

HEALTH CARE REFORM

Conflicts of Interest in Cardiovascular Clinical Practice Guidelines

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Background: Clinical practice guidelines (CPGs) serve as standards of care in practice, quality improvement, and reimbursement. The extent of conflicts of interest (COIs) in cardiology guideline production has not been well studied. Herein, we describe the scope of COIs in CPGs.

Methods: We examined the 17 most recent American College of Cardiology/American Heart Association guidelines through 2008. Using disclosure lists, we cataloged COIs for each participant as receiving a research grant, being on a speaker's bureau and/or receiving honoraria, owning stock, or being a consultant or member of an advisory board. We also cataloged the companies and institutions reported in each disclosure. "Episode" describes 1 instance of participation in 1 guideline by 1 person. "Individual" describes 1 person who may be involved in multiple episodes. "Company" describes a commercial or industry affiliation reported by an individual in a single episode. Analysis involved descriptive statistics and correlation analyses (Pearson correlation coefficient, χ^2 and R^2).

Results: Fifty-six percent of the 498 individuals reported a COI, corresponding to 56% of the 651 episodes. Being a consultant or member of an advisory board was the most common type. The percentage of episodes involving a COI varied between guidelines (range, 13%-87%). The number of episodes per individual was associated with both presence and number of disclosures ($P < .001$ for both comparisons). Of 478 companies, the number per guideline ranged from 2 to 242 companies (mean, 38 companies). One company was the most frequently reported company in 7 of 17 guidelines.

Conclusion: Conflicts of interest are prevalent in cardiology guidelines, but there seems to be a significant number of experienced experts without COIs.

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CLINICAL PRACTICE GUIDELINES (CPGs) have become a fixture in clinical medicine. Though individual clinical trials have meaningful impacts on patient care, CPGs are often adopted as the standard of care and taught as such in training programs at all levels. CPGs also play a prominent role in quality improvement initiatives.^{1,2} In addition, CPGs have an emerging role in national policy to guide reimbursement and serve as the standard of care in medical malpractice cases.³

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Although conflicts of interest (COIs) are found in all spheres of medicine^{4,5} their role in the formation of CPGs may be especially significant. Improper bias in the CPG production process can have a potentially

more widespread adverse effect on patient care than individual practitioners' COIs. Charges of undue industry influence surround official recommendations in recent guidelines.^{6,7} A review of authors' industry links and published opinions also highlights this issue.⁸ Such situations can lead to an erosion of trust in guidelines. A recent Institute of Medicine report⁹ on COIs in medical research, education, and practice highlights the fact that the scope of COIs in CPGs has not been well studied. Nonetheless, the American College of Cardiology (ACC) and the American Heart Association (AHA) have recently placed restrictions on official participation in educational events and guidelines production in line with the Council of Medical Specialty Societies (CMSS) code for interactions with companies.¹⁰⁻¹²

METHODS

We reviewed the ACC/AHA joint guidelines for this study. The most recent CPGs from the

ACC/AHA include documented disclosures of COI, explicitly list the companies and institutions involved in each COI for each author and reviewer, categorize the COIs by type into at least 4 categories (receipt of research grant; receipt of honoraria or being on a speaker's bureau [honoraria/speaker's bureau]; owning stock or having other type of ownership [stock/other ownership]; or being a consultant or member of an advisory board [consultant/advisory board]), and indicate whether the COI is moderate or significant in magnitude (defined as \leq \$10 000 or $>$ \$10 000, respectively).

The study was approved by the local institutional review board. Using the National Guideline Clearinghouse Web site (<http://www.guideline.gov/>), we cataloged disclosures from the most recent versions of the ACC/AHA guidelines through 2008. There were 2 "focused updates" of guidelines in 2009 but no official new guidelines or formal guideline revisions. The ACC and AHA officially adopted the CMSS code recommendations in 2010, which presumably introduced changes to the guideline process. Of the 19 available guidelines or the full revision updates, 2 guidelines^{13,14} did not include a list of disclosed COIs. We used the remaining 17 guidelines for our analysis.¹⁵⁻³¹

We use the term "episode" to describe 1 instance of participation in the production process of 1 guideline by 1 person. We use the term "individual" to mean 1 person who may be involved in multiple different episodes in different guidelines. We characterized individuals as an author or reviewer and identified the individuals who served as first author, chair, or co-chair. We define "company" as a unique commercial industry affiliation reported by an individual in a single episode. If 2 companies merged in the time between the production of different guidelines (eg, the companies were involved separately in a guideline produced in 2004 but merged in 2005, and the merged company was involved in a guideline produced in 2006), we considered them to be 2 different companies before the merger and a third different company following the merger. We separated commercial companies from governmental and noncommercial entities (ie, National Institutes of Health, Veteran's Administration, charities). We use the term "COI" to mean 1 reported affiliation causing a COI by 1 individual participating in 1 guideline. Individuals may have reported COIs with multiple companies in the same episode. Companies may be reported by multiple different individuals in the same guideline.

We also cataloged the number of companies/institutions each individual listed in each of the 4 categories mentioned herein. For each guideline, we generated a list of unique companies/institutions and compiled a list for each category of COI within a guideline, including a count of the number of different individuals with which the company had been involved. For guidelines that included data to categorize the degree of COI, we recorded the number of modest and significant COIs. Data analysis consisted of descriptive statistics and correlation analyses (Pearson correlation coefficient, χ^2 and R^2).

RESULTS

In the 17 guidelines, we found 651 episodes of participation by 498 individuals. On average, each individual participated in 1.31 episodes (range, 1-7). A total of 277 of the 498 individuals (56%) reported a COI. Over half of the episodes (365 of 651 [56%]) involved a COI. The most common form of COI was consultant/advisory board, followed by research grant, honoraria/speakers' bureau, and stock/other ownership (**Table 1**). There was an association between episodes in which at least 1 COI was reported and individual guidelines ($P < .001$). The per-

centage ranged widely across guidelines, from 13% (2 of 15 episodes) to 87% (13 of 15 episodes).

Role as guideline committee member (vs peer reviewer) was associated with COI (63% vs 51%; $P = .006$), as was role as chair/co-chair/first author (81% vs 55%; $P = .03$). Only 105 of the 498 individuals (21%) were involved in 2 or more guidelines. The percentage of individuals reporting a COI was higher among individuals with more episodes of participation, and the number of episodes of participation was associated with both presence of COIs ($P < .001$) and number of COIs ($P < .001$) (**Figure**).

There were 510 unique commercial companies involved in the 17 guidelines, with a wide range in the number of companies reported to be involved in different guidelines (mean, 38 companies; range, 2-242 companies) (**Table 2**). In contrast, there were only 18 unique noncommercial organizations reported to be involved in COIs (**Table 3**). We identified the commercial company involved in the greatest number of COIs in each guideline. One specific company was reported by more individuals than any other company in 7 of the 17 guidelines (**Table 4**).

Of the guidelines we analyzed, 6 included information characterizing COIs as modest vs significant. In these guidelines, there were 232 episodes, of which 150 involved COIs. Modest COIs were reported in 125 of 232 episodes (54%), whereas significant COIs were reported in 68 of 232 episodes (29%).

COMMENT

The popular media and members of the US Congress have focused their attention on COIs among individual physicians and researchers and in individual clinical trials.³² There has been less focus on COIs among participants in the production of guidelines. CPGs play an important role in synthesizing information for clinicians, as well as increasing uniform practice to certain standards and avoiding the uncontrolled use of medications, procedures, and devices for unproven indications.³³ As such, CPGs are often the vehicle through which clinical trial data are translated into clinical practice. National campaigns are urging the increased use of CPGs in everyday practice, including the AHA's "Get With the Guidelines" and the ACC's "Guidelines Applied in Practice."^{1,2} The patient safety/pay-for-performance/quality of care movements have also begun to incorporate CPGs into standards of care and reimbursement policies.³ Although not prevalent currently, CPGs do enter the legal realm in medical malpractice if they are considered standard of care.^{34,35}

Several controversial episodes involving COIs in guideline production have surfaced in recent years. In 1 instance, a guideline published in a supplement of a leading cardiology journal by the Screening for Heart Attack Prevention and Education Task Force,³⁶ composed of a number of prominent cardiologists, attracted considerable controversy when it was reported that the publication of the guideline was funded by a donation from a major pharmaceutical company, that the authors failed

Table 1. Number of Episodes Reported for Types of Conflicts of Interest in Each Guideline

Guideline ^a	Year	Total Episodes, No.	No. (%)				
			Conflicted Episodes	Research Grants	Honoraria/Speakers' Bureau	Stock/Other Ownership	Consultant/Advisory Board
Afib	2006	54	29 (54)	22 (76)	16 (55)	4 (14)	22 (76)
CABG	2004	24	7 (29)	6 (86)	3 (43)	2 (29)	4 (57)
CHF	2005	58	41 (71)	27 (66)	23 (56)	7 (17)	31 (76)
Device therapy	2008	34	27 (79)	16 (59)	10 (37)	4 (15)	24 (89)
Echo	2003	15	2 (13)	1 (50)	0	0	1 (50)
Intracerebral hemorrhage	2007	15	13 (87)	5 (38)	9 (69)	1 (8)	11 (85)
Ischemic stroke	2007	19	15 (79)	11 (73)	7 (47)	0	14 (93)
NSTEMI	2007	55	43 (78)	29 (67)	21 (49)	7 (16)	33 (77)
PAD	2005	51	19 (37)	9 (47)	13 (68)	4 (21)	14 (74)
PCI	2005	26	12 (46)	8 (67)	7 (58)	4 (33)	7 (58)
Periop	2007	55	27 (49)	11 (41)	16 (59)	4 (15)	16 (59)
Prevention stroke	2006	21	12 (57)	7 (58)	9 (75)	1 (8)	9 (75)
Secondary prevention	2006	36	21 (58)	16 (76)	16 (76)	2 (10)	16 (76)
STEMI	2004	68	41 (60)	29 (71)	18 (44)	6 (15)	26 (63)
Valve Dz	2005	43	15 (35)	6 (40)	6 (40)	4 (27)	11 (73)
Ventric/SCD	2006	44	24 (55)	16 (67)	9 (38)	5 (21)	20 (83)
Women	2007	33	17 (52)	8 (47)	9 (53)	0	13 (76)

Abbreviations: Afib, atrial fibrillation; CABG, coronary artery bypass graft surgery; CHF, chronic heart failure; echo, echocardiography; NSTEMI, non-ST-elevation myocardial infarction; PAD, peripheral arterial disease; PCI, percutaneous coronary intervention; periop, perioperative; STEMI, ST-elevation myocardial infarction; valve Dz, valvular heart disease; ventric/SCD, ventricular arrhythmias and the prevention of sudden cardiac death.

^a **Afib:** ACC/AHA/ESC 2006 Guidelines for the Management of Patients With Atrial Fibrillation²²; **CABG:** ACC/AHA 2004 Guideline Update for Coronary Artery Bypass Graft Surgery²⁰; **CHF:** ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult²⁶; **Device Therapy:** ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities²¹; **Echo:** ACC/AHA/ASE 2003 Guideline Update for the Clinical Application of Echocardiography¹⁹; **Intracerebral Hemorrhage:** Guidelines for the Management of Spontaneous Intracerebral Hemorrhage in Adults 2007 Update (AHA/ASA)²⁹; **Ischemic Stroke:** Guidelines for the Early Management of Adults With Ischemic Stroke (AHA/ASA)²⁸; **NSTEMI:** ACC/AHA 2007 Guidelines for the Management of Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction¹⁷; **PAD:** ACC/AHA 2005 Guidelines for the Management of Patients With Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic)²⁵; **PCI:** ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention²⁷; **Periop:** ACC/AHA 2007 Guidelines on Perioperative Cardiovascular Evaluation and Care for Noncardiac Surgery²⁴; **Prevention Stroke:** Primary Prevention of Ischemic Stroke (AHA/ASA)³⁰; **Secondary Prevention:** AHA/ACC Guidelines for Secondary Prevention for Patients With Coronary and Other Atherosclerotic Vascular Disease¹⁵; **STEMI:** ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction¹⁸; **Valve Dz:** ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease¹⁶; **Ventric/SCD:** ACC/AHA/ESC 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death²³; **Women:** Evidence-Based Guidelines for Cardiovascular Disease Prevention in Women (AHA).³¹

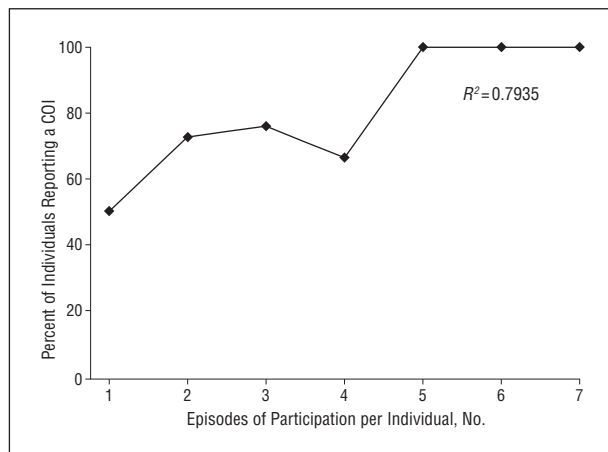


Figure. Episodes of participation per individual and percentage of individuals reporting conflicts of interest (COIs). The data points represent the percentage of individuals reporting a COI in a given cohort of individuals with the same number of episodes of participation.

to fully disclose their financial relationships, and that the guideline was never peer reviewed.

Our finding that most episodes of guideline participation involve COIs, and that most individuals involved in producing guidelines report COIs, is a cause for concern. These findings are a particular cause for con-

cern given the fact that many of the newest ACC/AHA guideline recommendations are based more on expert opinion than on clinical trial data.³⁷ However, our findings of the average number of companies (38) and the range of numbers of companies (2-242) reported per guideline are perhaps less salient than the finding that a few⁴ companies were most reported in multiple different guidelines, and that 1 company was most reported in 7 of 17 guidelines.

It has been asserted that guidelines rarely have an effect on clinical practice⁶; thus, COIs among guideline committee members is of lesser importance. It has, indeed, been documented that CPGs are not immediately implemented as the standard of care for a variety of reasons.³⁸ Concern over authors' bias was a small but nonetheless present factor. Leape et al³⁹ found that evidence behind guideline recommendations plays a factor in adherence to guidelines, whereas credibility of source does not. However, credibility and trust are 2 central issues in clinical medicine, especially in light of data showing that Americans' public confidence in the medical profession has declined.⁴⁰

DISCLOSURES

There is a relatively recent trend toward increased disclosure in guideline production. A study by Papani-

Table 2. Number of Companies Reported in Types of Conflicts of Interest in Each Guideline^a

Guideline	Total Companies, No.	No. (%)			
		Research Grants	Honoraria/Speakers' Bureau	Stock/Other Ownership	Consultant/Advisory Board
Afib	67	32 (48)	16 (24)	4 (6)	43 (64)
CABG	19	15 (79)	7 (37)	2 (11)	7 (37)
CHF	73	47 (64)	26 (36)	7 (10)	47 (64)
Device therapy	57	23 (40)	8 (14)	4 (7)	42 (74)
Echo	2	1 (50)	0	0	1 (50)
Intracerebral hemorrhage	38	5 (13)	8 (21)	1 (3)	31 (82)
Ischemic stroke	40	22 (55)	23 (58)	0	32 (80)
NSTEMI	242	206 (85)	27 (11)	15 (6)	34 (14)
PAD	48	27 (56)	12 (25)	3 (6)	34 (71)
PCI	41	29 (71)	7 (17)	7 (17)	11 (27)
Periop	47	21 (45)	20 (43)	6 (13)	29 (62)
Prevention stroke	39	19 (49)	24 (62)	3 (8)	24 (62)
Secondary prevention	53	30 (57)	23 (43)	3 (6)	40 (75)
STEMI	152	117 (77)	42 (28)	10 (7)	59 (39)
Valve Dz	41	15 (37)	11 (27)	3 (7)	21 (51)
Ventric/SCD	54	12 (22)	9 (17)	4 (7)	51 (94)
Women	42	23 (55)	18 (43)	0	27 (64)

^aSee Table 1, footnote a, for abbreviation expansions and a list of guidelines.

kolaou et al⁴¹ found that only 7 of 191 guidelines published in medical journals from 1979 to 1999 mentioned COIs, and all 7 were published in 1999. Most of the earlier ACC/AHA guidelines (and many current guidelines from other societies) mention that COIs are orally disclosed at guideline committee meetings. This type of disclosure allows other authors and representatives from the society to consider an individual's COIs; however, it does not extend the same opportunity to the guideline readers (the ones implementing the guideline). An international group published criteria for guidelines in the Appraisal of Guidelines for Research and Evaluation (AGREE) in 2003 and included a strong recommendation for disclosure of all relevant COIs.⁴² Another change toward increased disclosure involves filling out directive disclosure questionnaires with specific categories of COIs rather than general, open-ended disclosure statements.^{18,21} It is likely that questionnaires increase disclosure and standardization of definitions.⁴³

While publishing the tables of disclosures theoretically gives the readers and reviewers of the guidelines the same opportunity to evaluate the potential for bias in the overall recommendations, scrutinizing several pages of COIs in small print at the end of the guideline or reading the transcript of discussion about a recommendation may not be a high priority for a busy clinician. Furthermore, transcripts of the meetings are not available, and which participant(s) advocated specific recommendations cannot be discerned.

OTHER STRATEGIES

In addition to disclosure, several strategies have been proposed to deal with COIs.⁴⁴ Agencies that sponsor guidelines could mandate that guideline committee members have no COIs related to the guideline they are creating, as reflected in the newly adopted ACC/AHA regulations, which follow the CMSS code for interactions with

companies.¹¹ Among other regulations, the code prohibits direct company support of CPG development; requires publication of disclosures of all CPG panel members, advisors, and reviewers; requires that a majority of CPG panel members be free of COIs relevant to the CPG subject matter (including the chair); and requires the guideline sponsor to develop procedures for developing strategies that minimize the risk of actual and perceived bias of CPG panel members. The Institute of Medicine report on Conflicts of Interest in Medical Research, Education, and Practice, and the AGREE criteria involve similar recommendations.^{9,10,12,41} Another approach requires members to abstain from voting on issues related to their COIs while participating in the discussion.

It has been argued that excluding or limiting individuals with COIs is unrealistic because there simply are not enough experts without COIs.⁴⁵ In 2002, Choudhry et al⁴⁶ examined the relationship between guideline authors and the pharmaceutical industry by surveying the authors of guidelines for common adult diseases. In the 44 guidelines they analyzed, 100 of the authors replied to their survey (response rate, 52%), and of the authors who responded, 87% reported some type of relationship with the pharmaceutical industry.

Our study, however, found a much lower reported rate of COIs (56%). The discrepancy may relate to the fact that we reviewed more recent and cardiology-specific guidelines, that nonrespondents to the Choudhry et al⁴⁶ survey (63% in the United States and 29% in Canada) included a higher percentage of those without COIs, and/or that a larger number of the guideline participants included in our sample did not report all COIs but just those pertinent to the specific guideline. We also found that serving as an actual guideline committee member was associated with COIs, whereas serving as a reviewer was not. We found the same for chair/co-chair or first author vs other participants. If guideline committee members and committee chairs are potentially more

Table 3. Noncommercial Entities Reported^a

Entity	Guideline(s) (No. of Times Entity Reported)
American College of Cardiology	Device therapy; secondary prevention
Alberta Heritage Fund	Intracerebral hemorrhage
American Association of Neurological Surgeons/Congress of Neurologic surgeons	Intracerebral hemorrhage
American Board of Psychiatry and Neurology	Ischemic stroke
American Heart Association	Device therapy
Boston Medical Center	Device therapy
Center for Disease Control/University of North Carolina, Chapel Hill	Afib; prevention stroke
Center for Medicare and Medicaid Services	CHF
Harvard Healthcare	STEMI
International Atomic Energy Agency	Valve Dz
NCME	Prevention stroke
National Institutes of Health	CABG; CHF; NSTEMI (4); device therapy; secondary prevention (4); prevention stroke; women (2)
National Institute of Neurological Disorders and Stroke	Intracerebral hemorrhage; ischemic stroke
Swedish Heart and Lung Foundation	Afib
Brigham and Women's Hospital	Secondary prevention
University of Texas Health Science Center	Device therapy
Uniformed Services University of Health Sciences	Prevention stroke
Veteran's Administration	STEMI; secondary prevention; Afib; prevention stroke

^aSee Table 1, footnote a, for abbreviation expansions and a list of guidelines.

qualified than reviewers, it may be that the recent, more stringent ACC/AHA participation requirements on COIs will exclude qualified participants (especially the CMSS rule that the chair must be free of COIs). Regardless, our data suggest there is still a large pool of experienced and unconflicted guideline participants.

It has also been argued that relationships with industry may also bring a breadth of perspective and experience, especially if individuals have relationships with multiple different companies. Theoretically, these individuals may be less conflicted than those with fewer industry affiliations, although they may be just as biased toward recommending costly interventions over inexpensive therapies, watchful waiting, or supportive care. We found that individuals with more episodes of participation were more likely to report COIs. However, only a small number of individuals (21%) reported more than 2 episodes, and the average number of episodes per individual was low (1.3).

Most COIs in our study involved consultant/advisory board participation and research grants rather than the (theoretically) more conflicting COIs of stock ownership. A minority of the guidelines required individuals to provide dollar amounts or rate the COI as "modest" or "significant" (most often using the cutoff of

Table 4. Companies Most Reported in Each Guideline^a

Guideline	Company (No. of Times Reported)
Afib	Medtronic (16)
CABG	Medtronic (4), Merck (4)
CHF	Pfizer (18)
Device therapy	Medtronic (21)
Echo	Bristol-Myers Squibb (1), Agilent Technologies (1)
Intracerebral hemorrhage	Novo Nordisk (6)
Ischemic stroke	AstraZeneca (8)
NSTEMI	Sanofi-Aventis (20)
PAD	Bristol-Myers Squibb (5)
PCI	Medtronic (4), Bristol-Myers Squibb (4)
Periop	Medtronic (6)
Prevention stroke	Medtronic (5), Bristol-Myers Squibb (5), Boehringer Ingelheim (5), GlaxoSmithKline (5)
Secondary prevention	Pfizer (13)
STEMI	Pfizer (17), Merck (17)
Valve Dz	Bristol-Myers Squibb (4)
Ventric/SCD	Medtronic (16)
Women	Pfizer (9)

^aSee Table 1, footnote a, for abbreviation expansions and a list of guidelines.

\$10 000). While providing more details about COIs may give a reader a better sense of how conflicted a guideline writer or reviewer may be, the actual degree to which any individual may be influenced by any specific type of COI (or even a specific dollar amount) is impossible to assess. Individuals whose research is funded by a company may be just as interested in the financial success of the company as an individual receiving stock dividends. Nonetheless, there may be a difference between receipt of research funding, which is often administered by a third party (such as a university) and subject to its oversight, and stock ownership or payments for consulting work or participation in a speakers' bureau. Furthermore, \$10 000 of research funding is probably not very "significant" at all.

Finally, it is argued that the presence of COIs is not proof of bias. Individuals with a long history of working on guidelines and with industry may be well equipped to handle COIs and promote the best interests of clinical care over the interests of industry affiliations. It may even be preferable to include individuals who have access to the most up-to-date advancements through industry ties, especially in a rapidly advancing and technology-driven field such as cardiology. Otherwise, guidelines may quickly become out of date. Nonetheless, if guideline-producing agencies wish to avoid COIs among participants in the CPG production process, it may be advantageous to create a structured apprenticeship program in which clinicians and researchers with expertise or promise in certain clinical areas are taught how to produce guidelines and are kept "in the loop" of new developments. A requirement for this apprenticeship program could be avoidance or divestiture of COIs, or at least a training course on how to deal with COIs. Training CPG writers and reviewers may also streamline the CPG process and promote higher quality and more evidence-based recommendations.

STUDY LIMITATIONS

We examined only 1 professional society's guidelines. There are at least 10 other types of agencies that produce guidelines besides professional societies and over 2455 different guidelines on the National Guideline Clearinghouse Web site. We included only recent guidelines that reported COIs. The COI data were all self-reported and were not (to our knowledge) verified. A recent article in this journal has called into question the validity of self-reported disclosures.⁴⁷ It is clear from the COIs reported in our study that different individuals interpreted disclosure requirements differently. Some individuals disclosed relationships with government agencies and charity organizations, whereas 1 author disclosed that he or she "had multiple relationships with commercial entities that arise and are met as needed."^{25(pe616)} Our data on companies are complicated by mergers that took place between the writings of different guidelines. These mergers also complicate the accurate disclosure of COIs. While we attempted to account for these mergers, we relied on the information provided by the guidelines participants, which may not have been up to date. Another limitation of our analysis is the inability to evaluate other types of COIs, such as investigator bias.⁴⁸ For example, a guideline participant who performs research on cardiac magnetic resonance imaging (MRI), but has no financial COIs, may be biased toward recommending the use of cardiac MRI technology vs another imaging modality.

Finally, our study does not address the very important issue of the COIs of the professional societies that produce the guidelines, which often receive large donations from industry and rely on industry sponsorship and participation in scientific sessions.⁴⁹ Future discussions concerning methods to decrease COIs in guideline production should also apply to professional societies. The ACC has recently adopted the 2010 CMSS code, which, among other things, directs societies to avoid company influence in guidelines development processes or the dissemination of guidelines documents and prohibits acceptance of donations from donors who expect to influence society programs or positions.^{11,12} It is unclear, however, whether these measures applied to the guidelines produced prior to adoption of the code.

In conclusion, CPGs play an increasingly influential role in the practice of medicine. COIs are prevalent but vary widely in recent ACC/AHA guidelines. Individuals with greater involvement in CPGs reported more COIs. Although restricting participation may prevent some qualified individuals from serving in the guidelines production process, we found that a large percentage of individuals with guidelines experience reported no disclosures, suggesting there is a substantial pool of potential guideline writers and reviewers without COIs.

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INVITED COMMENTARY

Can We Trust Cardiovascular Practice Guidelines?

Clinical practice guidelines play an enormously important role in society and the practice of medicine. Individual physicians use CPGs to determine which diagnostic tests and therapeutic strategies are most appropriate for their patients. Government and third-party payers use CPGs to determine which procedures and drugs should receive reimbursement. Hospitals and clinics use these CPGs to decide when innovative, but expensive, therapies are sufficiently mature to warrant a major investment. Increasingly, government, the public and the media use CPGs as a benchmark to gauge the quality of medical practice for both hospitals and individual physicians.¹⁻³ Accordingly, protecting the integrity and reliability of CPGs is essential to society and fundamental to the practice of evidence-based medicine.⁴

INDEPENDENCE AND RELIABILITY OF CPGs IN CARDIOVASCULAR MEDICINE

In this issue of the *Archives*, Mendelson et al raise disturbing questions about the independence and reliability of CPGs in cardiovascular medicine. They report the presence of financial relationships with commercial entities for more than half of 498 authors of 17 major car-

diovascular CPGs published from 2004 through 2008. In defending such relationships, professional societies have frequently suggested that it is necessary to include individuals who have sufficient scientific expertise to properly weigh the evidence for and against alternative therapies. It is argued that nonparticipants in industry-sponsored research lack the skills necessary to interpret the complex scientific data that must be reviewed when writing a CPG. Such pronouncements are self-serving and not credible. As noted by Mendelson et al, if 44% of CPG writers were free of financial relationships with industry, surely there must be other independent experts.

The depth and breath of industry relationships reported in this article are extraordinary. Unexpectedly, financial ties between companies and CPG authors include relationships extending far beyond scientific collaboration. More than half of CPG writers served as promotional speakers on behalf of industry, and a substantial number actually held stock in companies affected by the CPG. For example, one-third of the writers of the percutaneous intervention CPG actually owned stock in companies affected by the CPG. Even if we were to accept the premise that scientific involvement by authors is reasonable, no conceivable logic can defend the practice of including promotional speakers and stockholders on CPG writing committees. Participants in speaker's bureaus es-