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Conflict of Interest Disclosure Among the Highest Earning Physicians Receiving Compensation From Vascular Device Companies

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Abstract

Objective: To characterize the association between payments made by vascular device companies to clinicians, and the conflict of interest (COI) declarations on relevant publications.

Summary Background Data: Close association between medical device companies and clinicians is essential in the advancement of surgical technology. When evaluating the efficacy of novel equipment, identification of these relationships can minimize the risk of bias in relevant studies.

Methods: Using the Open Payments Database (OPD), the 10 highest compensated clinicians from 10 vascular device companies were identified. In the population based bibliometric analysis, general payments, number of payments, h-index, and academic rank were identified. PubMed and Scopus were queried to identify author publications. Relevance to payment received and COI disclosures were identified for each article.

Results: The physicians identified earned $33,442,266.74 with a median of $92,500 in 2017. The authors published an average of 6.46+/−9.08 articles in 2018. Relevant COI was identified in 74%. In 50.5% of the relevant publications was a COI declared. The median h index of authors was 18+/−23. Community based physicians had a higher rate of COI disclosure (65.6%) compared to academic physicians (47.6%) (P = .008). Low h-index authors had a higher rate of COI declaration (71.4%) compared to high h-index (43.6%) (P = .001).

Conclusion: A high degree of inconsistency was found between self-declared COI and relevant articles published by the highest compensated physicians. We propose a policy of full disclosure and the addition of a link to each author's OPD page on all publications to increase access to potential COI.

Keywords

conflict of interest, vascular surgery, financial disclosure, compensation

Introduction

Given the large investment of time and money needed for new device development, a working relationship between scientists, clinicians, and industry is essential. Device manufacturers play an integral role in the development of new technologies. Surgical device manufacturers must develop a collaborative relationship with the clinicians who provide their expertise in developing and trialing new products. These relationships typically involve financial compensation provided to the physicians for their intellectual property and/or time. The ethical confines of research dictates disclosure of these financial relationships, as conflict of interest disclosure (COI) is essential in minimizing bias in the medical literature.

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It is estimated that 94% of physicians in the United States have a financial relationship with medical device or pharmaceutical industries.[1] A clinician-industry relationship may increase the risk for bias, or the perception of bias, in a study authored by a clinician or sponsored by industry. Proper COI disclosure on relevant publications may mitigate bias and lead to an increase in patient trust and consistently higher physician ratings from patients.[2] Disclosure of COI is more important than ever given the increase in private industry sponsored research.[3] However, there remains a lack of clear guidance for proper COI disclosure.[4]

In 2017, the medical device industry of the United States was valued at $156 billion, with vascular devices representing one of the most rapidly growing sectors.[5] In fact, vascular devices consistently rank as one of the highest grossing segments for many medical device companies.[6] Because of the recent interest in COI disclosure, this study sought to determine if a discrepancy exists between financial relationships and self-reported COI. The vascular device industry was selected because of the rapid growth and impact it has across many medical specialties.

Methods

We selected vascular device companies with a sponsorship role in the 2018 Society for Vascular Surgery (SVS) annual meeting. These companies include Abbott Laboratories, Bard Peripheral Vascular, Inc., Boston Scientific Corp., W.L. Gore and Associates, Inc., Medtronic, Inc., Cook Medical, Siemens Medical Solutions, LLC, Kinetic Concepts, Inc. (KCI) (An Acelity Company), Shockwave Medical, Inc., and Terumo Corp. Other company sponsors of the meeting were excluded either because no payment information was available (Getinge) or because payment information was inadequate (Silk Road, Cordis).

Physician Selection

The Sunshine Act was passed in 2010 which mandates the disclosure of all financial relations between clinicians and industry.[4] As a part of this act, financial reporting obligations to the Centers for Medicare and Medicaid services began in 2013 and is housed in the Open Payments Database (OPD).[4,7] Using the 2017 OPD, the 10 highest paid physicians from the 10 vascular device companies listed above were determined. The OPD releases payment information in three categories: general payments, research payments, and ownership or investment interest. Only general payments were used in determining physician compensation. This includes payments for charitable contribution, serving as speaker, consulting fees, ownership/investment, education, grant, royalty/license, honoraria, gifts, and travel.[7]

Of the 100 physicians assessed, only those receiving compensation greater than $10,000 in 2017 (n = 84) were included. If an author was a top 10 earner from multiple companies, financial compensation and relevant articles were assessed independently from the perspective of each manufacturer. This was done to ensure that article relevance could be established independently, and the author was not unfairly selected as failing to disclose COI where relevance could only be established for one manufacturer and not the other.

Publication Selection

PubMed and the Scopus Scholarly Database were used to compile total publications, articles published between January 1, 2018 – December 31, 2018, specialty, *h*-index, and institution type for each author. Database searches were performed using physicians first and last name. Articles were selected from 2018 to ensure that compensation had already been received prior to publication of the article (in 2017). Date of electronic publication was considered in the case that the electronic version was available sooner than the print version.

Article relevance to associated company was determined based on guidelines set forth by the International Committee of Medical Journal Editors (ICMJE). The guidelines state that "Financial interests…personal relationships or rivalries, academic competition, and intellectual beliefs" are all grounds for potential COI and should be reported as such.[8] With these guidelines in mind, we determined any equipment made by the associate vascular device company used by authors in publications to warrant a COI disclosure. In addition, publications arguing against the use of a rival device was deemed as an inherent rivalry and recorded as a COI.

Outcome Assessment

A full literature review of all publications from each author between January 1, 2018 – December 31, 2018, was performed to determine article relevance to associate company based on ICMJE guidelines. Determination of relevance was made by the first author of this manuscript, if presence of relevance was equivocal, the primary investigator/corresponding author made the final judgment. A full review of each publication was performed to determine if a self-disclosure of COI existed in the primary manuscript, supplemental data, or publishing journal website. We considered a discrepancy to exist when evidence of financial compensation from the OPD did not match self-disclosure of COI in any publicly available format. If COI was declared despite the publication not being deemed relevant to compensating company, we tallied positive presentation as a separate category to keep relevant article disclosures separated.

Table 1. Overview of all Payments by the 10 Vascular Surgery Device Companies.

Company name	Total Payments	No. of Payments	Mean payment	Net Sales, 2017
Boston scientific	$46,633 554.88	133 388	$349.61	$9.05 billion
Medtronic, Inc	$31,777 842.45	142 144	$223.56	$29.7 billion
Abbott labs	$27,675 352.11	164 393	$168.35	$27.4 billion
W.L. Gore	$5,786 356.91	24 659	$234.65	Privately held
Bard peripheral	$4,024 290.30	9317	$431.93	$216.99
KCI, Inc	$3,715 269.48	9133	$406.80	Privately held
Siemens medical	$2,466 632.80	7596	$324.73	$83.05 billion
Terumo corp	$1,216 252.19	6896	$176.37	$5.02 billion
Shockwave, Inc	$291,567.09	250	$1166.27	Privately held
Cook medical	$116,020.42	720	$161.14	Privately held

The total, overall general payments made by each of the 10 companies of interest across 2017. Net sales in 2017 reported directly from official annual report from each individual company. Privately held companies do not have publicly attainable annual sales reports.

Bibliometric Data

Each author is given a bibliometric data score known as the *h*-index. The *h*-index is defined as the authors' number of papers that have at least *h* citations and the number of papers that have no more than *h* citations each.[9] We used the median *h*-index (*h*-index ≥ 18) to stratify authors based on scholarly influence.

Statistical Analysis

Descriptive statistics were performed to characterize data and evaluate COI declarations and financial compensation. Independent *t*-tests were used to examine differences in mean values between 2 groups and analysis of variance for the comparison of means between 3 or more groups. Chi-square testing was performed to determine significance between categorical groups.

Results

Across the 10 vascular device manufacturers analyzed, a total of $123,703,138.63 was paid out across 498 496 payments to 116 333 clinicians in 2017 (Table 1). The 84 physicians included in this study received 27% of the total compensation provided by these manufacturers ($33,442, 266.77). The sample population (81 men [96.4%] and 3 women [3.6%]) received an average of 70.28 ± 97.16 payments with a median payment of $92,500 (Table 2). On average, each author in the sample population was compensated $393,438.43 ± 922 012 in 2017.

The selected authors had 9674 total publications across all time. In 2018 alone, the 84 authors published an average of 6.46 ± 9.08 articles (539 total articles). Of these 539 articles, 398 (73.8%) were deemed to be relevant to financial compensation received. However, only 201 (50.5%) of the relevant articles contained a self-declared COI. There were 3 instances of COI disclosure when the publication was not deemed relevant to compensation. Among the 84 physicians in the sample group, 66 had at least 1 publication relevant to their financial compensation (78.6%). Of these, 44 had at least one article in which they did not disclose a COI when appropriate (67%).

Of the 84 physicians, 45 were faculty at academic institutions (53.6%). There was no significant difference in mean industry compensation for academic ($257, 989.38±601 223.96) versus community ($545, 818.61±1 173 969.68) physicians (P = .15). Relevant article disclosure was significantly lower for academic (47.6%) compared to community (65.6%) physicians (P = .008). There was no statistically significant association between academic rank and payments or disclosure rate (P = .26) (Table 3).

The authors were stratified into high and low *h*-index based on the median of 18 (mean 24.64 ± 22.64). There was no statistically significant difference in average payment for high ($358,290.13 ± 784 505.95) versus low ($429,423.60 ± 1 052 901.51) *h*-index (P = .73) (Table 4). Authors with an *h*-index below 18 (n = 42) self-declared COI in 71.4% of relevant articles. High *h*-index (≥18) authors (n = 42) reported COI in only 43.6% of appropriate publications (P = .001).

There were 22 unique medical specialties that received compensation from the medical device companies selected. The most common specialties represented include cardiology (n = 24), vascular surgery (n = 14), diagnostic radiology (n = 6), and general surgery (n = 5) with all other specialties with fewer than 5 authors (see supplemental information for full list with publication information). Statistical analysis for rates of disclosure was performed only for specialties with greater than 20 relevant publications. Of these (cardiology, vascular surgery, diagnostic radiology, surgery, and internal medicine), diagnostic radiologists were the most likely to disclose a COI (71%), whereas cardiologists were the least likely (37%) (P = .0001). There was no significant difference in

Table 2. Payments Made by the 10 Vascular Supply Companies to the 84 Highest Paid Physicians.

Company name	Total Payment	No. of Payments	Mean Payment
Boston scientific	$20,201 575.07	96	$210,433.07
Medtronic, Inc	$3,829 013.81	886	$4321.69
Abbott labs	$2,661 153.68	2288	$1163.09
W.L. Gore	$1,175 668.14	684	$1718.81
Bard peripheral	$2,639 242.30	237	$11,136.04
KCI, Inc	$1,887 685.83	1215	$1553.65
Siemens medical	$411,328.27	258	$1594.30
Terumo corp	$289,234.34	197	$ 1468.19
Shockwave, Inc	$270,056.53	79	$3418.44
Cook medical	$51,680.10	8	$6460.01

The total general payments, number of payments and mean value per payment from each of the companies of interest to the 10 highest compensated physicians. Only physicians making greater than $10,000 were included for the highest compensated physicians.

Table 3. Academic versus Community Physicians.

Physician type	Relevant articles	COI Disclosure	% Disclosure	Avg. Pay (SD)
Community (n = 40)	**64**	**42**	**66%***	**$545,818.61 ($1,173 969.68)**
Academic (n = 45)	**334**	**159**	**48%***	**$257,989.38 ($607,084.60)**
Professor (n = 31)	240	119	50%	$180,526.34 ($203,446.34)
Associate professor (n = 7)	57	26	46%	$677,428.82 ($1,476 998.38)
Assistant professor (n = 6)	37	14	48%	$174,607.91 ($150,605.69)
Adjunct professor (n = 1)	0	0	N/A	$223,556.53

Comparison of COI disclosure and pay between academic and community physicians and between academic ranks. There was no significant difference in payment between any of the groups (P = .36 between all groups; P = .15 for academic vs community). There was a significant difference (P = .008) in disclosure rate between academic and community physicians. There was no significant difference in disclosure rate between academic rank.
Abbreviations: N/A = not applicable; COI = conflict of interest; Avg. = Average; *Statistically significant.

Table 4. High versus Low Scholarly Influence based on median *h*-index.

Physician type	Relevant Articles	COI Disclosure	% Disclosure	Avg. Payment (SD)
High *h*-index (≥18)	300	131	43.6%*	$358,290.13 (784 505.95)
Low *h*-index (<18)	98	70	71.4%*	$429,423.60 (1 052 901.51)

Relevant articles and reported COI from all articles published by the sample population in 2018. There was a significant difference in the disclosure rates (P = .001) between high and low *h*-index authors. Abbreviations: Avg. = Average; *Statistically significant.

disclosure between any of the other specialties with greater than 20 relevant publications (Table 5).

Discussion

This study provides an analysis of the financial relationship between vascular device manufacturers and the physicians receiving the highest compensation from them. Of the 539 articles published in 2018, roughly half of the articles contained a self-declared COI when necessary (50.5%). This is similar to the disclosure rate reported in the medical literature.[10]

There was no significant difference in compensation based on institution type, academic rank, or scholarly influence. There have been mixed reports regarding compensation differences based on academic rank.[11] However, a study performed by Cheng et al[12] analyzing industry compensation specifically for vascular surgeons, also did not find a significant compensation difference based on academic rank. In that study, over 1000 vascular surgeons across the United States were characterized via the OPD, and the median pay was found to be $814.[12] This is in vast contrast to the median of $92,500 reported in this study. However, the present study examined only the highest compensated physicians from a set of vascular supply companies, which included a multitude of medical specialties.

To the best of our knowledge, this is the first study to report a discrepancy in reporting between academic and

Table 5. Number of Authors and Disclosure Rate in 2018 by Specialty.

Specialty	Specialty (n)	Relevant Publications	Disclosures	Total Publications	% Disclosure
Cardiology	**24**	**165**	**61**	**201**	**37%***
Vascular	**14**	**47**	**27**	**75**	**57%**
Diagnostic radiology	**6**	**79**	**56**	**80**	**71%***
Surgery	**5**	**25**	**16**	**44**	**64%**
Cardiothoracic surgery	5	13	7	25	54%
Plastic surgery	4	2	2	5	100%
Neurosurgery	3	9	7	16	78%
Podiatry	3	2	1	9	50%
Anesthesia	2	6	4	10	67%
Internal medicine	**2**	**25**	**11**	**28**	**44%**
Interventional radiology	2	16	4	23	25%
Obstetrics/Gynecology	2	0	0	3	NA
Urology	2	0	0	0	NA
Gastroenterology	2	4	1	4	25%
Nephrology	1	1	1	4	100%
PMR	1	0	0	0	NA
Orthopedic surgery	1	3	2	14	67%
Infectious disease	1	0	0	0	NA
Emergency medicine	1	0	0	3	NA
Surgical Intensivist	1	1	1	1	100%
Emergency medicine	1	0	0	1	NA
Preventative medicine	1	0	0	3	NA

Frequency of author by specialty. One author, a top 10 earner from Terumo Corp. and Bard Peripheral Vascular, is a Cardiologist. Statistical analysis for disclosure rates was only performed for specialties that had >20 relevant publications (bolded). Of these, a significant difference in disclosure existed only between cardiology and diagnostic radiology (P = .0001).
Abbreviation: PMR = Physical Medicine and Rehabilitation; *Statistically significant.

community physicians. Ziai et al[13] performed a study analyzing COI disclosure for physicians compensated by medical device companies and found no such discrepancy to exist. However, Ziai et al analyzed physicians compensated by all medical device companies, not specifically vascular device manufacturers. Regardless, the difference in reporting between these two groups remains unclear.

This study also reports a discrepancy in COI reporting for authors based on scholarly influence. The *h*-index has been shown to be a stronger indicator of scholarly influence than number of publications alone.[14] A similar discrepancy in COI reporting based on scholarly influence has not been reported in the literature before. Zvider et al[15] performed a study analyzing *h*-index and compensation among over 1500 otolaryngologists and found no significant difference in *h*-index between those receiving compensation and those who are not. However, the same study found that physicians receiving greater than $1000 in compensation had significantly higher *h*-indices.[15] We found no such difference but did not analyze authors who earned under $10,000 and analyzed a different physician population.

It is unclear why academic faculty and authors with a higher *h*-index have been found to disclose COI at a significantly lower rate than their counterparts. For both groups, it is possible that they are following outdated guidelines or guidelines set forth by their institution that do not align with ICMJE recommendations. It is also possible that authors do not deem their compensation to be relevant if it is for a project unrelated to direct financial compensation. It is the opinion of this author that the absence of universal guidelines can contribute for the discrepancy in reporting rates. Additionally, administrative assistants who submit articles on the behalf of the authors may not inquire about all authors potential COI.[16] Finally, the date of compensation relative to a publication may also interfere with proper reporting, as there are no universal guidelines on how long compensation should remain relevant for future publications.

To ensure proper COI reporting, we recommend adherence to the Harmonized Disclosure Framework, published in December of 2021 by the Association of American Medical Colleges.[17] The recommendation is of full disclosure of all financial ties 24 months prior to publication. Within this full disclosure, the authors can designate which publications are relevant to the publication at hand. In addition, we recommend that industry-clinician relationships be reported directly on the home institution webpage of the physician. Finally, we recommend the addition of a direct URL link to the authors OPD webpage on all publications to allow for ease of access for any reader

interested in potential COI. Regarding existing medical literature, it is not feasible to review the entire collection for improper COI reporting. However, adhesion to this framework will increase transparency and allow for easier determination of COI in posterity.

Limitations

Limitations of this study include sample size. As previously stated, this study only characterized the highest earning physicians, which may not be descriptive of the population at large. Potential inaccuracies in the OPD may further limit this study. Many studies have found that inaccuracies exist in the OPD regarding physician specialty.[18] However, there is no other source for physician's financial compensation. In addition, we did not assess whether physicians receiving compensation from a vascular device manufacturer preferentially published articles related to products manufactured by that company. Finally, establishment of the presence of a COI may be subjective which may further limit the study.

Conclusion

We found discrepancy between relevant COI and declared COI in the highest compensated physicians who receive payments from vascular supply companies. Given, these findings we recommend a single, standardized COI reporting system, full disclosure of financial relationships, the addition of industry-clinician relationships on physician webpages, and OPD webpage URL links on all author publications.

Declaration of Conflicting Interests

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