Relationships Between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry

Original Contribution

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FROM ABSTRACT

Context
Increasing contact has been reported between physicians and the pharmaceutical industry, although no data exist in the literature regarding potential financial conflicts of interest for authors of clinical practice guidelines (CPGs).

These interactions may be particularly relevant since CPGs are designed to influence the practice of a large number of physicians.

Objective
To quantify the extent and nature of interactions between authors of CPGs and the pharmaceutical industry.

Design, Setting, and Participants
Cross-sectional survey of 192 authors of 44 CPGs endorsed by North American and European societies on common adult diseases published between 1991 and July 1999.

One hundred authors (52%) provided usable responses representing 37 of 44 different CPGs that we identified.

Main Outcome Measures
Nature and extent of interactions of authors with drug manufacturers; disclosure of relationships in published guidelines; prior discussion among authors regarding relationships; beliefs regarding whether authors' own relationships or those of their colleagues influenced treatment recommendations in guidelines.

Results
Eighty-seven percent of authors had some form of interaction with the pharmaceutical industry.

Fifty-eight percent had received financial support to perform research and 38% had served as employees or consultants for a pharmaceutical company.

On average, CPG authors interacted with 10.5 different companies.

Overall, an average of 81% (70%-92%) of authors per CPG had interactions.

Similarly, all of the CPGs for 7 of the 10 diseases included in our study had at least 1 author who had some interaction.

Fifty-nine percent had relationships with companies whose drugs were considered in the guideline they authored, and of these authors, 96% had relationships that predated the guideline creation process.

Fifty-five percent of respondents indicated that the guideline process with which they were involved had no formal process for declaring these relationships.

In published versions of the CPGs, specific declarations regarding the personal financial interactions of individual authors with the pharmaceutical industry were made in only 2 cases.

Seven percent thought that their own relationships with the pharmaceutical industry influenced the recommendations and 19% thought that their coauthors' recommendations were influenced by their relationships.

Conclusions
Although the response rate for this survey was low, there appears to be considerable interaction between CPG authors and the pharmaceutical industry.

Our study highlights the need for appropriate disclosure of financial conflicts of interest for authors of CPGs and a formal process for discussing these conflicts prior to CPG development.

THESE AUTHORS ALSO NOTE:

Interactions between physicians and the pharmaceutical industry are significant.

There is “significant contact between the pharmaceutical industry and academic researchers, faculty physicians, community physicians, residents, and medical students.”

“These types of interactions have been shown to influence prescribing patterns, stimulate requests for addition of drugs to hospital formularies, result in favorable publications and research articles, and be related to the lack of publication of unfavorable articles.”

"Clinical practice guidelines (CPGs) are intended to present a synthesis of current evidence and recommendations preformed by expert clinicians and may affect the practice of large numbers of physicians."

"As a result, any influence that the authors of CPGs experience from their interactions with pharmaceutical companies may be transmitted many times over to the readers of CPGs."

"Consequently, if individual authors have relationships that pose a potential conflict of interest, readers of these CPGs may wish to know about them to evaluate the merit of those guidelines."

METHODS

The authors asked 4 specific questions:
(1) How much interaction do authors of clinical practice guidelines have with drug manufacturers and what is the nature of this interaction?
(2) What physician-pharmaceutical interactions are disclosed in the published guidelines?
(3) Prior to beginning the guideline creation process, was there any discussion among the guideline authors regarding relationships with the pharmaceutical industry?
(4) Do guideline authors believe that their relationships or those of their colleagues influence the treatment recommendations that were put forth in the guidelines?

The list of medical conditions studied was the 20 most commonly prescribed drugs that are paid for by the Ontario Drug Benefit Program, and the 5 most common admission diagnoses to the internal medicine services at Ontario hospitals (ie, pneumonia, congestive heart failure, coronary artery disease, chronic obstructive pulmonary disease/asthma, and gastrointestinal bleeding).

Authors were asked whether they had any of 6 types of financial interactions with drug companies, including:

(1) Support for attendance at a symposium (eg, funds for travel expenses)
(2) Honorarium for speaking at a symposium
(3) Support for organization of an educational program
(4) Support for research
(5) Employment by or consultancy for the company
(6) Equity in the company

Also, authors were asked:

(1) Whether their relationships specifically involved companies whose drugs were considered or included in the guideline they authored

(2) Whether these relationships predated or postdated the guideline process
(3) Whether they believed their own relationships or those of their coparticipants influenced the recommendations that were put forward
(4) Whether there was discussion among the participants prior to beginning the guideline process regarding any relationships
(5) Whether this process was formalized, and how potential conflicts of interest were managed

RESULTS

The response rate was 52% of all authors initially included in the sample.

63% of authors currently residing in the United States did not respond and 29% of authors living in Canada did not respond. **[WOW!]**

"Twenty-eight (26%) of 107 authors responded with a letter attached to their survey. These letters could be interpreted as being supportive (21%), neutral (57%), or critical (21%) of our study." **[INTERESTING]**

87% percent of the responding authors had some form of interaction with the pharmaceutical industry.

58% had received financial support to perform research.

38% had served as employees or consultants for a pharmaceutical company.

On average, CPG authors interacted with 10.5 different pharmaceutical companies.

Authors who received support for research received this funding from a mean of 6.7 pharmaceutical companies,

Authors who served as employees or consultants for pharmaceutical companies did so for a mean of 5.7 companies.

"Overall, an average of 81% (70%-92%) of authors per guideline had interactions with the pharmaceutical industry."

59% of authors had relationships with companies whose products were specifically considered or included in the guideline they authored. Of these, 96% had relationships that predated the guideline process and 53% had relationships that postdated the guideline process.

"In the published versions of the 44 CPGs included in the study, authors declared that they had personal financial interactions with the pharmaceutical industry in only 1 guideline."

“In the majority of cases (42 of 44 guidelines), no declarations were made with respect to the authors' potential conflicts of interest.”

COMMENT

“Our results appear to indicate that most CPG authors have interactions with pharmaceutical companies and that a significant proportion work as employees/consultants for drug manufacturers.”

“Moreover, a majority of our respondents indicated that they had relationships with companies whose products were considered in the guideline that they authored, and of these, almost all had relationships that predated the guideline creation process.”

There is a large body of literature that indicates that these types of relationships are significant.

About 20% of the respondents believed that their colleagues' relationships influenced the recommendations that they put forward.

The authors question if:
“academicians and physicians underestimate the impact of relationships on their actions,” noting that bias may occur both consciously and subconsciously, and therefore, its influence may go unrecognized.

“Unlike relationships that individual authors or physicians have with the pharmaceutical industry, financial conflicts of interest for authors of CPGs are of particular importance since they may not only influence the specific practice of these authors but also those of the physicians following the recommendations contained within the guidelines.”

The authors suspect that low physician response rates in this study is because physicians may be “reluctant to disclose their relationships with the pharmaceutical industry” and because the cover letter that was sent to participants made no promise of anonymity.

Therefore, “it is possible that nonrespondents actually had a higher degree of interaction with the pharmaceutical industry than respondents.”

“Consequently, our low response rate may have actually biased our results by underestimating the already high degree of interaction that we observed.” [WOW!]

The authors note that the “experts who write guidelines are the same individuals who are most likely to receive financial support to conduct research.”

It is also "suggested that relationships with pharmaceutical industries are not the only type of potential conflicts of interest that exist. Concerns regarding obtaining continued funding from governmental agencies (eg, by ensuring that one's government-funded research is included in the studies cited by a CPG) or of individual academic promotion (eg, by ensuring that one's own research is included in the studies cited by a CPG) may also influence the guideline process and may serve as forms of 'dual commitment'." **[WOW!]**

RECOMMENDATIONS

"Authors must disclose relationships with the pharmaceutical industry before guideline meetings are held," disclosing:
(1) Relationships that predate the guideline process
(2) Relationships that involve large sums of money
(3) Relationships that involve equity positions in companies

"Authors with significant conflicts of interest should likely be excluded" from participating in the guideline creation process.

"We do think that authors who hold equity in a company whose products are being considered in the guideline process should be disqualified."

"There must be complete disclosure to the readers of CPGs of individual authors' financial relationships with the pharmaceutical industry."

CONCLUSIONS

"In conclusion, there appears to be a high degree of interaction between authors of clinical practice guidelines and the pharmaceutical industry."

"These specific interactions may influence the practice of a very large number of physicians."

Author/Article Information

"Disclaimer: This study received no financial support from the pharmaceutical industry."

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SUMMARY TABLE:

RELATIONSHIP	% OF AUTHORS		NO. OF COMPANIES	
Any Relationship	87	(80-94)	10.5	(1-37)
Travel Funding/Honorarium	53	(43-63)	5.4	(1-16)
Speaker Honorarium	64	(54-74)	7.3	(1-20)
Educational Program Support	51	(41-61)	4.7	(1-36)
Research Support	58	(48-68)	6.7	(1-26)
Employee/Consultant	38	(28-48)	5.7	(1-21)
Equity In Company	6	(1-11)	1.8	(1-4)

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KEY POINTS FROM DAN MURPHY

(1) Interactions between physicians and the pharmaceutical industry are significant.

(2) There is considerable interaction between CPG authors and the pharmaceutical industry.

(3) There is significant contact between the pharmaceutical industry and academic researchers, faculty physicians, community physicians, residents, and medical students.

(4) 87% of CPG authors had some form of interaction with the pharmaceutical industry.

(5) The average CPG authors interacted with 10.5 different drug companies.

(6) These types of interactions influence prescribing patterns, stimulate requests for addition of drugs to hospital formularies, result in favorable publications and research articles, and are related to the lack of publication of unfavorable articles.

(7) Most CPG authors have interactions with drug companies and that a significant proportion work as employees/consultants for drug manufacturers, and that a majority of authors had relationships that predated the guideline creation process.

(8) Physicians are reluctant to disclose their relationships with drug companies.

(9) The experts who write guidelines are the same individuals who are most likely to receive drug company financial support, academic promotion, etc.