

CLINICAL GUIDELINES

Further Evolution of the ACC/AHA Clinical Practice Guideline Recommendation Classification System



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

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For 3 decades, the American College of Cardiology (ACC) and the American Heart Association (AHA) have jointly developed clinical practice guidelines in an effort to align patient care with scientific evidence (1). The “2015 ACC/AHA/HRS Guideline on the Management of Patients With Supraventricular Tachycardia” (2) introduces the latest recommendation classification system (Table 1), which has continued to evolve. The present brief commentary summarizes and explains the changes incorporated in the current scheme. More detailed reviews of the evolution of ACC/AHA guideline methodology have been published (1,3-5).

CLASSES OF RECOMMENDATION AND LEVELS OF EVIDENCE

Guideline recommendations are categorized by the Class of Recommendation (COR) and Level of Evidence (LOE). The COR reflects the magnitude of benefit over risk and corresponds to the strength of the recommendation. Class I recommendations are strong and indicate that the treatment, procedure, or intervention is useful and effective and should be performed or administered for most patients under most circumstances. Class II recommendations are weaker, denoting a lower degree

The ACC/AHA Recommendation System described in this document (Table 1) was approved by the American College of Cardiology Board of Trustees and Executive Committee and the American Heart Association Science Advisory and Coordinating Committee and Executive Committee in June 2015.

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TABLE 1 ACC/AHA Recommendation System: Applying Class of Recommendation and Level of Evidence to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care* (Updated August 2015)

CLASS (STRENGTH) OF RECOMMENDATION	LEVEL (QUALITY) OF EVIDENCE†
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	LEVEL A ■ High-quality evidence‡ from more than 1 RCT ■ Meta-analyses of high-quality RCTs ■ One or more RCTs corroborated by high-quality registry studies
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	LEVEL B-R (Randomized) ■ Moderate-quality evidence‡ from 1 or more RCTs ■ Meta-analyses of moderate-quality RCTs
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	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
CLASS III: No Benefit (MODERATE) Benefit = Risk <i>(Generally, LOE A or B use only)</i> Suggested phrases for writing recommendations: ■ Is not recommended ■ Is not indicated/useful/effective/beneficial ■ Should not be performed/administered/other	LEVEL C-LD (Limited Data) ■ 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
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 C-EO (Expert Opinion) Consensus of expert opinion based on clinical experience

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

A recommendation with LOE C 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 preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; EO, expert opinion; LD, limited data; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.

of benefit in proportion to risk. Benefit is generally greater for Class IIa (moderate) recommendations and smaller for Class IIb (weak) recommendations, for which benefit only marginally exceeds risk. A COR of IIb suggests that implementation should be selective and based on careful consideration of individual patient factors and, for invasive procedures, available expertise. Class III is assigned when actions are specifically not recommended, either because studies have found no evidence of benefit or because the intervention causes harm.

The LOE denotes the confidence in or certainty of the evidence supporting the recommendation, based on the type, size, quality, and consistency of pertinent research findings. In general, for pharmacological treatments or therapeutic procedures, data from randomized controlled trials provide a higher LOE than do observational or retrospective studies, but other considerations apply to recommendations involving diagnostic testing, population-based interventions, or lifestyle modifications. High-quality, concordant evidence from more than 1 adequately powered

randomized controlled trial, meta-analyses of high-quality trials, or randomized controlled trial data corroborated by high-quality registry or practice-based studies qualifies as LOE A. Moderate-quality or less convincing evidence based on 1 or more trials, meta-analyses of moderate-quality studies, or data derived exclusively from registries or other sources that have not been externally validated are assigned LOE B and are now further delineated according to whether the evidence derives from randomized (B-R) or nonrandomized studies (B-NR). When firm scientific support for a recommendation is not available, the evidence is designated as LOE C. There is now a new subcategorization of lower-quality evidence, assigned either because data are limited (C-LD) (i.e., based on physiological preclinical studies, case reports, or studies with methodological deficiencies in design or execution) or because the recommendation is based on clinical experience and a consensus of expert opinion (C-EO).

The COR and LOE are assessed independently. When a recommendation is designated as LOE C, that does not imply that the recommendation is weak. In some cases, clinical benefit is self-evident, and the intervention is unlikely to undergo randomized study. Where available data are weak, conflicting, or absent, recommendations based on this relatively low level of evidence may provide guidance for patient care when clinicians need it most (3). Nevertheless, because in the past a relatively high proportion of recommendations were based on LOE C and a modest percentage were based on LOE A (6), greater emphasis is now placed on formulating recommendations supported by higher-quality evidence and limiting those based on lower-quality evidence.

EVOLUTION IN CONTEXT

These modifications align with recommendations promulgated by the Institute of Medicine in 2011 (7,8) and facilitate comparison of the strength (or COR) and quality (or LOE) with categories used by other guideline developers. The new scheme is intended mainly to increase the granularity and precision of the ACC/AHA system, while broadly retaining the COR and LOE categories familiar to readers of both U.S. and European cardiovascular guidelines. The changes have been implemented as part of the continuous evolution of guideline development to ensure comprehensive, objective assessment of all available evidence and delivery of recommendations in a uniform format that is most useful at the point of care. Among the many remaining challenges are the development of more objective and standardized criteria for assessment of the quality of evidence, incorporation of cost and health economic methodology into guidelines, formulation of more efficient processes for revising and updating recommendations as new evidence emerges, and creation of tools to integrate context-sensitive guideline recommendations with electronic health records (3,9). The structured system for classifying the strength of clinical recommendations and quality of the evidence supporting them spans all of these ongoing initiatives and remains at the heart of the guidelines.

Comprehensive disclosure information for the task force is available at <http://www.acc.org/guidelines/about-guidelines-and-clinical-documents/guidelines-and-documents-task-forces>.

REFERENCES

1. Jacobs AK, Kushner FG, Ettinger SM, et al. ACCF/AHA clinical practice guideline methodology summit report: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2013;61:213-65.
2. Page RL, Joglar JA, Al-Khatib SM, et al. 2015 ACC/AHA/HRS guideline for the management of adult patients with supraventricular tachycardia: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol*. 2015; 67:1573-616.
3. Jacobs AK, Anderson JL, Halperin JL. 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. *J Am Coll Cardiol*. 2014;64: 1373-84.
4. Gibbons RJ, Smith S, Antman E. American College of Cardiology/American Heart Association clinical practice guidelines: part I: where do they come from? *Circulation*. 2003;107:2979-86.
5. Gibbons RJ, Smith SC Jr, Antman E. American College of Cardiology/American Heart Association clinical practice guidelines: part II: evolutionary changes in a continuous quality improvement project. *Circulation*. 2003;107:3101-7.
6. Tricoci P, Allen JM, Kramer JM, et al. Scientific evidence underlying the ACC/AHA clinical practice guidelines. *JAMA*. 2009;301:831-41.
7. Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, Institute of Medicine (U.S.). *Clinical Practice Guidelines We Can Trust*. Washington, DC: National Academies Press; 2011.
8. Committee on Standards for Systematic Reviews of Comparative Effectiveness Research, Institute of Medicine (U.S.). *Finding What Works in Health Care: Standards for Systematic Reviews*. Washington, DC: National Academies Press; 2011.
9. Anderson JL, Heidenreich PA, Barnett PG, et al. ACC/AHA statement on cost/value methodology in clinical practice guidelines and performance measures: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2014;63:2304-22.

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