropriate use criteria “reasonable to do” clinical steps. Taken together, these documents define best practices based on evidence, measure how consistently these practices are implemented in patient care, and facilitate benchmarking of practice patterns relative to peers to promote quality improvement in the interest of safe and effective patient care.

The AHA scientific statements and the ACC clinical expert consensus documents represent another important educational product ancillary to CPGs. These documents provide expert opinion and evidence summaries on important focused cardiovascular topics too narrow or immature to warrant a full CPG but for which there is significant scientific and clinical interest.

ONGOING CHALLENGES

Responding to the continually expanding evidence base in a timely manner while maintaining rigorous processes

and methodology, that is, to lead rather than lag behind clinical practice, remains an ongoing challenge. The addition of formal systematic reviews, expansion of the peer review process to include patients and other stakeholders, and selection of the GWC in accordance with a strict RWI policy are time-consuming endeavors. Future challenges in delineation of RWI policy include recognition that manufacturers of recently approved devices are typically required to provide operator training to promote safe deployment of new technology. The ACC and AHA encourage training of clinicians to ensure sufficient expertise while requiring disclosure of industry-sponsored training by members of GWCs. Although the delivery of timely CPGs is essential, it is also important to balance speed with deliberation and accuracy and to allow new treatments to adequately dwell in the clinical arena to assess generalizability and long-term outcomes in clinical practice.

Most apparent, particularly to members of the GWC, are the gaps in evidence. A lack of quality studies in many areas contributes to the relatively high proportion of LOE C/E recommendations, particularly in the many specific conditions and circumstances where clinicians need guidance. Like the research on which most recommendations are based, clinical science is an iterative process in continual evolution. Initiatives such as the AHA's Get With the Guidelines and Mission: Lifeline and the ACC's Door to Balloon Alliance and Hospital2Home have led to improvements in quality of care. However, the relative paucity of funding for implementation science and other barriers challenge the uptake of CPG recommendations in the clinical community.

Furthermore, despite the privilege and reward of serving on ERCs or GWCs, the requisite time commitment may preclude participation in future endeavors as the demands of clinical practice and academic responsibilities continue to increase.

FUTURE DIRECTIONS

Looking to the future, it is clear that the ACC/AHA CPG methodology will evolve in response to a changing healthcare environment and the availability of new formats with which to deliver recommendations. Creation of ongoing "living" documents is under development on various digital platforms. Embedding CPG recommendations and prompts within electronic medical record systems and mobile devices accessible at the point of care will require new ways of crafting and parsing information into "bytes" of data that support individual recommendations and will require resource utilization efforts.

Although past GWCs have excluded cost considerations from recommendations, it is clear that with limited healthcare resources and rising costs, it is important and appropriate to consider cost, cost-effectiveness, and value. Going forward, it is recommended that the COR and LOE criteria summarizing the strength/level and quality of evidence supporting clinical benefit, based on validated evidence assessment tools, be supplemented by an assessment of value (17). Furthermore, although CPGs are more broadly disease based (rather than procedure based), the documents are sometimes crafted in silos; recognition and incorporation of multiple comorbidities will become increasingly important as the patient population ages and people live longer with more advanced cardiovascular disease. The future also may see innovations in clinical trial designs and an important interaction between CPGs and data registries, which may expand patient/subject subgroups of interest poorly represented in clinical trials and create a "learning health system" where a continuous cycle of evidence-based practice leads to feedback of practice-based evidence to validate and further refine clinical evidence (18).

To maintain consistency and facilitate implementation of CPG recommendations, it is important to harmonize our CPGs with those issued by other organizations within the United States and abroad. Notwithstanding differences in resources, economy, RWI policies, and availability of guideline-directed medical therapies, harmonization across CPGs has the potential to minimize confusion in the caregiver community and enhance adherence to recommendations.

Perhaps most important is to preserve the steadfast commitment to the development and dissemination of CPGs based on a thorough, unbiased evaluation of available evidence combined with a focus on patient-centric care and shared decision making. What will remain unchanged is the overall goal of providing guidance to clinicians to improve quality of care and outcomes for patients with cardiovascular disease.

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AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)*— THE EVOLUTION AND FUTURE OF ACC/AHA CLINICAL PRACTICE GUIDELINES: A 30-YEAR JOURNEY

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