

Evaluating Conflicts of Interest in Research Presented in CME Venues

NANCY L. DAVIS, PHD; JAMES M. GALLIHER, PHD; MINDY S. SPANO; DEBORAH S. MAIN, PHD;
MICHAEL BRANNIGAN, MA, PHD; WILSON D. PACE, MD

Introduction: There is much in the literature regarding the potential for commercial bias in clinical research and in continuing medical education (CME), but no studies were found regarding the potential for bias in reporting original research in CME venues. This pilot study investigated the presence of perceived bias in oral and print content of research findings presented in certified CME activities.

Methods: Research presentations at two national primary care CME activities, where authors had self-reported potential conflicts of interest, were peer reviewed and monitored for perceived commercial bias. Blinded and unblinded peer reviewers' and monitors' analyses of bias were compared to assess whether knowledge of potential conflicts of interest affected perceptions of bias.

Results: Knowledge of potential conflicts of interest appeared to increase awareness of potential commercial bias with regard to use of a single product in care and assurance that there was reasonable evidence to support the practice recommendation. A perception of the presenter's strong opinion regarding care did not appear to be influenced by knowledge of a potential conflict of interest.

Discussion: While limited, by study design, this research detected subjectivity and variability in perceiving commercial bias within research findings presented in CME venues. Further study of these questions is required to guide the resolution of conflicts of interest in research and CME.

Key Words: conflicts of interest, ethics, disclosure, education, medical, continuing

Introduction

A 2007 research report indicated that 67% of medical school and teaching hospital departments and 60% of de-

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Dr. Davis: Executive Director, National Institute for Quality Improvement and Education, Homestead, PA; *Dr. Galliher:* Research Director, American Academy of Family Physicians (AAFP) National Research Network, Leawood, KS; Department of Sociology, University of Missouri, Kansas City, MO; Department of Family Medicine, University of Colorado at Denver Health Sciences Center, Denver, CO; *Ms. Spano:* Senior Program Coordinator, AAFP National Research Network, Leawood, KS; *Dr. Main:* Professor of Family Medicine, Department of Family Medicine, University of Colorado at Denver Health Sciences Center, Denver, CO; *Dr. Brannigan:* Pfaff Endowed Chair in Ethics and Moral Values, Department of Philosophy and Religious Studies, The College of Saint Rose, Albany, NY; *Dr. Pace:* Director & Professor, AAFP National Research Network, Leawood, KS; Department of Family Medicine, University of Colorado at Denver Health Sciences Center, Denver, CO.

Correspondence: Nancy L. Davis, PhD, National Institute for Quality Improvement and Education, 285 Waterfront Drive E, Suite 100, Homestead, PA 15120; e-mail: ndavis@niqie.org.

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partment heads personally received funds or engaged in some other kind of financial relationship with industry.¹ These institutions and faculty conduct much of the clinical research and develop much of the continuing medical education in the United States. There is an ongoing concern that these academic-industry relationships inappropriately influence scholarly activity.

Highly visible findings, such as the increased risk of myocardial infarction from the use of Cox 2 inhibitors,²⁻⁵ highlighted concerns over the ethical conduct of research nationwide. The Cox 2 inhibitor episode has become defined by less than truthful disclosure of medical research.⁵ Unfortunately, it is but one of a series of high profile events over the past decade.⁶⁻⁹ This incident highlights that the ethical conduct of research is not only about the recruitment and treatment of research subjects or the interpretation of data but also includes the dissemination process.¹⁰⁻¹² In fact, the dissemination phase of the research process may be most susceptible to influence by the researchers' prior beliefs, funding sources, and the potential for media exposure.

Several forces, in cooperation, have interacted to increase "for-profit" industry funding of academic research significantly. Some of the influences that promoted collaboration between universities and specialty societies were (1) changes in federal law that allowed universities or other

entities to patent discoveries from federal research, (2) increasingly competitive federal dollars coupled with shrinking state and foundation support, and (3) the potential for breakthrough discoveries from advanced molecular and genetic techniques.^{12,13} Furthermore, the interplay between academic researchers and industry has become more complex with research, shareholder, royalty, endowment, consulting, and speaking arrangements resulting in relationships that may generate conflicts of interest.¹⁴ Many academic leaders believe that the extent and complexity of research conflicts of interest are rapidly increasing.¹⁵

In response to this growing relationship among academia, professional societies, and industry, some organizations have revised their guidelines for the ethical conduct of research at both the individual researcher and institutional levels.^{13,16–18} Numerous conferences and articles have explored the issues surrounding research conflicts and concerns that perception is reality with regard to bias.¹⁹ But studies to measure continuing medical education (CME) participants' perceptions of bias have shown them to be variable and therefore difficult to manage.^{20,21} Individual and institutional recognition of and response to potential conflicts vary widely, from complete prohibition of any apparent conflict, to a case-by-case negotiated resolution.²² The National Institutes of Health have recently increased their vigilance and now require all employees and their immediate family members to divest themselves of any apparent conflicts including affiliation with pharmaceutical or medical device companies. This approach has been advocated by others, but many institutions still allow individualized approaches to conflict of interest (CoI) resolution. Institutional review boards (IRBs) are now required to inquire regarding CoI, but not all IRBs consider it their role to resolve potential CoIs.

Recognizing that CME activities represent a forum where research results are disseminated to users, the Accreditation Council for Continuing Medical Education (ACCME) issued new Standards for Commercial Support in 2004 concerning independence of CME content and requiring resolution of any potential conflicts of interest. In addition, many peer-reviewed medical journals have recently moved from disclosure of CoI to resolution of CoI prior to accepting a manuscript for publication.^{23,24} Thus, relevant guidelines exist that call for the resolution of a CoI, rather than disclosure alone, from the research approval process through sanctioned dissemination. While the availability of guidelines is a step forward, they provide only a basic roadmap for individuals conducting research and developing CME. Guidelines that do not completely prohibit industry sponsorship leave considerable decision making about what is appropriate to the individual and the institution.

This pilot research investigated the oral and printed content of research presentations made at two national primary-care research forums whose lead presenters declared a "potential conflict of interest" related to the research on which they were reporting. We asked whether monitors

and peer reviewers detected any reference to commercial products limited to a single vendor, and whether the evaluators' knowledge of the potential conflict of interest had an effect on their reviews of these presentations. The study was limited to the perceptions of qualified, trained reviewers and monitors and did not include feedback from CME participants.

Methods

The study team reviewed all research abstracts accepted for either the American Academy of Family Physicians (AAFP) 2005 Scientific Assembly (SA) or the North American Primary Care Research Group (NAPCRG) 2005 annual meeting. These two venues account for a sizable number of CME research presentations annually—with each meeting having more than 500 CME presentations. In past years, slightly over 10% of CME presenters at the AAFP annual SA self-reported a potential CoI.

These abstracts and associated disclosures were reviewed by the study team for those that appeared to be evidence-based and disclosed a potential CoI or indicated commercial support for their research. The disclosures identified three types of potential conflicts as defined by AAFP's conflict of interest policy:

1. A significant financial interest in any commercial supporter of or providers of any commercial services discussed in this educational activity;
2. Material(s) will include discussion of unapproved or investigational uses of products or devices;
3. A full-time employee of the commercial enterprise.

The team reviewed 236 abstracts presented on evidenced-based research—24 at the AAFP SA and 212 at NAPCRG (see FIGURE 1). Eighteen abstracts met the criteria on the basis of their reported CoI and all were selected for the study. Once these abstracts were identified, we conducted a three-component investigation: (1) monitoring of all CME presentations during the public event by blinded and unblinded monitors, (2) blinded and unblinded peer review of the CME presentation slides (paper copy), and (3) in-depth telephone interviews with the presenters identified as having a CoI.

Peer reviewers were solicited from the pool of MD and PhD family medicine educators who served as reviewers for the conference's CME selection process and were paid a small stipend to perform these additional reviews. Reviewers were *initially* blinded to the type and specific potential conflict of interest reported by the presenter. Each reviewer was asked to evaluate the presentation (PowerPoint™) for apparent CoI, either in the presentation or in the research itself. After the initial review, each reviewer was informed as to the specifics of the potential conflict and asked to review the same presentation again.

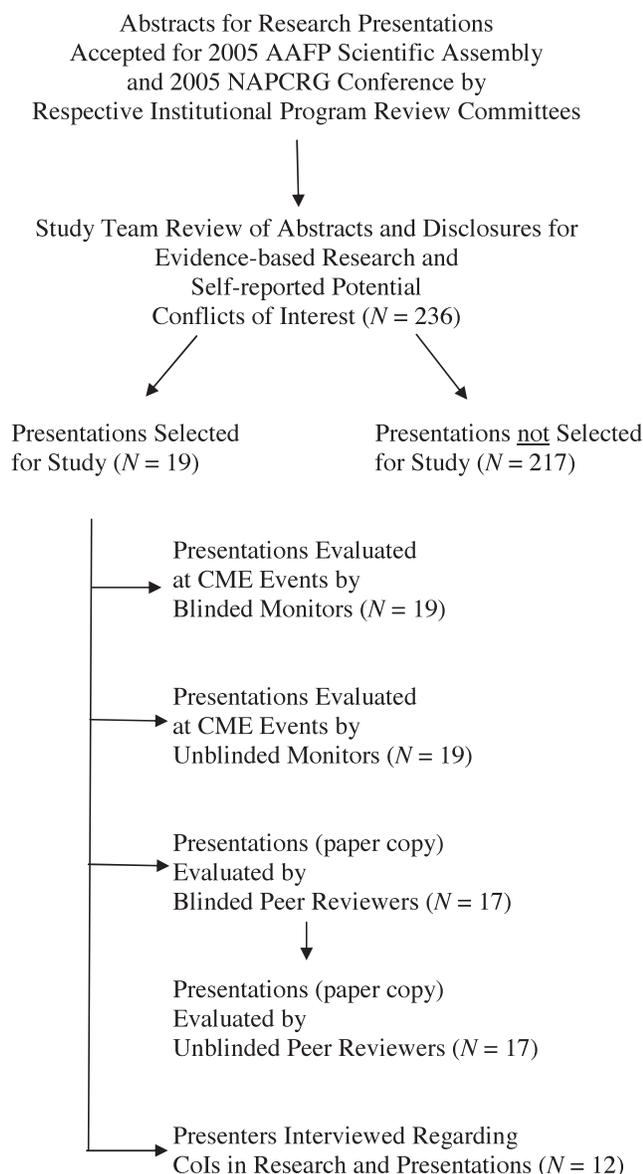


FIGURE 1. Research process associated with AAFP NRN and AAFP CME project on potential conflicts of interest in CME presentations of research results.

The presentations were monitored on-site at the CME event by two monitors trained to use the study evaluation form. Monitors were selected from members of the AAFP National Research Network, members of the AAFP Commission on Continuing Professional Development, and this project's study staff (for unblinded reviews only). One monitor was blinded to the specific conflict of interest while the second monitor was aware of the specifics of the disclosed conflict. Each monitor completed an evaluation form (available upon request) after each presentation. Each set of paired evaluations, from the presentation slides (PowerPoint™) and from the presentation itself, were compared to assess whether the presentations were perceived differently on the basis of prior knowledge of a potential CoI.

Finally, open-ended interviews were conducted with lead presenters who agreed to participate in this component of the study. The project interviewers explored with the presenters their awareness of their potential CoI, how they personally or institutionally dealt with the conflict, how they dealt with the conflict during presentations, and their own impressions of their successes or failures in handling potential conflicts.

The data obtained from both peer reviewers' and monitors' evaluations were analyzed using SPSS (version 14.0). After data entry, each electronic record was verified against the original evaluation form for completeness and accuracy. These quantitative data were analyzed using univariate descriptive statistics and described by percentages both within and across the two sets of evaluators (blinded vs unblinded monitors and peer reviewers). The analyses reported here were restricted to the evaluations performed by the monitors and peer reviewers. The study was approved by the Social Science Institutional Review Board at the University of Missouri, Kansas City, MO.

Results

The study team identified 18 (7.6%) of 236 abstracts pertaining to evidence-based research with disclosures indicating a potential CoI. One additional presentation was identified by the project team during its public delivery as clearly manifesting a CoI, even though the presenter had not disclosed it. Seven were given at the AAFP SA, representing 29.2% of all reviewed presentations, and 12 were delivered at NAPCRG, representing 5.5% of all reviewed presentations.

The nature of these self-reported conflicts is reported in TABLE 1. That table shows that the majority of presenters ($N = 13$) listed the CoI as "having a financial interest in or affiliation with a commercial entity." The least frequently reported CoI was "Content of material(s)/presentation(s) will include discussion of unapproved or investigational use of products or devices." Although it is encouraged that disclosure occur when off-label uses of products are presented, such discussions are acceptable in certified CME activities while not allowed in promotional presentations.

As planned, all 19 presentations were monitored by one blinded and one unblinded monitor. Seventeen (89%) were reviewed by a peer reviewer; for the other two, the lead presenter did not provide a paper or electronic copy of the PowerPoint™ presentation despite several requests.

The most important question asked of evaluators was, *Were commercial products including medications, devices, or specific tests limited to a single vendor mentioned or described during the presentation?* Blinded and unblinded monitors (BMs and UBMs) combined and blinded and unblinded peer reviewers (BPRs and UBPRs) had quite similar answers to this question across all presentations evaluated. Monitors and peer reviewers responded *yes* (53% vs 50%), *no* (42% vs 44%), and *unsure* (5% vs 6%) ($\chi^2 = 0.05$,

TABLE 1. Conflict of Interest Project: Specific Potential Conflicts of Interest Given by Presenters at Two National Research Venues in 2005

Presentation ID	CME Forum	Self-Reported Potential Conflict of Interest*
1 N1	AAFP SA	C Employee of CE**
2 N2	AAFP SA	C Employee of CE
3 N3	AAFP SA	A Presenter for CE
4 N4	AAFP SA	A Consultant for CE
5 N5	AAFP SA	A Presenter for CE
6 N6	AAFP SA	B Investigational use of med
7 N7	AAFP SA	A Financial support from CE
8 N8	AAFP SA	A Consultant for CE
9 N9	AAFP SA	A Consultant for CE
10 N10	AAFP SA	C Employee of CE
11 N11	AAFP SA	A Grant support from CE
12 N12	AAFP SA	A Consultant for CE
13 S13	NAPCRG	A Financial support from CE
14 S14	NAPCRG	C CEO of CE
15 S15	NAPCRG	A Financial support from CE
16 S16	NAPCRG	C Employee of CE
17 S17	NAPCRG	A Financial support from CE
18 S18	NAPCRG	A Financial support from CE
19 S19	NAPCRG	A Financial support from CE

*A. "I, or an immediate family member, have a significant financial interest in or affiliation with a commercial supporter of this educational activity and/or with the manufacturer(s) of commercial products and/or providers of any commercial services discussed in this educational activity."

*B. "Content of my material(s)/presentation(s) in this CME activity will include discussion of unapproved or investigational use of products or devices indicated below."

*C. "I am a full-time employee of the commercial enterprise listed below."

**CE = commercial entity.

$df = 2, p = .974$). However, when comparing blinded and unblinded evaluators, blinded evaluators' (monitors and peer reviewers combined) and unblinded evaluators' responses were *yes* (41% vs 61%), *no* (53% vs 33%), and *unsure* (6% vs 6%) ($\chi^2 = 2.91, df = 2, p = .234$).

BMs versus UBMs disagreed in their responses on nine presentations (47%) (TABLE 2), with the former more likely to answer *no* and their unblinded counterparts more likely to answer *yes/unsure* for six of these. Among reviewers, there was more agreement in their evaluations of presentations (82%). Nonetheless, for the three presentations in which the BPRs and UBPRs disagreed, the only response pattern was a failure of the latter to recognize the named commercial entity or services (*no* and *yes*).

For the question, *Did the presentation present a strong opinion about some aspect of clinical care?* (TABLE 3), BMs and UBMs disagreed on 7 of 19 (36%) presentations

while BPRs and UBPRs disagreed on only 2 of 17 (12%) presentations. In 3 of 7 instances when BMs and UBMs disagreed, the responses were *yes* for BM and *unsure* for UBM.

In responding to the question, *Were you convinced that the speaker presented reasonable evidence to support all the positions discussed?* (TABLE 4), monitors disagreed on 9 of the 19 (47%) presentations while reviewers disagreed on 6 of 17 (36%). For the 9 presentations in which monitors disagreed in their responses, BMs answered *yes* while UBMs answered *no/unsure* for 7 of these. And, for the 6 presentations in which reviewers disagreed, BPRs responded *yes* while UBPRs answered *no/unsure* for 3.

Discussion and Conclusions

The perception held by many scientists and nonscientists alike is that research funded by commercial sources is more likely to display bias than research funded by foundations or government agencies. There are concerns that the results and/or interpretations of results may be skewed as a result of the desire to find a particular result. Put otherwise, many people ostensibly believe that the conduct of research and reporting of results vary with the source of funding, and research either involving commercial products or funded by commercial entities smacks of bias and/or lacks scientific rigor. The results from this pilot study suggest some support for this view based on monitors' and/or reviewers' evaluations of the research presentations selected for study.

First, almost half (9 of 19) of the presentations reviewed by BMs and UBMs resulted in disagreement in their answers to the question, *Were commercial products . . . limited to a single vendor mentioned or described during the presentation?* Disagreement was considerably less for peer reviewers (18%). For both sets of evaluators, however, the primary pattern of disagreement showed the blinded responded *no* while the unblinded responded *yes/unsure*. This pattern was observed for 6 of 9 presentations for monitors and 3 of 3 presentations for reviewers. This suggests that knowledge of the presenter's CoI increases awareness of a single product in the presentation.

Second, the majority of blinded and unblinded evaluators of the research presentations articulated a *strong opinion about some aspect of clinical care*. For peer reviewers, knowledge of the nature of the CoI did *not* affect their responses to the question relative to their responses when blinded—they agreed in their responses for 88% (15 of 17) of the presentations. For BMs versus UBMs, however, there was more observed discrepancy. They disagreed in their responses to 7 (37%) presentations. The dominant pattern of disagreement was *yes* (BM) and *unsure* (UBM) for 3 presentations. For this question, there was the least amount of disagreement between blinded and unblinded evaluators in their responses. This suggests that knowledge of the CoI had very little effect on evaluators' assessment of the presenters' strong opinion regarding the nature of care.

TABLE 2. Conflict of Interest Project: Summary Results From Evaluations of Presentations by Blinded and Unblinded Monitors and Reviewers

Question: "Were any commercial products including medications, devices, or specific tests limited to a single vendor mentioned or described during the presentation?"

Blinded vs. Unblinded Responses	Blinded vs. Unblinded Monitors		Blinded vs. Unblinded Peer Reviewers		Combined Blinded vs. Unblinded Evaluators	
	Number	Percentage	Number	Percentage	Number	Percentage
Evaluators Agree						
Yes-Yes	6	32	7	41	13	36
No-No	4	21	6	35	10	28
Unsure-Unsure	0	0	1	6	1	3
Total	10	53	14	82	24	67
Evaluators Disagree						
Yes-No	2	11	0	0	2	6
Yes-Unsure	0	0	0	0	0	0
No-Yes	5	26	3	18	8	22
No-Unsure	1	5	0	0	1	3
Unsure-Yes	1	5	0	0	1	3
Unsure-No	0	0	0	0	0	0
Total	9	47	3	18	12	33
Total	19	100	17	100	36	100

Third, blinded versus unblinded evaluators displayed considerable discrepancy in their responses to the question, *Were you convinced that the speaker presented reasonable evidence to support all the positions discussed?* Monitors disagreed in their responses to 47% of the presentations. For seven of these latter nine presentations, the dominant disagreement patterns were *yes* and *no/unsure*. These latter patterns again suggest that knowledge of the presenter's CoI

negatively affected the UBM responses to this question regarding the scientific strength of the research presentation. Alternatively, the BPRs versus UPRs did not display as much discrepancy in their responses: they disagreed on six (35%) presentations. For three of these presentations, the pattern of disagreement was *yes* and *no/unsure*.

On the basis of comparisons of blinded versus unblinded evaluators' responses to these three questions, the results

TABLE 3. Conflict of Interest Project: Summary Results From Evaluations of Presentations by Blinded and Unblinded Monitors and Reviewer

Question: "Did the presentation present a strong opinion about some aspect of clinical care?"

Blinded vs. Unblinded Responses	Blinded vs. Unblinded Monitors		Blinded vs. Unblinded Peer Reviewers		Combined Blinded vs. Unblinded Evaluators	
	Number	Percentage	Number	Percentage	Number	Percentage
Evaluators Agree						
Yes-Yes	11	58	13	76	24	67
No-No	1	5	2	12	3	8
Unsure-Unsure	0	0	0	0	0	0
Total	12	63	15	88	27	75
Evaluators Disagree						
Yes-No	0	0	0	0	0	0
Yes-Unsure	3	16	0	0	3	8
No-Yes	1	5	1	6	2	6
No-Unsure	1	5	0	0	1	3
Unsure-Yes	1	5	1	6	2	6
Unsure-No	1	5	0	0	1	3
Total	7	36	2	12	9	26
Total	19	100	17	100	36	100

TABLE 4. Conflict of Interest Project: Summary Results From Evaluations of Presentations by Blinded and Unblinded Monitors and Reviewers

Question: “Were you convinced that the speaker presented reasonable research evidence to support all the positions discussed?”

Blinded vs. Unblinded Responses	Blinded vs. Unblinded Monitors		Blinded vs. Unblinded Peer Reviewers		Combined Blinded vs. Unblinded Evaluators	
	Number	Percentage	Number	Percentage	Number	Percentage
Evaluators Agree						
Yes-Yes	8	42	6	35	14	39
No-No	2	11	2	12	4	11
Unsure-Unsure	0	0	3	18	3	8
Total	10	53	11	65	21	58
Evaluators Disagree						
Yes-No	5	26	1	6	6	17
Yes-Unsure	2	11	2	12	3	8
No-Yes	0	0	1	6	1	3
No-Unsure	1	5	1	6	2	6
Unsure-Yes	1	5	0	0	1	3
Unsure-No	0	0	1	6	2	6
Total	9	47	6	36	15	43
Total	19	100	17	100	36	100

show that (1) the monitors were more likely to disagree in their responses compared to peer reviewers; (2) the first and third questions resulted in the most disagreement compared to the second question; and (3) disagreement also appears patterned for the first and third questions. One possible reason why disagreement was more pronounced for monitors is that BMs and UBM were different persons—their answers were independent of each other. Alternatively, the peer reviewer for a given presentation was the same person—that person’s second review of the presentation was given with knowledge of both the CoI and her/his first evaluation. It may have been more difficult for the reviewer to answer the evaluation questions differently the second time given knowledge of the first answer.

Knowledge of presenters’ reported CoI appears to have affected both UBMs’ and UBPRs’ responses to questions 1 and 3. There was more disagreement for these two questions compared to the second question related to “the presenter’s opinion on some aspect of clinical care.” Indeed, it is difficult to theorize how responses to this question might differ on the basis of evaluators’ knowledge of a presenter’s CoI.

For the other two questions, however, observed disagreement was not only more pronounced, but also patterned to some extent. If we interpret a response of *no* to question 1, *Were commercial products . . . limited to a single vendor mentioned or described during the presentation?*, as *favorable* and a response of *yes/unsure* as *unfavorable*, the primary pattern of disagreement between blinded versus unblinded evaluators was favorable versus unfavorable. Alternatively, if we interpret a response of *yes* to question 3, *Were you convinced that the speaker presented reasonable evidence to support all the positions discussed?*, as *favorable* and a response of *no/unsure* as *unfavorable*, the primary pattern of

disagreement between blinded versus unblinded evaluators was favorable versus unfavorable.

The results suggest that at least some evaluators or “recipients of research results” may perceive that commercial CoIs do indeed adversely affect the research process, including the interpretation and reporting of study results. Addressing this question more fully would require a much different study from the one reported here.

There are limitations to this study. First, we identified only 19 evidence-based research presentations that were subsequently observed and evaluated by monitors at two national research forums. These 19 presentations were delivered by 17 presenters (two presenters each delivered two). For 18 of these, the presenter stipulated a potential CoI falling into one of three categories described. Only 17 of 19 PowerPoint™ presentations delivered by 15 individuals were made available and evaluated by the project’s peer reviewers. Given these relatively small numbers, the results must be interpreted cautiously. Second, the study design would have been stronger had the project employed multiple monitors and reviewers (blinded and unblinded) for the same presentation. We simply do not know how the results might have differed given more evaluators; they might have agreed more (or less) for a given presentation or agreed more (or less) across all presentations. Because this was a pilot study, resources did not allow for multiple sets of evaluators. Third, the design also would have been stronger if we had employed *independent* blinded and unblinded peer reviewers as we did with presentation monitors. The responses to each of the three questions showed that disagreement between the blinded and unblinded evaluators was greater for the monitors than for the peer reviewers. Monitors and reviewers may have interpreted the degrees of their perceptions

differently on the basis of wording of questions in the evaluation instruments.

While it is common in CME venues to survey physician learners as to their perception of commercial bias, that was intentionally not a part of this study. Previous results of AAFP CME participants' evaluations have shown wide variation and often have not correlated with monitors' evaluations specifically looking for bias. For that reason, this study focused on trained peer reviewers and monitors.

The focus of this pilot was to compare peer reviewers' and monitors' perceptions of commercial bias when blinded to the potential risk of bias and when knowing of the potential risk. Reviewers and monitors were not necessarily content experts and able to discern whether research data had been suppressed or embellished as a result of the researchers' bias.

This study found subjectivity and variability in perceiving commercial bias in research and CME. It seems to validate the importance of disclosure of conflicts of interest to consumers of research findings so as to increase their awareness of potential bias. Further, knowledge of the presenter's conflict of interest seems to cause the consumer to question the strength of scientific evidence being presented. Clearly there must be more study of these questions to guide the resolution of conflicts of interest in research and CME.

The results of this pilot indicate that future research with a larger sample should include comparisons of trained reviewers and monitors with general CME participants. Use of content experts can validate whether research data are presented or suppressed as a result of bias toward a particular commercial product. A larger body of literature is now available to support the impact of commercial bias on learners.

Subsequent to this study, much has been added to the literature regarding management of commercial bias in clinical research and CME. Proceedings of the 2007 AAMC-hosted Symposium on the Scientific Basis of Influence and Reciprocity posit that disclosure, the most common response to conflicts of interest, may give physicians a feeling of "moral license" to exaggerate in their own best interest and that current mechanisms for addressing conflicts may not adequately take into account the biological and psychological process that can influence judgment and decision making.²⁵ The AAMC, in 2008, released policy statements recommending the acceleration of implementation of CoI policies in human subject research and strict limits of industry support of medical education.^{26,27}

In addition to new policy, instruments have been developed to assist CME providers in their endeavors to ensure commercial-bias-free CME content. Barnes et al. developed and tested a risk stratification tool to assess influence in CME content. Their 2007 published report concluded that such a tool can help CME providers identify activities that should be closely monitored for noncompliance with the ACCME Standards for Commercial Support.²⁸ Takhar et al. developed an instrument to measure bias in CME.²⁹ Both of these papers and the work of Cain

Lessons for Practice

- Knowledge of the presenter's CoI may increase learners' awareness of a single product in the presentation.
- Knowledge of the CoI appeared to have little effect on evaluators' assessment of the presenters' strong opinion regarding the nature of care.
- There was no consensus from evaluators whether knowledge of CoI affected perception of strength of evidence in presentations.
- CME providers must be diligent about investigating potential conflicts of interest in the reporting of original research. Researchers are often not aware of the need to disclose conflicts of interest during presentation of findings.
- More study is required to guide resolution of conflicts of interest in research and CME.

and Detsky³⁰ emphasize the subjectivity of bias and thus the difficulty in measuring it.

The current climate of controversy over commercial support of clinical research and continuing medical education speaks to the need for continued study of the influence of such support and the ongoing efforts to control bias to ensure high quality, evidence-based patient care.

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