Comparison of Conflicts of Interest among Published Hernia Researchers Self-Reported with the Centers for Medicare and Medicaid Services Open Payments Database

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BACKGROUND: Many healthcare providers have financial interests and relationships with healthcare companies. To maintain transparency, investigators are expected to disclose their conflicts of interest (COIs). Recently, the Centers for Medicare and Medicaid Services developed the Open Payments database of COIs reported by industry. We hypothesize that there is discordance between industry-reported and physician self-reported COIs in ventral hernia publications.

STUDY DESIGN: PubMed was searched for ventral hernia studies accepted for publication between June 2013 and October 2015 and published by authors from the US. Conflicts of interest were defined as payments received as honoraria, consulting fees, compensation for serving as faculty or as a speaker at a venue, research funding payments, or having ownership/partnerships in companies. Conflicts of interest disclosed on the published articles were compared with the financial relationships in the Open Payments database.

RESULTS: A total of 100 studies were selected with 497 participating authors. Information was available from the Open Payments database for 245 (49.2%) authors, of which 134 (26.9%) met the definition for COI. When comparing COIs disclosed by authors and data in the Open Payments database, 81 (16.3%) authors had at least 1 COI but did not declare any, 35 (7.0%) authors had COIs other than what they declared, and 20 (4.0%) declared a COI not listed in the Open Payments database, for a combined discordance rate of 27.3%.

CONCLUSIONS: There is substantial discordance between self-reported COI in published articles compared with those in the Centers for Medicare and Medicaid Services Open Payments database. Additional studies are needed to determine the reasons for these differences, as COI can influence the validity of the design, conduct, and results of a study. (J Am Coll Surg 2017;224:800–804. © 2017 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

Bias is any tendency that prevents unprejudiced consideration of a question. With research, it can occur during study design, study implementation, data analysis, and publication. More importantly, bias can alter study findings, resulting in inaccurate or incorrect results and conclusions. One of the important potential sources of bias that can impact all stages of study development and reporting is conflict of interest (COI). A common source of COI is financial interests, such as financial relationships between medical researchers and healthcare companies.

To provide readers and reviewers transparency when interpreting study results, authors are expected to disclose their COI. However, the current system relies on individuals to self-report their COI, and publishing journals might (or might not) verify and monitor the disclosure process. It is unclear how effective this process is and journals still have no valid method for assessing COI.

In 2010, the Patient Protection and Affordable Care Act required the Centers for Medicare and Medicaid Services to collect information from applicable manufacturers and distributors of drugs, devices, and biological products. The information collected includes financial relationships with healthcare providers and fiduciaries, such as consulting fees, speaking fees, and ownership interests. The Open Payments database was established to provide a transparent view of these financial relationships, allowing healthcare professionals and patients to make informed decisions about their healthcare needs.
group purchasing organizations to report their financial relationships with physicians and hospitals. This industry-reported information is made available to the public in the Open Payments database (OPD) (http://openpaymentsdata.cms.gov) and is updated on a 12-month cycle every June 30. Physicians and hospitals are given 45 days to review and dispute potentially inaccurate data. In September 2014, the first report was published and included payments from August 1, 2013 through December 31, 2013 (5 months). In 2013, there were 4.46 million transactions published, for a total of $3.91 billion. In 2014, there were 11.86 million transactions published, for a total of $7.49 billion. And in 2015, there were 11.90 million transactions published for a total of $7.52 billion. As opposed to the information published for 2014 and 2015, the data for 2013 represents a 5-month period only, which explains the difference in total payments and number of transactions.

No gold standard for identifying COIs exists; the accuracy of the database cannot be validated. However, the results from the database can be compared with other sources, such as self-reported COIs from research publications. The aim of this study was to assess the concordance between self-reported COIs among peer-reviewed publications on ventral hernia repair and those reported in the OPD.

METHODS

Search strategy

PubMed was searched for ventral hernia studies published from June 2013 and October 2015 using the search term ventral hernia. Only clinical research studies pertaining to ventral hernias from authors reporting affiliations in the US were included because OPD reports on US healthcare providers only. Consecutive studies meeting inclusion criteria were selected.

Data extraction

All authors from included articles were recorded, along with the self-reported, published COIs listed on the published article. Each author was searched in the OPD and COIs were recorded. Authors not listed in the OPD were assumed to have no industry-reported COIs or payments. Conflict of interest was defined by the latest revised regulations on the Responsibility of Applicants for Promoting Objectivity in Research made by the Public Health Service and the Office of the Secretary of the US Department of Health and Human Services. Payments received in the 12 months before the acceptance date of the study for honoraria, consulting fees, compensation for serving as faculty or as a speaker at a venue, research funding payments, or having ownerships/partnerships in companies. Only travel or food expenses of more than $5,000 from a single source were considered a COI.

Four categories of disclosure were identified: full disclosure where self-reported and industry-reported COI completely correlated, incomplete industry disclosure, incomplete self-disclosure, and no COI (Table 1).

Table 1. Categories of Conflict of Interest Disclosure

<table>
<thead>
<tr>
<th>Self-disclosure</th>
<th>Industry disclosure (Open Payments database)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Full disclosure</td>
</tr>
<tr>
<td>No</td>
<td>Incomplete industry disclosure</td>
</tr>
<tr>
<td>No</td>
<td>Incomplete self-disclosure</td>
</tr>
<tr>
<td>No</td>
<td>No conflict of interest</td>
</tr>
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</table>

Statistical analysis

Based on a preliminary, exploratory evaluation of 10 articles, the estimated difference between self-reported and OPD-reported COIs was 30%. Assuming an $\alpha$ of 0.05, $\beta$ of 0.20, and a 10% reduction in effect size (ie 27% difference) to achieve a more conservative estimate, we estimated a sample size of 100 studies would be needed. The primary end point was difference in reported COIs and was assessed using McNemar’s test. Differences in payments were reported as median and range, which prevents outliers from skewing the data, and were compared using Mann-Whitney U test.

RESULTS

A total of 303 consecutive articles were screened to identify 100 articles that met the inclusion criteria. Exclusions included no US authors (n = 185), nonclinical studies (n = 5), letter (n = 1), and inability to access full text (n = 12).

Authors

There were 497 authors for the 100 included articles. Information was available in the OPD for 245 (49.2%) authors, of which 134 (26.9%) met the criteria for a COI. Most authors were not listed in the OPD (n = 252) or were listed and received only small amounts (less than $5,000) in the form of food and travel (n = 129). When comparing OPD COIs with self-reported COIs disclosed in articles, 81 (16.3%) authors had at least 1 COI but did not declare any, 35 (7.0%) authors had other COIs besides the ones they declared, and 20 (4.0%) declared a COI not listed in the OPD (total discordance = 27.3%; $p < 0.001$). Eighteen (3.6%) authors completely disclosed their COIs (Table 2).
Table 2. Conflicts of Interest by Authors (n = 497)

<table>
<thead>
<tr>
<th>Self-disclosure</th>
<th>Yes</th>
<th>%</th>
<th>No</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>18</td>
<td>3.6</td>
<td>20</td>
<td>4.0</td>
</tr>
<tr>
<td>No</td>
<td>116</td>
<td>23.3</td>
<td>343</td>
<td>69.0</td>
</tr>
</tbody>
</table>

**Articles**

Of the 100 articles, 33 had an author with a self-reported COI, and 75 had an author with a COI listed in the OPD (p < 0.001) (Table 3).

**Payments**

The total payments listed in the OPD received by all authors (n = 497) was $20,838,011.72 (median $0; range $0 to $1,256,191). The majority of authors were not listed in the OPD (n = 252). Those who had a COI payment received significantly more than those who had non-COI payments, such as food payments less than $5,000 from a single source (Table 4; p < 0.005).

**DISCUSSION**

Financial COI is common among medical practitioners and researchers. In this study, one-half of all published authors had some financial interaction with industry (eg, meals and travel expenses), and one-fourth had a COI. Collaboration between industry, scientists, and medical practitioners inevitably leads to financial relationships. However, the surprising finding from this study is the substantial discordance between self-reported COIs and industry-reported COIs in the OPD.

There are multiple potential explanations for this discordance. The OPD is constructed from industry-reported financial relationships and relies on National Provider Identifier numbers. The accuracy of the database is unknown, and currently, no reliable method to validate the results is available. Although medical practitioners are given the opportunity to review and edit the posted results, it is unlikely that this routinely occurs. Another potential reason is the lack of agreement between different journals about defined criteria for which commercial relationships should be disclosed. Some COIs might not be perceived as relevant to an article by the reporting author, and therefore might not be reported. For example, an author writing an article on hospital readmissions after ventral hernia repair might not think it is necessary to report that he or she is a consultant for a mesh company if this seems unrelated. Potential solutions to this include reporting all COIs, standardizing what a relevant COI is, and allowing an unbiased third party to determine what is relevant. Finally, a valid COI that is not reported might simply be due to an oversight by the author or journal. For example, in the current system with multiple authors, many journals might ask only one author to respond if there are any COIs, as opposed to directly reaching out to each author. Authors, coauthors, and editors might consider searching the OPD database as a routine part of manuscript submission.

Currently, many authors, institutions, and societies have policies on management of COIs, including self-reporting, financial distancing, self-regulation, self-disqualification from participation, and peer review by a peer with no conflict. However, it is unclear how effective these methods are, as they have not been thoroughly evaluated, and case reports of violations with significant clinical ramifications have been reported. For example, this article suggests that self-reporting without oversight might not be effective. Regardless of the disclosure status (disclosed or undisclosed), COI by itself might have a negative impact on clinical evidence, public opinion, and decision making, as it can inadvertently introduce bias to a study and decrease research transparency.

Some published reports have demonstrated that studies with a COI compared with studies with no COI are more likely to report favorable outcomes. Researchers with conflicts were more likely to selectively choose parameters to produce better results, report larger magnitudes of differences than expected, or perform clinical studies without publication due to unexpected outcomes. As a result, conclusions drawn by the medical and public community based on published studies can be flawed. However, it is unknown whether unreported COIs have any impact on study results. It would seem plausible that these studies can have results that differ from studies with no COI.

Due to the considerable potential concerns with COI, the process of publishing and reporting COI should be improved by developing evidence-based guidelines and standardizing disclosure processes among journals and meetings. Collaboration with industry is vital to progress and, currently, two-thirds of all biomedical research is supported by industry. However, without safeguards, this collaboration can also cause harm. Much of the currently published research is poor quality, prone to bias, and at risk for making incorrect practice recommendations. Improving the quality of research and
management of COIs can go hand in hand. The Institute of Medicine has published recommendations on controlling COIs, including development of stronger COI management policies; reforming relationships between scientists and industry; increasing education on COI; public reporting (eg OPD); restriction of participation of individuals with COIs in research of human subjects and guideline development; creation of incentives to decrease COIs; and increased oversight.23

There are a number of limitations with this study. First, the accuracy of the OPD cannot be validated. Only correlation or discordance can be assessed. Second, the relevance of COIs is unknown, and the authors might have not reported “irrelevant” COI, meeting individual journal requirements. Third, the OPD can only track healthcare providers with a National Provider Identifier number, which not all authors have, including statisticians, medical students, and research associates/assistants. However, exclusion of these authors could only increase the proportion of eligible authors who have a COI or have discordant COI. Fourth, although we have demonstrated discordance in reporting COI, its impact on study results is unknown. However, other studies have demonstrated that COI can affect results, so it is possible that unreported COIs could have a similar or greater impact on results. Future studies are needed. Finally, this study has only assessed COIs in ventral hernia research. Similar projects in other specialties, as well as comparative studies among specialties, are needed. Based on the current study, we can only conclude that COIs and discordant reporting in ventral hernia research is prevalent and might or might not be any different than that in other specialties.

CONCLUSIONS

The current practice of reporting COIs is based on the honor system, with self-reporting of relevant COIs. Until recently, there has been no method to corroborate self-reported COIs. The new availability of public registries can assist editors in ensuring that COIs are being accurately reported; however, there is currently substantial discordance in self-reported and industry-reported (Centers for Medicare and Medicaid Services OPD) COIs. Additional study is needed to assess the reason and relevance of these differences.

Author Contributions

Study conception and design: Olavarria, Holihan, Cherla, Kao, Ko, Liang
Acquisition of data: Olavarria, Perez
Analysis and interpretation of data: Olavarria, Holihan, Cherla, Perez, Liang
Drafting of manuscript: Olavarria, Holihan, Kao, Liang
Critical revision: Olavarria, Kao, Ko, Liang

REFERENCES


Table 4. Amounts Received

<table>
<thead>
<tr>
<th>Variable</th>
<th>Per author, $ median (range)</th>
<th>Overall, $</th>
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<tbody>
<tr>
<td>All authors (n = 497)</td>
<td>0 (0–1,314,846)</td>
<td>20,838,011</td>
</tr>
<tr>
<td>Authors listed in database (n = 245)</td>
<td>5,345 (10–1,314,846)</td>
<td>20,838,011</td>
</tr>
<tr>
<td>Non-COI (n = 136)</td>
<td>0 (0–4,532)</td>
<td>66,673</td>
</tr>
<tr>
<td>COI, overall (n = 134)</td>
<td>79,203 (1,615–1,314,846)</td>
<td>20,771,338</td>
</tr>
<tr>
<td>COI, fully reported (n = 18)</td>
<td>90,105 (3,640–371,958)</td>
<td>2,443,620</td>
</tr>
<tr>
<td>COI, incompletely self-reported (n = 116)</td>
<td>79,203 (1,615–1,314,846)</td>
<td>18,327,718</td>
</tr>
<tr>
<td>COI, incomplete industry-reported (n = 20)</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

COI, conflict of interest (payments received in the 12 months before the acceptance date of the study for honoraria, consulting fees, compensation for serving as faculty or as a speaker at a venue, research funding payments, or having ownerships/partnerships in companies); non-COI, non-conflict of interest (travel or food expenses less than $5,000 from a single source).


