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PERFORMANCE MEASURES

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

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Executive Summary

Traditionally, resource utilization and value considerations have been explicitly excluded from practice guidelines and performance measures formulations, although they often are implicitly considered. This document challenges this historical policy. With accelerating healthcare costs and the desire to achieve the best value (health benefit for every dollar spent), there is growing recognition of the need for more explicit and transparent assessment of the value of health care. Thus, from a societal policy perspective, a critical healthcare goal should be to achieve the best possible health outcomes with finite healthcare resources.

Consideration of cost/resource utilization as an outcome presents special challenges. Frequently, the scientific evidence base is inadequate to accurately assess cost-benefit. Also, costs may vary widely by practice setting, locality, and nationality, and over time. Moreover, individuals bear the burden of adverse health outcomes, yet costs typically are shared by society (e.g., by families, employers, government, premium payers, fellow employees, taxpayers). Finally, attitudes differ among stakeholders about the extent to which cost should influence treatment decisions for individual patients and who should bear these costs. Consequently, resource utilization debates often become highly politicized, and significant conflicts of interest among individuals impaneled to formulate resource-based guidelines may be difficult to avoid.

A transparent and consistent approach to considering value is needed when making healthcare decisions. This must begin with an understanding of key economic concepts, including allocation of resources to produce more health care of various types, methods for assessing the monetary value of these resources, and the perspective used for making this assessment of the value of healthcare expenditures (i.e., societal perspective, individual patient costs, hospital costs, and payer costs). Methodological challenges include limitations in the robustness and quality of value evidence, regional variations in costs, and outdated (temporally dynamic) and biased data.

Despite these challenges, the writing committee agreed that progress has been made in these areas and that the

need for greater transparency and utility in addressing resource issues has become acute enough that the time has come to include cost-effectiveness/value assessments and recommendations in practice guidelines and performance measures. The writing committee chose to emphasize the nomenclatures of "value" and "resource utilization" over "cost." Given evidence and resource limitations, the writing committee also recognized the need to selectively target guidelines and performance measures for initial resource use evaluation. A plan for performing a thorough, independent literature search and a consistent method for assessing the quality and potential for bias of identified articles should be prospectively designated. The evidence base then should be synthesized to provide an overall value classification together with a supporting level of evidence, which should be reported alongside but separate from the scientific class and level/quality of evidence.

The proposed level of value (LOV) categories, outlined in Section 5 of this paper, are high value (H), intermediate value (I), and low value (L), augmented as appropriate with uncertain value (U) and value not assessed (NA). For example, high value might be set at <$50,000 and low value at >$150,000 per quality of life-year added, indexed to gross domestic product (GDP) or as otherwise determined by agreed-on societal norms. The value category (i.e., H, I, L, U) would be supplemented by a level/quality of evidence paralleling those for scientific level of evidence (i.e., A, B, and C) and based on the robustness of the database supporting the value category. These value assessments would also inform development of performance measures. Class I recommendations determined to be of low value would not be recommended as performance measures. Because the value of a given care practice will change if the cost or benefit of the practice changes, timely review and updates of guidelines will be even more important when value determinations are included in the guidelines.

This report stresses that the value category should be only one of several considerations in medical decision making and resource allocation. Providers and society may be willing to pay more for the only effective treatment for a rare disease (e.g., congenital versus adult cardiac care). As noted, given differing methodologies, quality of evidence, and temporal and geographic dynamics of resource and value assessments, the value level of a recommendation should be given separately and not averaged together with the level/quality of evidence from clinical trial results as a single metric. It is anticipated that these will usually be concordant, but in some cases, discordance may be noted (e.g., an intervention is shown to provide a small incremental health care benefit but at a high cost in resources). Defining how medical decision making should be affected in specific instances by such discordance between value and guideline recommendations is controversial, but highlighting these instances explicitly and transparently will further inform appropriate discussion and policy making.

1. Preface

1.1. Scope

Traditionally, explicit considerations of resource utilization and value in health care have been excluded from clinical practice guidelines and performance measures. However, given accelerating health care costs and the desire to optimize value for each healthcare dollar spent, there has been growing recognition of the need for more explicit and transparent considerations of resource utilization in medical practice. To address this issue, this document summarizes the rapidly evolving healthcare landscape; assesses the reasons for and against considering resource utilization and value in recommendations for practice guidelines and performance measures; reviews relevant, contemporary economic concepts; and proposes a level of value assessment to complement the traditional Class of Recommendation (COR)/Level of Evidence (LOE) system for recommendations, seen in Appendix 1. Finally, future directions and needs are highlighted.

1.2. Structure and Membership of the Writing Committee

The members of the writing committee included experienced clinicians and specialists in cardiology, health economics, and performance measures methodology.

1.3. Disclosure of Relationships With Industry and Other Entities

The ACC/AHA Task Force on Performance Measures and the ACC/AHA Task Force on Practice Guidelines make every effort to avoid actual, potential, or perceived conflicts of interest that may arise as a result of relationships with industry or other entities (RWI). All members of the writing committee, as well as peer reviewers for this document, were required to disclose all current relationships and those existing within 12 months before initiation of this writing effort. It was also required that the writing committee co-chairs and at least 50% of the writing committee members have no relevant RWI. Because this is a methodology document and the writing committee did not define performance measures or develop guideline recommendations, members' relationships with pharmaceutical and device companies were not considered relevant to the topic of this document. The only relationships that were considered relevant were relationships with commercial grouper tools, such as episode treatment groupers that group related services into episodes of care. Cost and resource information is then generated for these episodes.

Any writing committee member who developed new RWI during his or her tenure on the writing committee was required to notify staff in writing. These statements

are reviewed periodically by the task forces and members of the writing committee. Author and peer reviewer relationships with industry and other entities relevant to the document are listed in Appendix 2 (writing committee members) and Appendix 3 (peer reviewers). Additionally, to ensure complete transparency, writing committee members' comprehensive disclosure information, including relationships not relevant to the present document, is available online at http://jaccjacc.cardiosource.com/DataSupp/TFPM_TFPG_Comprehensive_RWI_Authors_and_Peer_Reviewers.pdf. Disclosure information for both task forces is also available online at http://www.cardiosource.org/ACC/About-ACC/Who-We-Are/Leadership/Guidelines-and-Documents-Task-Forces.aspx.

The work of the writing committee was supported exclusively by the American College of Cardiology (ACC) and the American Heart Association (AHA) without commercial support. Writing committee members volunteered their time for this effort. Meetings of the writing committee were confidential and attended only by committee members and staff from the ACC, AHA, and American Medical Association–Physician Consortium for Performance Improvement (which provided a liaison to this writing committee).

2. Introduction

2.1. Background

The ACC and AHA have jointly developed clinical practice guidelines for nearly 3 decades, based on their shared belief that the medical profession should play a major role in the evaluation and synthesis of the evidence that will guide the care of patients with cardiovascular disease. Expert analysis of the available data on the risks, benefits, and alternatives to specific treatments, procedures, and management strategies (i.e., medical programs) can improve the quality of care and patient outcomes. Moreover, clinical practice guidelines serve as the underpinnings for performance measures used to characterize and improve the quality of cardiovascular care. Together, the ACC and AHA have also developed an explicit methodology to select and create performance measures (1,2).

Although review and analysis of existing evidence has the potential to favorably affect health care spending by targeting the use of resources to the most effective therapies, to date, considerations of value and resource use have been explicitly excluded from formal consideration in formulating ACC/AHA clinical practice guidelines and performance measures, although they may have been implicitly considered. Guideline writing committees are encouraged to be informed about cost when information is available, but data on clinical efficacy and outcomes constitute the primary basis for their recommendations. However, given the challenge of accelerating health care costs combined with finite resources, there is an ever-increasing need to be more explicit and transparent about value, which can be defined as the incremental health benefits of a therapy or procedure relative to its incremental net long-term costs. Additionally, the U.S. Food and Drug Administration does not include cost or value in its approval process, further necessitating that medical societies bring this issue forward.

The approach taken by other physician specialty societies in considering costs in developing clinical guidance documents has varied. A recent survey reported that slightly more than half of the largest U.S. physician societies explicitly consider costs in developing their guideline documents, although their approach remains vague (3). The authors concluded by recommending greater transparency and rigor in the approach to cost consideration in guideline documents from medical societies going forward.

Although the ACC/AHA guidelines have not explicitly addressed the issue of costs in the past, the ACC and AHA have addressed issues related to resource stewardship since ACC/AHA guidelines were first produced. Indeed, the first guideline (1984) dealt specifically with the appropriate use of pacemakers and was written at the request of the Health Care Financing Administration (now the Centers for Medicare & Medicaid Services) because of the agency's concern about the rapidly increasing number of pacemaker implants. In moving toward an explicit consideration of resource utilization and value in the ACC/AHA clinical guidance documents, the overarching goal of this document's writing committee is to facilitate the achievement of the best possible health within the confines of available resources.

2.2. Sustainability of the Healthcare System

For the past 40 years, U.S. spending on health care has been growing substantially faster than the economy. From 1997 to 2010, per capita spending doubled from $4,166, or 13.7% of the GDP, to $8,402, or 17.9% of the GDP (see Figure) (4). The projected future increase in Medicare expenditures is a major contributor to the estimated future federal budget deficit and represents a nonsustainable trend. At the state level, the annual increase in total Medicaid expenditures has consistently exceeded the increase in state tax revenues for 40 years; total state spending on Medicaid now surpasses kindergarten to 12th-grade education spending by a considerable amount (5). A less well-recognized future concern for states is the projected health-benefit costs for retired state employees and teachers. The growth of healthcare costs as a percentage of GDP, future Medicare projections, the current Medicaid burden, and state retiree benefit obligations all contribute to unsustainable future healthcare costs. This should be a concern to all healthcare professionals.

Increases in healthcare costs have fueled concerns about the overuse and misuse of costly procedures and therapies. Most of the discussion has centered on overuse, because

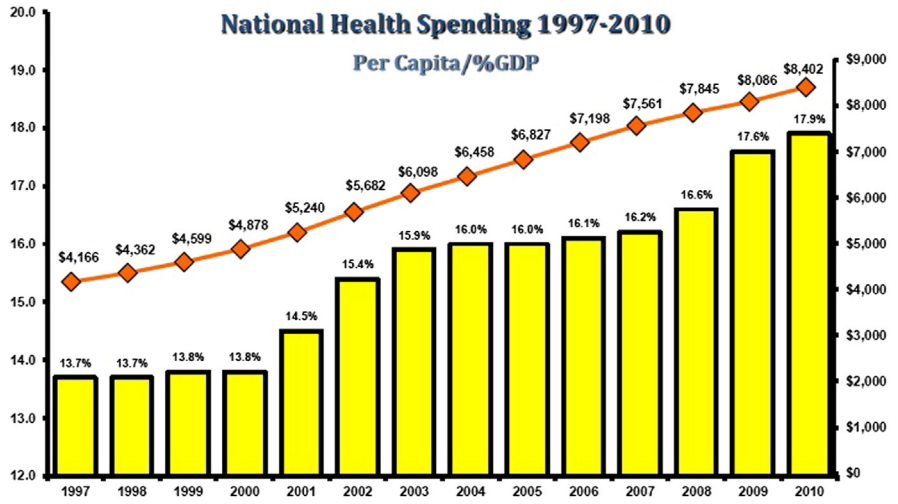

Figure. National Health Spending 1997–2010

Figure: Whether expressed as a percentage of GDP, as per capita spending, or as total national US health expenditures (shown here), healthcare spending has risen dramatically from 1997 to 2010.
Source: National health expenditures. National Institute for Health Care Management (6).
National health expenditures as a percent of gross domestic product. Centers for Medicare and Medicaid Services (7).
GDP indicates gross domestic product.

the former is more expensive, at least initially, although correction of underuse is also relevant to optimizing health care and controlling long-term costs. It is estimated that overuse wastes $210 billion annually (8). Regional variation in care across the United States is another issue; for >20 years, the Dartmouth Atlas Project (http://www.dartmouthatlas.org) has documented significant regional variations in use of medical care without significant differences in health outcomes. The variation in care is primarily due to regional differences in practice rather than different rates paid by Medicare, poverty level (where the poor may be sicker), rates of illness, or patient acuity (9). The central issue is that more care and higher spending do not necessarily translate into better quality of care or outcomes. Indeed, population metrics indicate that the health of several developed nations exceeds that of the United States, although their per capita healthcare expenditures are far less (10).

2.3. Value in Healthcare

Given the escalating costs of health care, variations in delivery of care, and potential for inappropriate use of therapies and procedures, many authorities have concluded that all involved in the healthcare system need to increase emphasis on value in health care (11). One definition of value is that it represents health care that has positive results (improved patient outcomes, safety, and satisfaction) at a total cost that is reasonable and affordable. Care is of high value if it enhances outcomes, safety, and patient satisfaction at a reasonable cost. Care is of low value if it contributes little to outcomes, safety, and satisfaction or incurs an inappropriately high cost. Unfortunately, the current reimbursement fee-for-service system fosters more procedures and more care, which is not necessarily better or of higher value. Although the traditional approach to evidence review for development of the ACC/AHA guidelines and performance measures has not formally considered value provided for money spent, the writing committee believes that it is now imperative to modify this paradigm and consider value and cost in future guidelines and performance measures. As payment models evolve, it will be important that patients continue to have access to high-value care. The importance of adding cost-effectiveness information is not just to curb the excesses of the fee-for-service system but also to guard against the unintended effects of capitation-based reimbursement.

A simple example illustrates this issue. In the non-invasive evaluation of patients with chest pain who are able to exercise and have normal resting electrocardiograms, the ACC/AHA guidelines have recommended treadmill exercise electrocardiographic testing as a first step (12). A recent randomized study compared this strategy with exercise myocardial perfusion imaging as the first step in evaluating a population of women at low to intermediate risk (13). Outcomes over 2 years were not significantly different between the 2 groups. However, costs were far higher in the group evaluated with initial exercise myocardial perfusion imaging. Thus, exercise treadmill electrocardiographic testing without imaging was more cost-effective (greater benefit for cost expenditure).

Given these considerations, the recommendation to consider cost and value in the guideline development process has these goals: 1) to enhance overall value in the

delivery of cardiovascular care and 2) to involve healthcare professionals in the difficult decisions that must be made to increase value in the U.S. healthcare system. This need is emphasized by the unsustainable increase in healthcare costs, finite healthcare resources, and the critical role healthcare professionals play in resource utilization. The emergence and rapid growth of accountable care organizations is a societal effort in this direction and for which valid resource and cost-effectiveness information, together with appropriately aligned incentives for healthcare professionals, will be critical. In this context, we refer to the health and economic benefits of a health promotion or disease mitigation measure as value and are cognizant of but eschew such implications as worth, quality, usefulness, importance, desirability, reasonableness, and appropriateness. Subsequent sections of this document will outline a proposed methodology to explicitly incorporate the issue of value into future guidelines and performance measures.

3. Reasons to Consider Resource Utilization and Value in Recommendations for Guidelines and Performance Measures

The ACC/AHA guidelines and performance measures are based on the principle that comprehensive analysis of clinical data documenting benefits and risks of diagnostic or therapeutic strategies and procedures can improve the effectiveness of patient care and optimize patient outcomes. The conventional premise governing performance measures and guideline recommendations, however, is that all healthcare professionals should act in the best interests of their patients without regard to costs. This premise was never realistic, because medical recommendations always have economic consequences for patients and may expose them to high out-of-pocket costs. It would not be in the patient's best interest for the clinician to ignore costs and recommend treatments that the patient cannot afford (e.g., forcing the patient to choose between paying for groceries or medications). In 2007, a large percentage (62.1%) of personal bankruptcies in the United States were caused by medical bills (14). Protecting patients from financial ruin is fundamental to the precept of "do no harm" (15). Furthermore, even when the costs of medical care are borne collectively rather than individually, rising health insurance premiums and taxes that support government-provided health benefits are paid ultimately by all consumers (and patients). Decisions by clinicians control the bulk of these expenditures, and good stewardship is essential. Consequently, clinical practice guidelines and performance measures that consider value will enhance the sensitivity of providers, payers, and patients to the limits of available healthcare resources and generate the best possible set of outcomes in that context. An important challenge in implementation is the lack of training among medical professionals with respect to health economics and knowledge of cost-effectiveness and value of medical strategies; the growing importance of recognizing the cost of care highlights the need to integrate training in these issues into medical schools and training programs.

3.1. Arguments in Favor of Incorporating Resource and Value Considerations

Economic evaluations, including cost-effectiveness analyses, can help decision makers appreciate the implications of choices and clarify factors influencing relative benefits. In addition to informing clinicians about their responsibility to their patients, economic analyses can guide those making coverage decisions and inform developers of practice guidelines to ensure that recommendations yield the greatest value from available healthcare resources (16). Currently, algorithms for diagnosis or management of disease states, including appropriate use of clinical interventions, typically consider a broad spectrum of differential diagnoses and patient care approaches, which essentially assume that resources are unlimited. The principal consideration is not cost awareness but a comprehensive, informed, and evidence-based approach in which incentives are balanced by the need to consume resources more wisely.

3.2. Limitations, Challenges, and Arguments Against Incorporating Resource and Value Considerations

Barriers to acceptance of guideline recommendations based on value include widespread unwillingness to acknowledge that resources are limited, distrust of government and other policy decision makers, and lack of confidence in the science of value determination (cost-effectiveness) (17). Another limitation is that the value of care (cost-effectiveness) is not constant; it may vary over time and from one location to another because of differences or changes in resource availability, efficiency, and cost structure. Further, cost defined as dollars spent as a resource measure is confounded by contractual allowances and other insurance, provider, and payer variables. Hence, the writing committee favors the concept of cost as true resource utilization.

Another challenge involves the integration of long-term costs, such as development of the infrastructure required to provide an intervention in acute situations (e.g., in the emergency department or intensive care unit) into a per-treatment cost through amortization over the useful life of a given resource. The decision to make the initial investment entails an array of considerations that are separate—or at least distant—from those regarding the cost-effectiveness of implementation at the patient care level. Increasingly, however, as these barriers are identified, methods to overcome them have been developed.

In the United States, no national consensus has emerged regarding the role of cost-effectiveness considerations in healthcare decision making. Even if consensus that such data should inform decision making were achieved, the high-quality economic information needed to formulate recommendations that encompass most spending choices is limited. Attempts to use cost-effectiveness criteria to establish spending priorities have been limited and generally less successful than in some other countries, where initiatives are largely intended to control overall healthcare expenditures in the face of fixed healthcare budgets (18). Nevertheless, although data on cost-effectiveness are not comprehensive, the evidence that is available is informative and increasing. It is the hope of the writing committee that this document will encourage routine assessment of cost-effectiveness in the future, such that, for example, when a new technology is evaluated in multicenter trials, the study design will include an analysis of comprehensive resource utilization and cost-benefit.

The writing committee also recognizes that its focus on the value of individual procedures and therapies in this document does not address system changes that may improve efficiency of cardiovascular care, such as expansion of interdisciplinary cardiac care teams, greater emphasis on prevention, coverage of the uninsured, and replacing fee-for-service (including self-referral) with accountable care (capitated) care reimbursement models.

3.3. Special Considerations

Given the many current limitations and controversies in assessing optimal resource utilization (19), the goal of incorporating considerations of value into guideline recommendations should be to provide information rather than to be prescriptive. Efforts to incorporate value should focus on interventions associated with high costs or volume. Published studies of resource use, identified by using standard search techniques and reviewed by using general criteria for quality, should be part of a comprehensive evidence review (20), noting that the methodology to assess the quality of economic studies is not as well developed as that used to judge efficacy in clinical trials.

3.4. Summary

The objective of incorporating value into guideline recommendations is to supplement evidence of safety and efficacy with information about the resources needed to achieve health improvements. Although guideline writing panels may find data sufficient to make firm recommendations based on resource considerations in only a limited number of circumstances, incorporating value into recommendations will encourage more thoughtful investigation and discussion of economic issues going forward and, when resources are constrained, may prioritize implementation of services with the greatest value.

4. Key Economic Concepts

4.1. Scarcity and Opportunity Costs

Several important concepts underlie the approach that economists use to examine issues in health care, the most fundamental of which is the concept of scarcity. Simply put, societies do not have enough resources to satisfy all of their citizens' wants and needs. Therefore, choices, or more precisely trade-offs, must be made. Introductory economic courses express this need for trade-offs as "guns versus butter": a society that decides to invest more in the production of weapons (defense) will have fewer resources to invest in the production of food. The need for trade-offs, in turn, underlies the economist's notion of cost as that which must be sacrificed to obtain something else ("opportunity cost").

The opportunity cost of medical care is whatever else we might desire that cannot be produced because of the decision to produce more health care. In a wealthy society, such as the United States, it may seem that there are sufficient resources to do almost anything without any sacrifice. The growing U.S. national debt, driven to a substantial extent by the cost of government healthcare programs, however, is a reminder that the notion of inexhaustible wealth is an illusion and that deferring trade-offs does not eliminate the need to make them.

4.2. Efficiency, Cost-Benefit, and Cost-Effectiveness

A second critical economic concept is that of efficiency. Given the issue of scarcity and the need for trade-offs, mainstream economists accept that the objective of economic policy is to maximize the well-being (sometimes referred to as utility) of the members of society collectively. Economists regard the discipline of economics as a tool to provide policy makers with the information needed to make more informed choices in the pursuit of this objective. Cost-benefit and cost-effectiveness analysis are tools that quantify the efficiency of different policy choices by relating the incremental costs of producing the new good or service to its incremental benefits, which can be viewed as a measure of value (benefit provided for a given cost).

Economists prefer cost-benefit analysis because it measures the benefits of an intervention or program in monetary terms and leads to the simple rule that the policy should be adopted if the benefits (in dollars) exceed the costs (in dollars). Clinicians and health service researchers, however, have generally been uncomfortable with measuring health benefits in terms of dollars and therefore prefer to use cost-effectiveness analysis, in which health benefits are expressed as improvements in survival or quality-adjusted survival, which does not require putting a dollar value on human life.

Cost-effectiveness analysis is best suited to decisions made in allocating a fixed budget to maximize

collective utility. Centralized decision making of this sort is rarely made, even in single-payer health systems, so cost-effectiveness in medicine is used as a measure of clinical value informing policy but is not directly used to allocate healthcare resources.

4.3. Societal Perspective

Another key principle in the economic evaluation of health care is that all costs associated with a medical intervention or program should be counted, regardless of who pays for them (i.e., a "societal perspective"). This principle is important because healthcare costs are often divided among patients, providers, and payers, each of whom may be more concerned about their share of the cost than the total cost. Shifting costs from a hospital to a patient or from an insurer to a provider does not save money; it merely redistributes it. Thus, all costs should be included, irrespective of who pays for them.

4.4. Initial and Subsequent Costs

Another important principle of economic evaluation is that health care decisions may have long-term economic effects, so the analysis should include both initial and subsequent costs of a given care program. For example, early discharge of patients from the hospital may decrease initial costs of care but might increase total costs if patients are readmitted more often. The decision to implant a medical device might incur substantial "downstream" costs for monitoring, device-related complications, and subsequent device repair or replacement. An important corollary to this principle is that the overall net cost of an intervention may be substantially lower or even "pay for itself" if it prevents future clinical events. Conversely, an initially low-cost medical decision can incur substantial overall costs due to the subsequent need for additional treatments, occurrence of clinical events, or both. Therefore, the time horizon of an economic evaluation must be of sufficient duration to include all costs and health benefits of the medical intervention or program under study. For studies involving chronic diseases, cost-effectiveness guidelines recommend a life-long time horizon. This often requires a model to project or simulate costs and benefits beyond the time frame of a clinical trial, which can create challenges.

4.5. Patient-Centered Outcomes and Quality-Adjusted Life-Years

Determining the health benefits of a medical intervention or program is more difficult (and may be more influential on the results of the analysis) than determining its overall cost. Incremental health benefits include such things as improvements in symptoms, functional capacity, well-being, and length of life. One key principle of economic evaluation is that these clinical consequences should be assessed by using patient-centered outcomes, such as symptoms or major clinical events, rather than by changes in surrogate markers (e.g., cholesterol levels). In the final analysis, medical interventions or programs benefit patients by extending their survival, improving their quality of life, or both.

The Quality-adjusted life-year (QALY) is the standard measure of outcomes used in economic evaluation. It represents years of survival adjusted for quality of life using a scale of utilities ranging from 0 (equivalent to death) to 1 (perfect health). The utility scale is constructed so that patients assign equal value to interventions that generate the same improvement in QALYs, regardless of whether this is accomplished by lengthening survival or improving quality of life. Economic evaluation of a medical intervention, service, or program is often expressed using a cost-effectiveness ratio (i.e., dollars per QALY). An important advantage of using QALYs to evaluate outcomes is that the decision maker can compare the relative value of interventions for different diseases using a common measure. In practice, it can be difficult to measure QALYs, because the tools available to assess the quality weights (utilities) have methodological limitations and may yield different results. Despite the controversies about the use of QALYs in economic evaluation, which are outside the scope of the present discussion, QALYs represent the preferred measure of clinical effectiveness in health economic evaluations (21).

4.6. Incremental Cost-Effectiveness Ratio

A final key concept of economic evaluation is that the value of an intervention or a program must be considered in incremental terms compared with the relevant alternatives. Cost-effectiveness analysis applies this principle by comparing the intervention or program of interest with the best available alternative, much like when a clinical trial compares a new drug with an active control rather than with a placebo. The incremental cost-effectiveness ratio (ICER), which is used to compare a new intervention or program with its alternative (alt.), is expressed symbolically as follows:

$$\mathrm{ICER} = \frac{(C_{\mathrm{new}} - C_{\mathrm{alt.}})}{(\mathrm{QALY}_{\mathrm{new}} - \mathrm{QALY}_{\mathrm{alt.}})}$$

where C indicates the net cost of the intervention/program and QALY indicates the quality-adjusted life-years that result from that intervention/program.

4.7. Use of Cost-Effectiveness Analysis in Healthcare Decision Making

It is ultimately a matter of judgment whether a medical program (i.e., an intervention or strategy) produces sufficient improvement in medical outcomes to justify its added costs. Consequently, no single level of the ICER indicates that a program is acceptable or worthwhile. In the United States, the annual cost of dialysis for end-stage renal disease provided an early benchmark for the assessment of cost-effectiveness because, although dialysis was costly, the U.S. Congress mandated that it should be paid for as

part of the publicly funded Medicare program. This historical precedent is the origin of the oft-cited $50,000 per QALY benchmark for an acceptable cost-effectiveness ratio (22). Many would argue that this number is out of date because the cost of renal dialysis is now higher (23), but programs below (i.e., more favorable than) this benchmark continue to be generally accepted in the United States.

The World Health Organization (WHO) has suggested a rough benchmark of 3 times the GDP per capita as an upper threshold for an acceptable level of cost-effectiveness in a given country (24). In 2011, the GDP per capita in the United States was approximately $48,000, which implies an upper cost-effectiveness threshold near $150,000 per QALY. Programs with cost-effectiveness ratios above this range would generally be considered economically unattractive, whereas programs with cost-effectiveness ratios below 1 GDP per capita would generally be considered affordable and cost-effective ($50,000 per QALY in an economy with a per capita GDP of the United States).

Cost-effectiveness assessment involves uncertainty. The cost-effectiveness acceptability curve is a commonly used graphical way of representing this uncertainty. It reports the probability that a program under consideration would be cost-effective over the range of critical willingness-to-pay thresholds (25). The uncertainty of cost-effectiveness findings arises from a number of sources, including variation in costs, statistical uncertainty in many outcome parameters, and model variability.

The cost-effectiveness ratio of a medical program (intervention or strategy) is not the only consideration in making health care decisions. Other considerations, such as equity and available funds, may override efficiency issues reflected in cost-effectiveness estimates. For instance, policy makers may wish to consider the distributional effects of a program (i.e., how it affects different segments of the population), or they may be willing to pay more for the only effective treatment for a rare disease. Consequently, economic evaluations are important to consider when setting healthcare policy, but they should not be the only factor in decision making on the allocation of healthcare resources.

Finally, the total budgetary impact of a medical program also needs to be considered, as it may not be possible to pay for all healthcare programs that have favorable cost-effectiveness ratios. For instance, the total cost of implementing a new program may be unaffordable if there are many affected individuals or the cost of treating each individual is very high. This is particularly an issue for interventions that affect large segments of the population such as management of hypertension, hyperlipidemia, diabetes mellitus, heart failure, and other common conditions.

4.8. Challenges in Conducting and Evaluating Economic Analysis

A number of different guidelines describe cost-effectiveness methods but are largely consistent in their recommendations (26).

Systematic reviews have considered the strength of evidence of economic evaluations, paying special attention to methodological differences. Different criteria have been developed to evaluate the quality of cost-effectiveness studies (27). One of the earliest, most comprehensive, and most frequently cited set of criteria was developed for the *British Medical Journal* (20,27) (Table 1).

Attempts to define criteria for quality of economic analysis and to standardize methodology have been only partially effective. Several reviews have found that the quality of cost-effectiveness studies is uneven (27–32). Economic analysis is intrinsically more complex than analysis of clinical trials or observational data due to the need for extrapolative modeling in the absence of empirical data on all needed points.

There are potential limitations in comparing cost per QALY gained across studies (33,34). There can be significant heterogeneity in study design (e.g., trial analyses versus modeling), costing methods, discounting, measures of effectiveness, mechanisms for quality adjustment, and time horizons (21,33–38). It is recommended that the quality of each economic study considered be assessed using a standard, validated tool. The Quality of Health Economic Studies (QHES) instrument (Table 1) (33) is one available tool to assess the quality of economic studies. We recommend that writing committees initially consider using the QHES tool or an alternative widely used and validated tool and that the tool selected for use be explicitly stated in the Methods section of each guideline.

Another limitation in determining the cost-effectiveness of a treatment or procedure for an individual patient is that cost and effectiveness may differ across patient subgroups, yet data may be inadequate to estimate cost and effectiveness in these subgroups. A treatment applied to a high-risk patient will generally provide more value than the same treatment applied to a low-risk patient, because the absolute benefit of treatment is greater in the high-risk patient even when the cost of treatment is the same. As with determining the effectiveness of treatment for an individual patient, clinical judgment often is required to select care that is of high value (and cost-effective). Cost-effective clinical care therefore involves careful selection of diagnostic tests and medical therapies for patients, which is in line with the purpose of guidelines. The reader is referred to prior reviews for specific examples of cost-effectiveness analysis applied to cardiovascular conditions (39-41). Given these considerations, value assessments should clearly specify in which populations and countries/healthcare systems the cost-effectiveness of treatment has been determined and hence would apply. For the ACC/AHA guidelines, it generally may be assumed that a U.S. perspective is given precedence, although consideration of relevant international experience also is to be encouraged.

In summary, cost-effectiveness analyses alone may not fully convey the total cost burden to society of a diagnostic test or therapy, which is influenced by the cost of the test or

Table 1. Quality of Health Economic Studies Instrument

	Questions	Points	Yes	No
1.	Was the study objective presented in a clear, specific, and measurable manner?	7		
2.	Were the perspective of the analysis (societal, third-party payer, etc.) and reasons for its selection stated?	4		
3.	Were variable estimates used in the analysis from the best available source (i.e., randomized control trial - best, expert opinion - worst)?	8		
4.	If estimates came from a subgroup analysis, were the groups prespecified at the beginning of the study?	1		
5.	Was uncertainty handled by (1) statistical analysis to address random events, (2) sensitivity analysis to cover a range of assumptions?	9		
6.	Was incremental analysis performed between alternatives for resources and costs?	6		
7.	Was the methodology for data abstraction (including the value of health states and other benefits) stated?	5		
8.	Did the analytic horizon allow time for all relevant and important outcomes? Were benefits and costs that went beyond 1 year discounted (3% to 5%) and justification given for the discount rate?	7		
9.	Was the measurement of costs appropriate and the methodology for the estimation of quantities and unit costs clearly described?	8		
10.	Were the primary outcome measure(s) for the economic evaluation clearly stated and did they include the major short-term was justification given for the measures/scales used?	6		
11.	Were the health outcomes measures/scales valid and reliable? If previously tested valid and reliable measures were not available, was justification given for the measures/scales used?	7		
12.	Were the economic model (including structure), study methods and analysis, and the components of the numerator and denominator displayed in a clear, transparent manner?	8		
13.	Were the choice of economic model, main assumptions, and limitations of the study stated and justified?	7		
14.	Did the author(s) explicitly discuss direction and magnitude of potential biases?	6		
15.	Were the conclusions/recommendations of the study justified and based on the study results?	8		
16.	Was there a statement disclosing the source of funding for the study?	3		
	TOTAL POINTS	100		

Modified with permission Ofman, Joshua J., et al. "Examining the value and quality of health economic analyses: implications of utilizing the QHES." Journal of Managed Care Pharmacy 9.1 (2003):53–61 (33).

therapy, the prevalence of the condition for which the test or therapy is indicated, and the degree to which guideline recommendations are followed in practice (35,37). Despite these limitations, cost-effectiveness studies are increasing in number and quality. More than 1,400 original cost-effectiveness studies had been published by 2006 (42), and the quality of studies has increased (43).

5. Considerations for Cost-Effectiveness/Value Assessment

5.1. Value Assessment Proposal for Guidelines and Performance Measures

ACC/AHA clinical practice guideline writing committees create recommendations by using a hierarchical grading system to classify information obtained from randomized clinical trials, nonrandomized studies, expert panel consensus, and case studies. This system synthesizes the data to establish the benefit of diagnostic approaches and treatments compared with risk (COR, ranging from the highest [I] to the lowest [III]) and integrates the precision and, implicitly, the quality of the underlying evidence (LOE, from the best [A] to the poorest [C]) (2). In comparing risks and benefits, the writing committees ultimately develop a qualitative determination as to whether the benefits outweigh the risks. In general, this assessment is based on the number and types of supportive studies and their statistical significance rather than the absolute magnitude of the benefit or the value provided (cost-effectiveness) (2). This approach provides a higher class of recommendations to those diagnostic tests and therapies where statistically significant and clinically relevant differences are replicated in several randomized clinical trials, irrespective of value (2).

This document's writing committee recommends enhancing the ACC/AHA system for guideline development to include an assessment of value when data are available and reliable. Although other terms, including cost-effectiveness, cost utility, resource utilization, and efficiency were considered, the writing group favored the primary use of the term "value." The writing committee

recommends that a level of value be provided in the clinical guideline accompanying individual recommendations, particularly for Class I and IIa recommendations, when supporting data are available. Specifically, the writing committee proposes that the literature search for each recommendation be expanded from the current search for outcomes evidence to include a search for health economic data, including cost-effectiveness/resource use/value analyses. Further, the writing committee proposes that whenever reports are available and graded as being of good quality (e.g., by using QHES [Table 1]), a value assessment for that recommendation should be included in the guidelines. However, the writing committee also believes that explicitly defining a level of value to directly change the class of recommendation or level of (clinical) evidence (i.e., COR/LOE) is problematic and could vary, depending on the particular disease state, the particular intervention, the particular outcome, and the particular health care delivery system. By providing a meaningful framework for converting the available data on magnitude of benefit and cost-effectiveness into a level of value to accompany the COR, our cost methodology report will help establish a standard for clinical guidelines to convey the level of value (i.e., high, intermediate, or low) provided by diagnostic tests and therapies.

Under this suggested revision, guideline recommendations would consist of the COR, level or quality of evidence, and level of value (Table 2). The inclusion of this additional value assessment provides a framework in which the rational use of diagnostic tests and therapies can be communicated based on available evidence, supporting more efficient use of resources.

To illustrate, under current guideline development conventions, a therapy for which 2 randomized controlled trials demonstrated a statistically significant reduction in all-cause mortality with benefits exceeding risks would be given a Class I recommendation with an "A" level of evidence, irrespective of cost, cost-effectiveness, or value. Under the proposed approach, if the therapy provided a large and enduring reduction in mortality, was of modest cost, or both, and published studies demonstrated that the cost per QALYs gained was <$50,000 or the therapy was economically dominant (produced health gains and cost savings), the therapy would be given a Class I recommendation, an "A" level of evidence, and an "H" (high) level of value. Conversely, if the cost-effectiveness of this therapy was less favorable and studies demonstrated the cost per QALYs gained was >$150,000, it would be given an "L" (low) level of value recommendation. In exceptional cases, a resource-intensive therapy that may provide the only effective/lifesaving treatment available for a rare or advanced condition may be assessed as being of "low value" but considered appropriate by society. In these cases, the designation "high-resource utilization" may be preferred, potentially adding a parenthetical (e.g., effective/lifesaving) rather than applying the term "low value."

As noted above, the present writing committee defined high, intermediate, and low value according to the WHO-CHOICE (***Cho***osing ***I***nterventions that are ***C***ost-***E***ffective) project http://www.who.int/choice/cost-effectiveness/en/(http://www.who.int/choice/costs/CER_thresholds/en/), which provides a framework for cost-effectiveness thresholds that can be applied globally to a wide range of health interventions (21,36,38). The 3 categories of cost-effectiveness are highly cost-effective (less than GDP per capita), cost-effective (between 1 and 3 times GDP per capita), and not cost-effective (>3 times GDP per capita) (24). In adapting these WHO-CHOICE recommended thresholds, the values shown in Table 2 were selected by the writing group as initial threshold recommendations. In the future, these thresholds may need modification as additional information becomes available or different national consensus standards for value-based thresholds are developed.

Table 2. Proposed Integration of Level of Value Into Clinical Guideline Recommendations*

Level of Value
High value: better outcomes at lower cost or ICER <$50,000 per QALY gained
Intermediate value: $50,000 to <$150,000 per QALY gained
Low value: ≥$150,000 per QALY gained
Uncertain value: value examined but data are insufficient to draw a conclusion because of no studies, low-quality studies, conflicting studies, or prior studies that are no longer relevant
Not assessed: value not assessed by the writing committee

Proposed abbreviations for each value recommendation:
Level of Value: H to indicate high value I, intermediate value; L, low value; U, uncertain value; and NA, value not assessed
*Figures used in this table are based on U.S. GDP data from 2012 and were obtained from WHO-CHOICE Cost-Effectiveness Thresholds (24).
GDP indicates gross domestic product; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year; and WHO-CHOICE, World Health Organization Choosing Interventions that are Cost Effective.

5.2. Recommendations for Implementation of Value Assessment

This document's writing committee recognizes that integrating studies of cost-effectiveness and healthcare value into the guideline development process may be potentially resource intensive. Guideline writing committees or commissioned systematic review committees need to be explicit about the approach used. It is not necessarily the role of guideline writing committees to conduct their own formal cost-effectiveness analyses, but having a well-defined and objective approach to systematically evaluating the available published studies on cost-effectiveness and grading their quality is important. For example, cost-effectiveness evaluations may be delegated to an appropriately trained and experienced evidence review committee. An explicit delineation of the formal process for evaluating existing cost-effectiveness evidence should be developed by societies, including the ACC and AHA. This process should take steps to minimize potential conflicts of interest among members of writing committees or groups performing a

systematic review. There is wide variability in the quality of cost-effectiveness studies. For reliability and reproducibility, the quality of cost-effectiveness studies should be evaluated using consistent and objective methods. At a minimum, the present writing committee proposes that a health economist be available to every guideline writing committee or related evidence review committee; the health economist should be involved in the selection and grading of resource-related studies. A comprehensive literature review across all relevant guidelines statements should be made, and, as noted above, a standardized approach to study evaluation (e.g., initially the QHES instrument) should be used.

The systematic reviews of cost-effectiveness analyses should preferentially use the societal perspective in defining cost-effectiveness. The societal-level approach for value recommendations, however, contrasts with the patient-level approach for diagnostic and treatment recommendations of the ACC/AHA guidelines. To emphasize this contrast in using value recommendations by the practitioner, we propose separating value recommendations from the diagnostic/treatment recommendations (e.g., in separate tables and text).

In addition, for the ACC/AHA guidelines, value recommendations generally should be limited to assessments of cost-effectiveness information generated in or relevant to the United States and/or North America (to avoid confusion with health economic analyses generated in other healthcare settings). Special attention should be given to ensuring that the value assessment is based on the entire clinical population included in guideline recommendations. Caution is also suggested with the recognition that guidelines often assume that treatment benefits apply uniformly across the entire population studied. However, both benefit and cost often differ among patient populations, and thus value is also likely to vary in important ways across subgroups. It is hoped that these proposed revisions to the guideline development process, that is, conveying information on those therapies that have the strongest evidence and provide the greatest value, may allow for better prioritization in healthcare resource utilization and may optimize efficiency in achieving superior outcomes.

How might clinicians use this information in making treatment decisions for individual patients in their practice? Given the state of the science, gaps in the value evidence base, and the frequency with which it may change, the ACC and AHA will not yet be prescriptive regarding how best to incorporate value when using guideline recommendations at the point of care. Rather, where available, value should be recognized and broadly considered when integrating the risk-benefit ratio, LOE, and quality of evidence of a specific recommendation in a specific patient. At present, each clinician should start by considering relevant, highly graded COR/LOE recommendations (i.e., I-IIa/A-B). Second, the clinician should then review the LOV assessment. A high LOV adds a strong endorsement to proceed with the treatment or test. In the case of alternative recommendations, a higher LOV evaluation of a treatment/test may suggest its selection over a lower LOV alternative. In the exceptional case of a treatment with a high COR/LOE but low LOV (e.g., possibly, use of a left ventricular assist device as a bridge to transplant) that is deemed uniquely effective/lifesaving, the designation "high resource utilization" rather than "low value" may be applied and may support appropriate and selective use. For lower COR recommendations (e.g., IIb), a low LOV may reinforce a decision to forego the treatment/test. Clinical judgment and individual circumstances may be especially important for intermediate-value treatments/tests and discrepancies between COR/LOE and LOV. The use of LOV as a tiebreaker in uncertain clinical scenarios rather than prescriptive requirements should strike the correct balance in informing and enhancing clinical practice. As the science and methodology of value assessment evolve, so too will the ACC/AHA grading system.

Finally, how will patients and the public respond to this initiative? The potential for its being viewed negatively, as limiting quality of care and therapeutic options, is real. On the contrary, and fortunately, discussions among groups of informed lay public and patient representatives have endorsed the need for thorough, objective assessments of value in medical care and concerns about inappropriate resource utilization in contrast to simple cost comparisons (44). Moreover, the ACC and AHA remain committed to engaging patient representatives (45) who now serve on the Task Force on Practice Guidelines and guideline writing committees in the discussion and dissemination of these concepts.

6. Special Considerations for Performance Measures

Performance measures are an integral part of the cycle of quality of care improvement. Once the evidence from randomized clinical trials and observational studies is summarized into clinical practice guidelines, the ACC/AHA Task Force on Performance Measures evaluates those recommendations with the strongest evidence to consider which should become a clinical performance measure. If guideline recommendations tell clinicians what they should consider, performance measures tell them which of these recommendations they must follow to optimize patient outcomes. Performance measures therefore are useful as direct measures of the quality of care given by a provider or provider group. To be reflective of provider quality, performance measures and definitions also must possess several key attributes, including being clearly and precisely defined and being able to be reliably, reproducibly, and practically assessed in real-world clinical practice. Performance measures also should be

"actionable," suggesting actions that can be taken by providers and health systems to improve care.

Although direct consideration of the cost or cost-effectiveness of a procedure or therapy has not been traditionally one of the key attributes considered when selecting a performance measure, economic issues have been implicitly considered. In a recent update to the methodology used to create performance measures, the Task Force on Performance Measures summarized its views on the topic as follows:

> *The writing committee believes that it is important to consider both the cost-effectiveness and total cost burden of potential performance measures before selection. Although these may change over time, explicitly quantifying the cost-effectiveness of treatments at the time that performance measures are created is aligned with the Institute of Medicine (IOM) goal for a more efficient healthcare system and will minimize the likelihood that unintended economic consequences for society and hospitals emerge from adopting a measure.* (2)

In this same document, the Task Force on Performance Measures stressed the need for unbiased and high-quality cost-effectiveness analyses for given therapies, acknowledging the general challenges in calculating ICERs (e.g., the appropriate comparator group, time horizon, or perspective) as noted above. This task force also recognized the difficulty in defining an empirical cut-point for the cost-effectiveness ratio that would preclude selecting a given intervention for incorporation into a performance measure.

The framework described above for the explicit consideration of cost in guideline recommendations has important implications for performance measurements. Previously, any Class I guideline recommendation could be considered as a potential performance measure, provided that the other criteria, such as validity, reliability, and existing gaps in care and feasibility, could be demonstrated. The introduction of value assessments as part of guidelines recommendations will inform developers of performance measures in prioritizing Class I recommendations for consideration. Class I recommendations labeled a poor value would not be considered for performance measures. Class I recommendations of uncertain value or with no available value data would have lower priority than those of high value.

7. Future Directions

This report describes how the ACC and AHA can begin to address the cost/value of care when making guideline recommendations or developing performance measures. However, several barriers will need to be overcome before a value can be fully incorporated into guidelines or performance measures documents.

The primary barrier is the lack of high-quality data on cost and value (cost-effectiveness) of interventions or procedures used in practice. Fortunately, a growing number of clinical trials now include an economic component that can serve to estimate the cost of care for a new treatment or diagnostic test during the trial period. Cost of care and survival rates that differed at completion of the trial will likely differ at subsequent times. Thus modeling is often required to determine the benefit and cost of an intervention over the patient's lifetime. Such models are often limited owing to imprecise estimates of treatment effects, competing risks, and future costs of care. As such trials and modeling data become available, they can be added to future updates of guidelines and performance measures. For now, it expected that a minority of care practices in cardiology will have adequate economic data to inform a recommendation on value, but it is anticipated that over time this proportion will increase. The appropriate method for evaluating studies of cost-effectiveness is unclear. An additional future initiative should include a review of all available grading tools, and if these are lacking, potentially development and validation of a customized tool to best serve the ACC/AHA guidelines for grading cost-effectiveness/resource utilization studies.

The optimal cost-effectiveness threshold for determining value also is not entirely clear. As discussed above, the WHO has recommended that this threshold be tied to the wealth of the country as defined by GDP per capita. Given the uncertainty in the optimal threshold, we recommend the use of 2 thresholds initially: a lower threshold to identify an upper boundary for good value and a high threshold to identify poor value, with the remaining values considered intermediate.

The cost of care and hence the value of a given intervention often changes more rapidly than evidence of benefit. For example, if a medication becomes generic 1 year after a guideline is written, the value determination would no longer be accurate and may have changed from poor (low) to good (high). The ability to rapidly reassess value and subsequently update guideline recommendations will be important to accommodate changes in value over time. Further, care originally assessed as high value can become low value, such as when care is extended beyond a specific patient group in which efficacy has been proven.

Another area of uncertainty is the incorporation of quality of life into value. Clearly, a treatment that improves quality of life at a reasonable cost has some value even if it does not improve life expectancy. Combining quality and length of life provides a more accurate estimate of the benefit of any intervention or program. Cost-effectiveness analysis makes the assumption that all QALYs are equivalent, but healthcare decision makers may favor interventions that benefit disadvantaged groups, including those with little life expectancy (e.g., the elderly) and those with a baseline lower quality of life (e.g., those with certain birth defects). Decision makers must consider both equity and optimization of population health.

Incorporation of value assessments may have an immediate impact, as low-value care generally should not be the

basis of performance measures unless there are exceptional considerations regarding equity or other specific justifications. Future performance measure documents may incorporate the cost of implementing the measures in addition to the value of the care. By determining the value (cost-effectiveness) of an intervention or program, it can then be determined if and how much additional funds should be spent implementing performance measures (or other quality improvement activities) such that the combined value of treatment and implementation still represents high value. In conclusion, this document's writing committee acknowledges that it is time to accept the challenge inherent in determining how best to integrate quality care, quality of life, and improved outcomes with value to patients and society by including value information in guideline and performance measure recommendations.

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Key Words: ACC/AHA guidelines ■ ACC/AHA performance measures ■ cost ■ quality indicators ■ quality measurement.

Appendix 1. ACC/AHA Classification of Recommendations and Level of Evidence

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	SIZE OF TREATMENT EFFECT			
	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	**CLASS IIa** *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	**CLASS IIb** *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	**CLASS III** *No Benefit* or **CLASS III** *Harm* Procedure/ Test / Treatment COR III: No benefit / Not Helpful / No Proven Benefit COR III: Harm / Excess Cost w/o Benefit or Harmful / Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit is not recommended is not indicated should not be performed/ administered/ other is not useful/ beneficial/ effective
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		COR III: Harm potentially harmful causes harm associated with excess morbidity/mortality should not be performed/ administered/ other

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

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes mellitus, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

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

Appendix 2. Author Relationships With Industry and Other Entities (Relevant)—ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures

Committee Member	Employer/Title	Consultant	Speaker	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
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This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. A person is deemed to have a significant interest in a business if the interest represents ownership of > 5% of the voting stock or share of the business entity, or ownership of >$10,000 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. Please refer to http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx for definitions of disclosure categories or additional information about the ACC Disclosure Policy for Writing Committees.

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Appendix 3. Reviewer Relationships With Industry and Other Entities (Relevant)—ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures

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Joseph Drozda	Mercy Health System—Associate Director, Outcomes Research	None	None	None	None	None	None
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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***.

Appendix 4. Abbreviations

COR = Class of Recommendation
GDP = gross domestic product
ICER = incremental cost-effectiveness ratio
LOE = Level of Evidence
LOV = level of value
QALY = quality-adjusted life-year
QHES = Quality of Health Economic Studies
TFPM = ACC/AHA Task Force on Performance Measures
WHO = World Health Organization