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CLINICAL RESEARCH

Cost and Value in Contemporary Heart Failure Clinical Guidance Documents

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ABSTRACT

OBJECTIVES This study sought to evaluate the frequency and nature of cost/value statements in contemporary heart failure (HF) clinical guidance documents (CGDs).

BACKGROUND In an era of rising health care costs and expanding therapeutic options, there is an increasing need for formal consideration of cost and value in the development of HF CGDs.

METHODS HF CGDs published by major professional cardiovascular organizations between January 2010 and February 2021 were reviewed for the inclusion of cost/value statements.

RESULTS Overall, 33 documents were identified, including 5 (15%) appropriate use criteria, 7 (21%) clinical practice guidelines, and 21 (64%) expert consensus documents. Most CGDs (27 of 33; 82%) included at least 1 cost/value statement, and 20 (61%) CGDs included at least 1 cost/value-related citation. Most of these statements were found in expert consensus documents (77.7%). Three (9%) documents reported estimated costs of recommended interventions, but only 1 estimated out-of-pocket cost. Of 179 cost/value-related statements observed, 116 (64.8%) highlighted the economic impact of HF or HF-related care, 6 (3.4%) advocated for cost/value issues, 15 (8.4%) reported gaps in cost/value evidence, and 42 (23.5%) supported clinical guidance recommendations. Over time, patterns of inclusion of statements and citations of cost/value have been largely stable.

CONCLUSIONS Although most contemporary HF CGDs contain at least 1 cost/value statement, most CGDs focus on the high economic impact of HF and its related care; explicit inclusion of cost/value to support clinical guidance recommendations remains infrequent. These results highlight key opportunities for the integration of formalized cost/value considerations in future HF-focused CGDs. (J Am Coll Cardiol HF 2022;10:1–11) © 2022 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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ABBREVIATIONS AND ACRONYMS

ACC = American College of Cardiology

ADA = American Diabetes Association

AHA = American Heart Association

CGD = clinical guidance document

CMR = cardiac magnetic resonance

HF = heart failure

TTE = transthoracic echocardiography

The increasing societal and patient-level costs associated with heart failure (HF) are among the most pressing issues facing cardiovascular medicine in the modern era (1,2). In 2012, the estimated global economic burden of HF was $108 billion per annum, of which expenditures in the United States constituted more than 28%, and these costs are expected to increase over the next several decades (3). By 2030, total cost of HF in the United States is projected to approach $70 billion, at which time >8 million patients with HF will be exposed to increasing levels of cost sharing, treatment-related expenses, and other indirect costs (4-6). Although poised to diminish the morbidity and mortality associated with HF significantly, the expanding choices of pharmacological and device-based interventions come with financial complexity. On average, patients with chronic HF take 7 prescription medications per day (7), and novel HF therapies often lack less costly generic options. Further, more than 80% of patients with HF have at least 2 additional major comorbid conditions, such as diabetes or chronic kidney disease, that engender additional direct and indirect costs (8). Complicating these concerns remains the issue that the highest HF burden—and therein the greatest need—lies in lower- to middle-income regions of the world, where resource scarcity is a key barrier (9,10). Ultimately, these considerations call for greater awareness of, competency regarding, and sensitivity to cost/value-related issues in the cardiovascular community.

Given their potential to influence clinician behaviors, clinical guidance documents (CGDs) are well positioned to effectuate efforts to maximize the value of HF-related care. However, the extent to which contemporary HF CGDs consider cost and value remains poorly defined. In this study, we sought to ascertain the frequency with which existing contemporary HF CGDs include considerations of cost and value, as well as to assess the nature of these considerations.

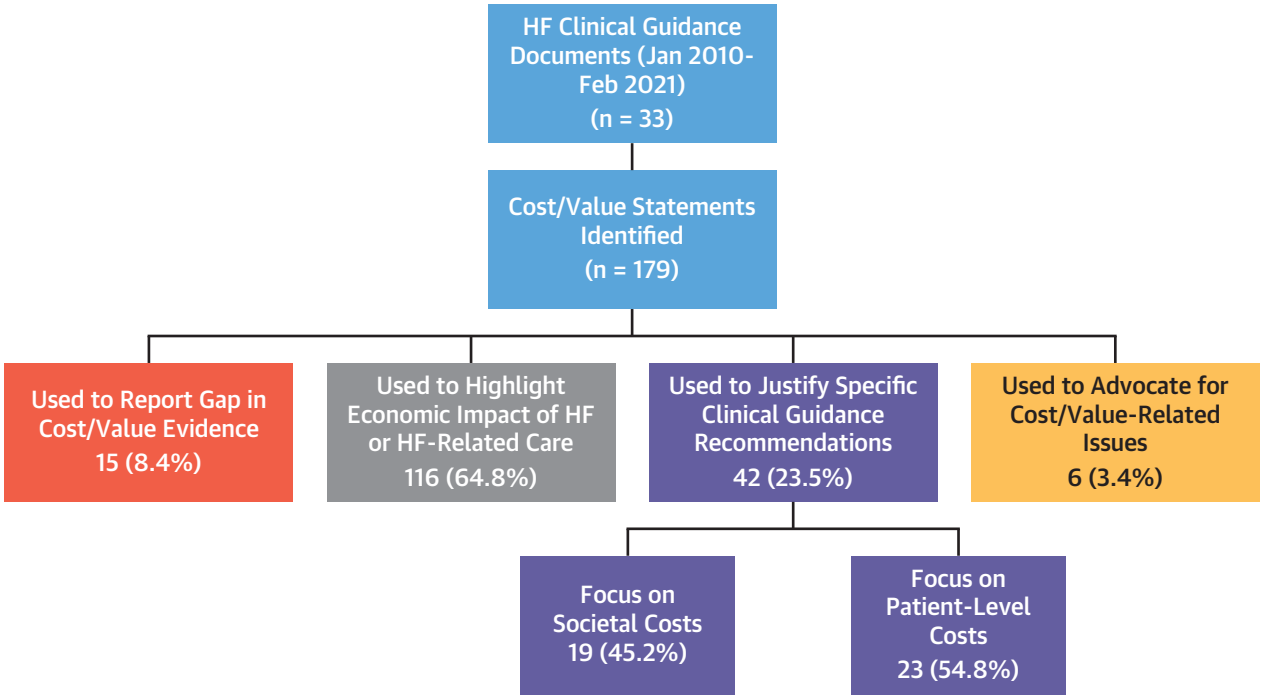
METHODS

DOCUMENT SELECTION. CGDs published between January 2010 and February 2021, with a principal focus on heart failure (HF), were identified by searching content put forth by several major cardiovascular organizations: the American College of Cardiology (ACC), American Heart Association (AHA), Heart Failure Society of America, and European Society of Cardiology. Clinical practice guidelines, expert consensus documents, and appropriate use criteria were included in the analysis. Position statements and performance measures were excluded. Document sections not devoted strictly to the diagnosis or management of HF or that were focused on specific entities within the scope of HF (eg, myocarditis) were excluded from the analysis. Otherwise, sections dedicated to acute and chronic HF, regardless of stage, New York Heart Association functional class, or left ventricular ejection fraction, were included.

ANALYSIS OF DOCUMENT METHODOLOGY, COST AND VALUE SECTIONS, AND PRICE TRANSPARENCY. If reported, document methodology sections were reviewed for the inclusion of cost/value. If present, these cost/value considerations were classified according to a protocol adapted from a previous study (11). Briefly, cost/value considerations in methodology sections were classified as follows: 1) explicit (a statement that cost or value was considered in the CGD development); 2) implicit (including a statement that costs could be considered only in selected instances); 3) excluded (a statement that cost/value was omitted during development); and 4) unmentioned. Each document was also reviewed for the presence of sections specifically devoted to cost/value. To evaluate for price transparency, documents were reviewed for the presence of estimated out-of-pocket costs for HF-related device- or drug-based interventions.

ABSTRACTION AND CLASSIFICATION OF COST AND VALUE STATEMENTS AND CITATIONS. Cost/value statements, liberally defined as any instance in which cost or value was mentioned, were abstracted from each document by a single author (J.W.O). Each statement was subclassified by 2 authors (J.W.O and S.H.) on the basis of how it was used: 1) to highlight the economic impact of HF or HF-related interventions; 2) to advocate for cost/value-related issues; 3) to highlight cost/value as a gap in evidence; and 4) to justify specific clinical recommendations (**Central Illustration**). There was strong inter-rater reliability with respect to statement categorization (κ statistic = 0.80). Statements in category 4 were further subclassified according to whether they focused on management of societal costs vs patient-level costs. Statements in category 4 were also subclassified by whether the cost/value statement was used to support use or discourage use of an intervention, the rationale for use or nonuse, and whether supporting evidence was provided. The rationale provided for use or nonuse was adjudicated in a manner similar to that of a previous study (11).

CENTRAL ILLUSTRATION **Cost/Value Statement Classification Schema**



Ostrominski, J.W. et al. J Am Coll Cardiol HF. 2022;10(1):1–11.

Cost/value statements (n = 179) were identified in 33 contemporary heart failure (HF) clinical guidance documents (published between January 2010 and February 2021) and classified according to how they were used in each document. Nearly 2 of every 3 cost/value statements were used to highlight the economic impact of heart failure and its related care, whereas less than one-fourth of these statements were used to support clinical guidance recommendations.

Briefly, categories included the following: 1) recommending use given equal effectiveness at lower cost in routine cases; 2) recommending use because the incremental benefit justified additional cost; 3) recommending use to reduce future costs; 4) discouraging use because the cost-to-benefit ratio was uncertain; and 5) discouraging use because incremental benefit did not justify additional cost. Discrepancies were resolved by consensus with consultation of a third investigator (M.V.).

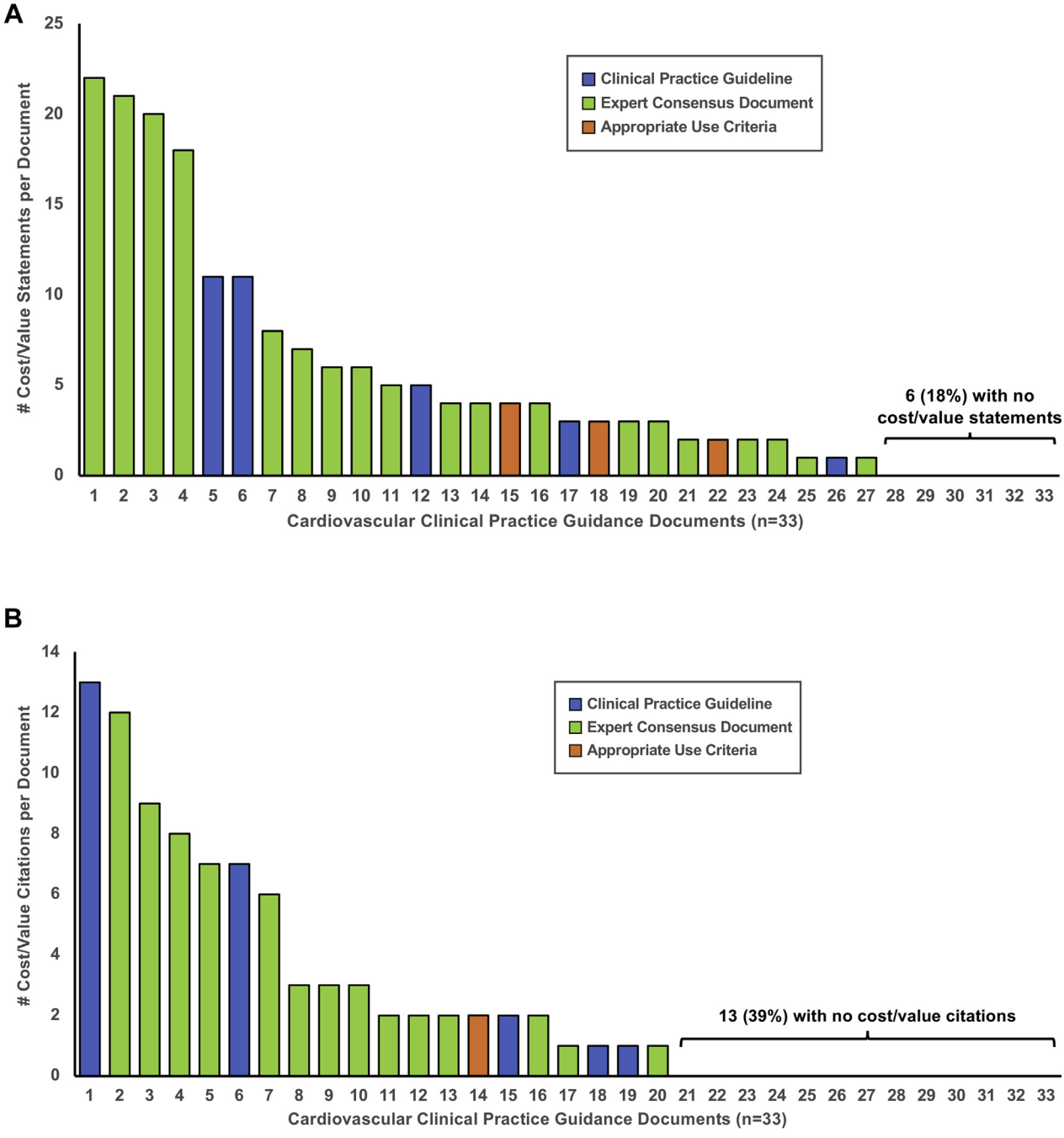
The citations accompanying each cost/value statement, if applicable, were also reviewed and categorized as cost-effectiveness/utility analyses or other (descriptive) analyses in the same fashion. All references sections were also reviewed to identify additional cost/value-related citations. To establish whether more recent documents exhibited different patterns of inclusion of cost/value content, the frequency of inclusion of cost/value statements and citations was compared between documents published in 2010-2015 and those published in 2016-2021.

STATISTICAL ANALYSIS. Frequency of inclusion of cost/value sections, citations, and statements was expressed as a percentage of all documents. Subtypes of cost/value statements were expressed as a percentage of all statements. Comparisons of continuous outcomes were performed using Wilcoxon rank-sum testing. Statistical analyses were performed using STATA software version 16.1 (StataCorp LLC). No patient-level data were accessed to require ethical approval or review by the Brigham and Women's Hospital Institutional Review Board.

RESULTS

DOCUMENT CHARACTERISTICS. Overall, 33 HF CGDs were identified, including 5 (15%) appropriate use criteria, 7 (21%) clinical practice guidelines, and 21 (64%) expert consensus documents. All CGDs included in the analysis are detailed in Supplemental Table 1. Of 15 (45%) CGDs that included methodology sections, cost/value was mentioned in 7. In only 1 of these 7 instances was cost/value stated to be

FIGURE 1 **Cost/Value Statements and Citations per Document**

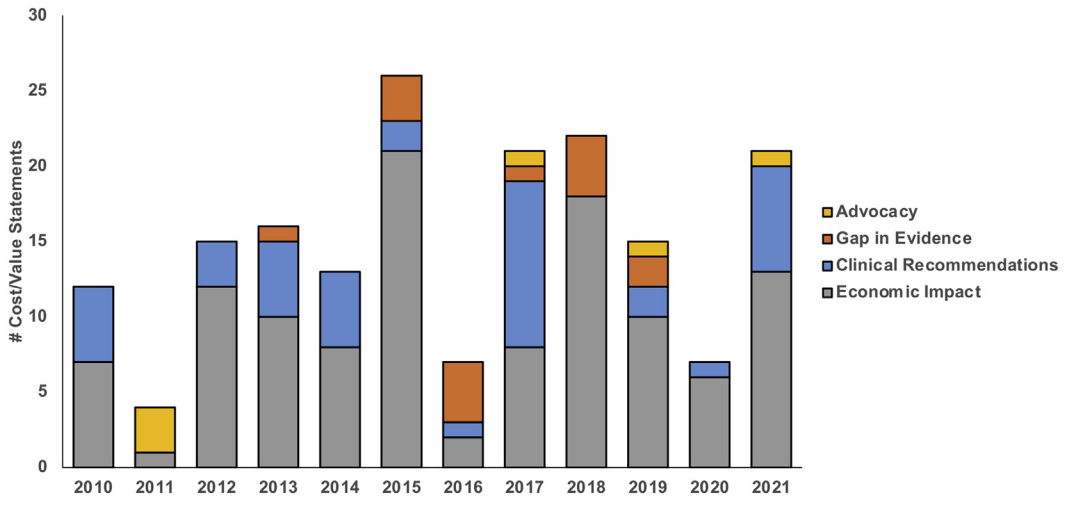


(A) Most contemporary heart failure–focused clinical guidance documents (27 of 33; 82%) included at least 1 cost/value statement, with a median of 3 cost/value statements per document (IQR: 1-6). Most of these statements were found in expert consensus documents. **(B)** Slightly fewer clinical guidance documents (20 of 33; 61%) included at least 1 cost/value-related citation (overall median 1 [IQR: 0-3]).

explicitly included in the development of clinical guidance recommendations. Cost/value was reported to be implicitly included in the 6 remaining methodology sections.

Eight (24%) documents included sections devoted to discussion of cost/value issues, of which 3 reviewed cost/effectiveness or cost/benefit of HF-related interventions, 3 appraised the economic

FIGURE 2 **All Cost/Value Statements by Statement Category, 2010 to 2021**



Appreciable variation was observed in the number of cost/value statements over time, but more recently published clinical guidance documents had a similar frequency of cost/value statements as compared with those published before 2016 ($P = 0.56$). Cost/value statements highlighting the economic impact of heart failure were the most common overall, and they were the only cost/value statement type encountered during every year of the study interval.

impact of HF or HF-related care, and 2 discussed guidance for the management of patient-level costs of care. Three (9%) documents reported estimated costs of HF-related devices, only 1 of which estimated out-of-pocket cost. No documents reported estimated out-of-pocket costs for recommended HF-related pharmacological therapies.

COST AND VALUE STATEMENTS AND CITATIONS. A total of 179 statements related to cost/value were identified in 27 (82%) CGDs (median 3 [IQR: 1-6]) per document (**Figure 1A**). Most of these statements were found in expert consensus documents (77.7% vs 17.3% in clinical practice guidelines and 5.0% in appropriate use criteria). These patterns were preserved following accounting for the number of documents of each type (median 4 cost/value statements per expert consensus document vs median 3 per clinical practice guideline vs median 2 per appropriate use criteria). Twenty (61%) CGDs included at least 1 cost/value-related citation (overall median 1 [IQR: 0-3]) (**Figure 1B**), of which 34 (39%) represented cost-effectiveness or cost-utility analyses and 53 (61%) were descriptive.

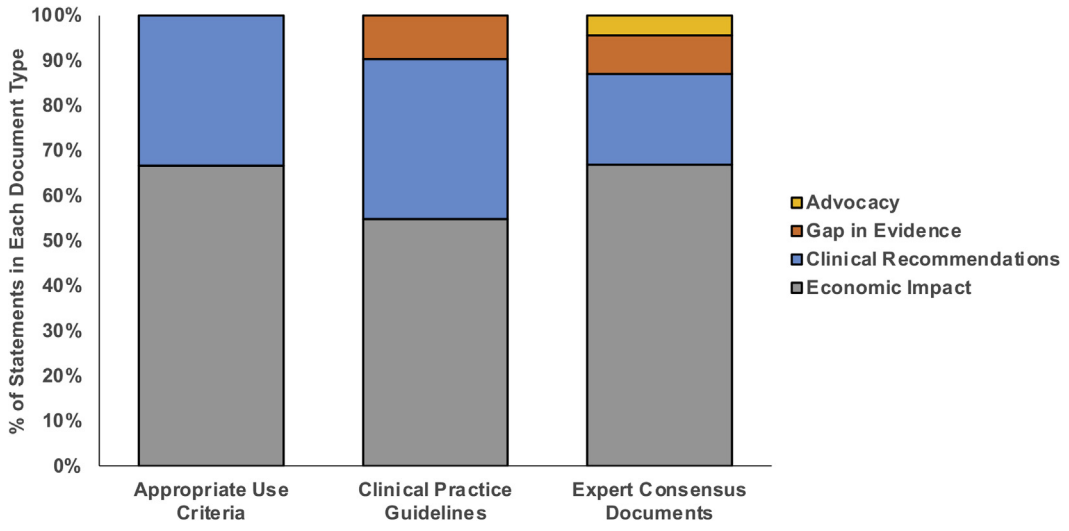
More recently published CGDs had a frequency of cost/value statements similar to those published before 2016 (median 4 [IQR: 2-6] for documents published between 2010 and 2015 vs median 3 [IQR: 0.5-6.0] for documents published between 2016 and 2021; $P = 0.56$). Similar patterns were observed for inclusion of cost/value citations (median 2 [IQR: 0-3] for documents published between 2010 and 2015 vs median 0.5 [IQR: 0.0-2.5] for documents published between 2016 and 2021; $P = 0.33$). **Figure 2** highlights the distribution of cost/value statements over time.

Of the 179 statements, 116 (64.8%) highlighted the economic impact of HF or HF-related care, 6 (3.4%) advocated for cost/value issues, 15 (8.4%) reported gaps in cost/value evidence, and 42 (23.5%) supported clinical guidance recommendations. Examples of statement categories are presented in Supplemental Table 2. Economic impact statements remained most common across each document type (expert consensus documents, clinical practice guidelines, appropriate use criteria) (**Figure 3**). Expert consensus documents were the only document type to include cost/value statements from all 4 types of categories assessed.

Of the cost/value statements supporting clinical guidance recommendations, 19 (45.2%) focused on the management of societal cost, whereas 23 (54.8%) focused on patient-level cost. Of the statements focusing on patient-level costs, 18 were published between 2016 and 2021 as compared with 5 between 2010 and 2015, denoting an increasing focus on the management of patient-level cost over the study interval.

Of the 42 cost/value statements supporting clinical guidance recommendations, 38 (90.5%) supported

FIGURE 3 Distribution of Cost/Value Statements by Category, by Document Type



Expert consensus documents were the only document type to include cost/value statements from all categories.

use of an intervention, whereas 4 (9.5%) discouraged use of an intervention. Of those statements supporting intervention use, 33 recommended use to avoid future costs (eg, HF education before discharge and continuous home ambulatory inotropic agent infusions for patients with end-stage HF), 3 recommended use citing equal effectiveness at lower cost in routine cases (eg, transthoracic echocardiography [TTE] compared with cardiac magnetic resonance [CMR] as first-line cardiovascular imaging modality), and 2 recommended use because the incremental benefit justified additional cost (eg, cardiac resynchronization therapy in selected patients with HF and aerobic training programs for patients with HF in skilled nursing facilities). A total of 29 of the 38 statements recommending use were not accompanied by any specific supporting evidence. Of the remaining 9 statements, 2 were supported by cost-effectiveness analyses of randomized trials (for cardiac resynchronization therapy and comprehensive HF disease management programs), and 1 was supported by a preliminary cost analysis of a small pilot trial (observation unit-based HF management). All others were supported by observational evidence.

All 4 statements discouraging use referred to diagnostic interventions; there were no examples of a statement supporting nonuse of a specific therapeutic intervention because of cost/value. Of these 4 statements, 3 supported nonuse of screening initiatives for asymptomatic left ventricular systolic dysfunction; routine use of TTE and/or biomarker-based screening was discouraged, citing uncertain cost/benefit as a result of insufficient prospective cost-effectiveness data. The 1 remaining "nonuse" statement supported nonuse of routine CMR over TTE for follow-up in patients receiving cytotoxic chemotherapy and cited that the incremental benefit of CMR over TTE does not justify the additional cost.

DISCUSSION

Despite their central role in guiding clinical decision making and use of health care resources, few cost/value statements were observed in contemporary clinical practice guidelines and appropriate use criteria. When included, the high economic impact of HF and HF-related care is frequently mentioned in contemporary HF CGDs; however, explicit integration of cost/value in clinical guidance recommendations remains infrequent. Over time, patterns of inclusion of statements and citations of cost/value have been largely stable.

Historically, cardiovascular clinical practice guidelines have included cost/value considerations only implicitly and instead have focused on safety and efficacy of recommended interventions (12-14). To address the increasing demand for explicit cost/value considerations to manage cost at the societal level, a 2014 ACC/AHA Task Force recommended several modifications to existing guideline development protocols, most notably the statement that a level of value should accompany conventional

TABLE 1 Key Opportunities for Cost/Value Consideration in Future HF Clinical Guidance Documents

Key Opportunities	Examples in Practice
Opportunities to manage society costs	
Prioritize the generation of and inclusion of high-quality cost/value data in CGD development	• NICE's performance of dedicated cost/value evidence reviews and publication of short summary cost/value evidence statements • Use of validated tools, such as the Quality of Health Economic Studies instrument, to adjudicate the quality of existing cost/value studies • ACC/AHA's emphasis on the importance of conducting independent high-quality cost-effectiveness analyses where cost/value evidence is lacking
Where high-quality data are available, improve integration of cost/value into CGDs by providing a LOV for all Class I and IIa recommendations	• Cost-effectiveness–based LOV published for PCSK9 inhibitors in the 2018 ACC/AHA CPG on the management of blood cholesterol
Improve transparency regarding relative benefit of recommended interventions	• American Society of Clinical Oncology's Value Framework highlighting head-to-head comparisons whenever possible
Improve alignment between patients and clinicians on value propositions of cardiovascular therapies	• Inclusion of patients and caregivers on CGD development committees, as well as their involvement in value determinations
Opportunities to manage patient costs	
Promote and improve price transparency	• Reporting of median wholesale price and drug acquisition cost ranges for antihyperglycemic therapies in the American Diabetes Association's Living Standards of Medical Care • National Comprehensive Cancer Network's visual representation of the affordability of recommended drugs or drug regimen in its Evidence Blocks system
Where possible, highlight available programs for cost reduction	• ACC's 2021 ECD for Optimizing HF Care mentions GoodRx, a free-to-use platform for drug coupons and cost comparison
Develop clinical pathways for HF management when cost is a barrier to access for the patient	• The American Diabetes Association's explicit diabetes management pathways for when "cost is a major issue"
Provide explicit guidance for cost-based discussions between patients and providers	• Consensus guidelines for patient-physician communication, including cost discussions, as published by the American Society of Clinical Oncology
Develop resources for the identification and management of financial toxicity in patients with HF	• Development and use of clinic-based checklists
Consider development and implementation of multicomponent patient-centered value frameworks	• The American Society of Clinical Oncology Value Framework • European Society for Medical Oncology's Magnitude of Clinical Benefit Scale
Consider systems-level guidelines and recommend evidence-based structural interventions to navigate cost issues and improve access	• Patient navigator and pharmacist programs in cardiovascular clinics
Consider highlighting important advocacy opportunities or policy issues in CGDs to promote cost-management interventions or systems	• ACC's 2017 and 2021 ECDs for Optimizing HF Care suggested advocacy for automatic transparent cost-sharing systems • ESC's 2019 clinical practice update for HF used informal sections, such as "Practical Comments." alongside guidance recommendations to subserve discussion of cost-related or advocacy issues

ACC = American College of Cardiology; AHA = American Heart Association; AUC = appropriate use criteria; CGD = clinical guidance document; ECD = expert consensus document; ESC = European Society of Cardiology; HF = heart failure; LOV = level of value; NICE = National Institute for Health and Care Excellence; PCSK9 = proprotein convertase subtilisin/kexin type 9.

recommendations on the basis of clinical data (eg, level of recommendation) when high-quality economic data are available (12). Levels of value have since been published in multiple non-HF clinical practice guidelines (15,16). For instance, in the 2018 ACC/AHA guideline for the management of blood cholesterol, proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors received a designation of low value (>$150,000 per quality-adjusted life-year) on the basis of concomitant list prices (15). Levels of value can serve as a relatively stable metric across different countries and health care coverage schema. Unfortunately, in many cases, independently conducted cost-effectiveness and value assessments are lacking. The generation of high-quality data on cost-effectiveness and value for all established and emerging interventions should be prioritized.

We observe low or variable adherence to the foregoing recommendations in HF clinical practice guidelines, including the 2016 and 2017 ACC/AHA/Heart Failure Society of America focused updates, for which no levels of value or explicit appraisals of available economic data were reported (17,18). When coupled with the observation that the inclusion of cost/value statements and citations did not change over time, it does not appear that the 2014 ACC/AHA Task Force on cost/value methodology has significantly influenced the development of HF-related CGDs. Just as it takes time for guideline recommendations for therapeutics to translate into practice, it may take years before documents incorporate cost/value more regularly and explicitly. Additionally, although the 2014 Task Force provided overarching guidance, it may be helpful for individual guideline leadership to provide writers with an explicit framework for consideration and integration of these issues, as well as regularly including health economists in guideline development. Finally, the lack of an apparent change in

TABLE 2 Median Monthly Cost of Selected Pharmacologic Therapies for HFrEF in the United States

Class	Compound(s)	Dosage Strength, mg	Median AWP (min-max), $[a]	Median NADAC, $[a]	Medicare Part D Coverage, %[b]	Copayment Range, $[b]	Target Daily Dose[c]
β-Blocker	Bisoprolol	5	68 (37-68)	14	99	0-1	10 mg once daily
		10	68 (37-68)	15	99	0-1	
	Carvedilol	3.125	127 (3-128)	1	100	0-1	25-50 mg twice daily
		6.25	127 (3-128)	1	100	0-1	
		12.5	127 (3-128)	2	100	0-1	
		25	128 (4-128)	2	100	0-1	
	Metoprolol succinate	25	32 (5-106)	4	100	0-1	200 mg once daily
		50	33 (9-84)	4	100	0-1	
		100	48 (9-88)	6	100	0-1	
		200	76 (9-92)	14	100	0-2	
Vasodilators	Hydralazine	10	36 (11-37)	4	100	0-1	75 mg 3 times daily
		25	46 (13-46)	4	100	0-1	
		50	51 (15-51)	5	100	0-1	
		100	91 (25-91)	9	100	0-1	
	Isosorbide dinitrate	5	89 (85-89)	33	99	0-57	40 mg 3 times daily
		10	98 (66-98)	35	99	1-85	
		20	107 (77-107)	37	99	1-62	
		30	118 (118-140)	51	96	1-38	
		40	1,904 (1,849-1,960)	—	88	0-1,960	
ACE Inhibitors	Captopril[d]	12.5	140 (108-154)	63	92	0-58	50 mg 3 times daily
		25	150 (59-168)	62	92	0-61	
		50	261 (128-261)	75	92	0-101	
	Enalapril[e]	2.5	79 (11-87)	10	100	0-1	10-20 mg twice daily
		5	102 (15-111)	9	100	0-1	
		10	117 (15-117)	8	100	0-1	
		20	157 (22-166)	12	100	0-1	
	Lisinopril	2.5	19 (190 20)	1	100	0-1	20-40 mg once daily
		5	29 (2-29)	1	100	0-1	
		10	30 (2-30)	1	100	0-1	
		20	32 (2-32)	1	100	0-1	
		30	45 (43-45)	2	100	0-1	
		40	46 (5-47)	1	100	0-1	
ARB	Losartan	25	50 (5-92)	2	100	0-1	150 mg once daily
		50	69 (5-73)	3	100	0-1	
		100	92 (6-99)	4	100	0-1	
	Valsartan	40	233 (97-700)	14	99	0-1	160 mg twice daily
		80	278 (116-367)	16	99	0-1	
		160	300 (125-395)	16	99	0-1	
ARNI	Sacubitril/valsartan	24-26	699	559	100	1-10	97-103 mg twice daily
		49-51	699	559	100	1-10	
		97-103	699	559	100	1-10	
SGLT2 Inhibitor	Dapagliflozin	10	639	511	45	5-613	10 mg once daily
	Empagliflozin	10	658	526	93	3-19	10 mg once daily

Continued on the next page

guideline practice may reflect a persistent lack of high-quality cost/value data, as highlighted earlier. To tailor the recommendations of the 2014 ACC/AHA Task Force to HF content, we have provided a list of potential opportunities for future HF CGDs (Table 1).

Appropriate use criteria documents, which typically have been constructed to provide practical, scenario-based guidance in use of cardiovascular procedures or testing, may have unique considerations for the integration of cost/value. Writers of appropriate use criteria documents are encouraged to incorporate cost/value in each recommendation, which may explain the relatively lower frequency of detailed cost/value discussions in these documents. However, a methodology update in 2018 highlighted the goal of incorporating more transparent discussion of available cost/value studies in future appropriate use criteria documents, as well as longer-term goals of integrating scarcity and opportunity costs, cost-

TABLE 2 Continued

Class	Compound(s)	Dosage Strength, mg	Median AWP (min-max), $[a]	Median NADAC, $[a]	Medicare Part D Coverage, %[b]	Copayment Range, $[b]	Target Daily Dose[c]
MRA	Eplerenone	25	125 (123-130)	30	92	1-50	50 mg once daily
		50	125 (125-130)	30	92	1-50	
	Spironolactone	25	13 (6-14)	2	100	0-1	25-50 mg once daily
		50	24 (23-26)	4	100	0-1	
Selective I_f Inhibitor	Ivabradine	5	590	470	100	2-9	Target HR 50-60 beats/min; max dose 7.5 mg twice daily
		7.5	590	476	100	2-8	
sGC Stimulator	Vericiguat	2.5	699	–	0	714	Max dose 10 mg once daily
		5	699	–	0	714	
		10	699	–	0	714	

Prices are n or median (IQR), unless otherwise indicated. [a]Calculated for 30-day supply (AWP or NADAC unit price × number of doses/day × 30 day); median AWP or NADAC listed alone if only 1 product/price available. Used NADAC unit prices published in February 2021. Generic prices used if commercially available. [b]Percent Medicare Part D and Medicare Advantage plans covering selected drug and typical copayment ranges for monthly supply of selected drug obtained through GoodRx. [c]Target doses of selected agents extracted from Maddox et al (1). [d]Prices calculated for 3 times daily dosing. [e]Prices calculated for twice daily dosing.

ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; ARNI = angiotensin receptor and neprilysin inhibitor; AWP = average wholesale price; I_f = funny current; HFrEF = heart failure with reduced ejection fraction; max = maximum; min = minimum; MRA = mineralocorticoid antagonist; NADAC = National Average Drug Acquisition Cost; sGC = soluble guanylate cyclase; SGLT2 = sodium-glucose cotransporter 2.

effectiveness analyses, and value-based recommendations for health systems (19).

The high burden of HF-related costs is borne not only at the societal level, but also at the level of patients and caregivers. Accelerating levels of cost sharing have been associated with worse HF outcomes and have broader health and health equity implications (5,20,21). We did observe an increasing focus on the management of the patient-level cost of HF and HF-related care, driven largely by the 2017 and 2021 ACC expert consensus documents for the optimization of HF treatment (1,22). These documents provided new and explicit guidance for managing patient-level costs, largely related to cost reduction and medication access measures. Although they are a significant step forward, numerous opportunities remain.

In addition to potentially supporting high-value health care decision making, price transparency has been cited as a central goal to improve access to cardiovascular therapies (6,23,24). In this analysis, however, no document reported estimated out-of-pocket costs for recommended HF drugs. Despite the challenges associated with this strategy, including the opacity of prescription drug costs (25) and the wide variation by geographic location (26), pharmacy, or payer contract, other guideline-producing societies have implemented drug price transparency efforts. To encourage clinical cost consideration, the American Diabetes Association (ADA) reports ranges of average monthly costs of recommended antihyperglycemic therapies, on the basis of average wholesale prices and National Average Drug Acquisition Costs (27-29). The ADA has also developed explicit diabetes management pathways for clinical situations in which costs are limiting (27). Crucially, recent studies have shown that patients with HF are highly receptive to medication-related cost discussions (30,31), and greater price transparency may help to inform cost-sensitive and value-focused care efforts. As an example of how the ADA's price transparency approach may be applied in HF CGDs, median monthly costs for selected HF drugs, expressed as average wholesale prices and National Average Drug Acquisition Costs with estimated Medicare Part D copayment ranges, are displayed in **Table 2**. Even with these estimates, given variability in clinical practice related to conveying cost information to patients, standardized cost education and decision-making tools are needed for their implementation.

Importantly, because of the large variation in health systems and regulatory policies, as well as the opacity of drug pricing policies for different regions of the world, multiple issues relating to cost/value considerations and drug price transparency become more complicated on consideration of the global perspective. Purchasing power parity, or the relative purchasing power of different countries' currencies as illustrated by the Big Mac Index, adds yet another layer of complexity (32). Notably, the impact of purchasing power parity on the region- and country-level cost of HF therapies remains underexplored. Although CGDs developed by professional societies in the United States and Europe are often applied in lower- to middle-income countries, these issues highlight the need for practice guidelines, including cost/value considerations, to be tailored to the

population for which they are intended. Otherwise, the sustainability of under-resourced health systems may be compromised.

Although we believe in the potential for care optimization with the inclusion of cost and value considerations in CGDs, we also recognize that decisions regarding their integration and use are complex. Guideline writers already carry enormous responsibility in evaluating the safety and efficacy of available therapies. Whether explicit and transparent consideration of cost and value in guidelines may promote appropriate and equitable access to therapies is not entirely certain. CGDs are currently used to facilitate access by justifying coverage to payers for expensive but effective therapies. Conversely, if cost and value are introduced more routinely into CGD development, there is potential for payers to leverage these statements adversely and deny coverage of these higher-cost therapies. In some cases, lower-cost interventions may not have sufficient evidence to support routine use, or best available evidence-based therapies for individual patients may run counter to value-based strategies to optimize societal health. Ultimately, these concerns illustrate the need for value considerations to achieve balance between providing an added layer of information and being too prescriptive (12).

STUDY LIMITATIONS. The main limitations of this study include qualitative review and exclusion of other document types, such as performance measures. Furthermore, we focused on U.S. and European documents given that these documents are commonly viewed as international guidelines and are applied in countries outside the United States and Europe, but we recognize that other country- and region-specific guidance documents are increasingly available.

CONCLUSIONS

Although most contemporary HF CGDs contain at least 1 cost/value statement, these CGDs have generally focused on the economic impact of HF, with less explicit consideration of cost/value in clinical guidance recommendations. To promote cost-sensitivity and value-based care efforts, we propose potential opportunities for future HF-focused CGDs.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: Although most contemporary HF CGDs focus on the high economic impact of HF, explicit inclusion of cost/value to support clinical guidance recommendations remains infrequent.

TRANSLATIONAL OUTLOOK: To support value-focused and cost-sensitive HF care efforts, future HF-focused CGDs may consider key opportunities for formalized integration of cost/value.

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KEY WORDS appropriate use criteria, clinical practice guidelines, cost, expert consensus documents, heart failure, value-based medicine

APPENDIX For supplemental tables, please see the online version of this paper.