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Original Research

Conflict of Interest Disclosure in American Arthroplasty Surgical Literature

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ABSTRACT

Background: Relationships between industry and physicians are critical for innovation in the field of arthroplasty surgery. However, these relationships can present a conflict of interest (COI) for medical research and are required to be disclosed by most journals. The rate of accurate disclosures by physicians has not been studied in arthroplasty surgery.

Methods: The names of all authors publishing in *The Journal of Arthroplasty* and *Arthroplasty Today* between 2014 and 2018 were obtained from MEDLINE. Financial disclosure statements were obtained from the journal websites and manually compared against Open Payments. Statistical comparisons were made using chi-square testing with significance defined as $P < .05$.

Results: From 2014-2018, 3147 articles were published with 4038 authors meeting inclusion criteria. Of authors with financial disclosures, 2298 (57%) authors correctly disclosed. The total value of disclosed COI equaled $1.71 billion. The total value of undisclosed conflicts of interest equaled $334 million. For payments >$1,000,000 physicians disclosed accurately 86% of the time. For payments between $100 and $9999 physicians accurately disclosed 26% of the time. Senior authors disclosed correctly 72% of the time, which was significantly higher compared to middle and first authors.

Conclusions: There is a high prevalence of inaccurate disclosures in the field of arthroplasty surgery. This suggests a need to further educate early-career physicians on what constitutes a COI. Standardization of disclosure forms and verifications with the Open Payments Database can help increase the rate of accurate disclosures.

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Introduction

Arthroplasty surgery is inherently tied to the industry of surgical implants, with the relationships between surgeons and the device industry leading to advancements in the field. To gain an advantage over competitors, medical device companies are constantly seeking to improve on existing technologies with the ultimate goal of improving patient outcomes [1,2] and gaining market share. These companies often leverage existing relationships with physicians by exchanging royalties, stock options, or other incentives for advice or ideas.

Outside of direct consulting relationships, these companies also direct money toward education, speakership positions, and research [3], allowing surgeons to familiarize themselves with a company's specific product and providing resources for physicians to improve their surgical techniques. Recent surveys demonstrate that prior experience with an implant and published evidence of improved outcomes are important factors in implant preference [4,5].

Even though physician-industry relationships are important to the advancement of the field of arthroplasty, these relationships may bias research findings and practice patterns [6,7]. In an effort to identify potential bias, these relationships are required to be reported publicly on websites such as the Center for Medicare and

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Medicaid Services Open Payments Database (OPD). Furthermore, most academic journals go to great lengths to ensure authors accurately disclose industry relationships and conflicts of interest [8,9]. However, some authors report confusion regarding what constitutes a conflict of interest (COI) and what financial information is necessary to disclose [10]. Additionally, studies have reported the practice of self-disclosing conflicts of interest is replete with errors [11-15].

The purpose of this study was to analyze the accuracy of author's self-reported conflicts of interest through a comparison between the OPD and 2 major arthroplasty journals: *The Journal of Arthroplasty (JoA)* and *Arthroplasty Today*.

Material and methods

All articles published in *JoA* and *Arthroplasty Today* between January 2014 and December 2018 were extracted from MEDLINE. Author names, location of practice, doctoral status, and COI statement were obtained from the respective journal website. Authors who published multiple articles during the reviewed period were included for each instance of publishing as their COI statement or relationships with industry may have changed.

Articles were excluded if they did not include a COI statement. Authors were excluded if they did not have a medical doctorate or doctorate of osteopathy, as nonphysicians are not included within the OPD. Authors were additionally excluded if they did not have any entries in the OPD during the included time period, as the OPD does not contain payments made to foreign authors, medical students, or nonphysician scientists.

The full names of all authors were queried in the OPD using Salesforce Object Query Language (SoQL) queries per the OPD programming interface. In cases where multiple physicians with the same or similar names were present, location of practice and practice specialty were used to confirm the correct physician. If no matching physician was found, the author was assumed to have no entries in the OPD. Entries prior to 2014 were excluded due to high rates of inaccuracies prior to 2014 [16]. However, more recent studies suggest the accuracy of reports in the general payments database to the OPD are nearly 90% [17]. Payments in the OPD were included for an author within a calendar year prior to the publication date as well as the year of publication up until 90 days prior to publication to allow for lag time between submission and publication. The date, amount, and type of payment were recorded. COI statements were individually compared to payments noted within the OPD. If differences were found between the COI statement associated with an author and the OPD database, the payment was recorded as undisclosed. Accurately disclosed payments were also recorded. All payments received were considered broadly relevant to the published article, as the detail within the OPD does not allow for determination of relationship between a payment and a specific subject. Entries in the OPD that had been contested by the author were excluded.

Statistical comparisons were made utilizing chi-square test using a Bonferroni correction due to multiple comparisons where appropriate. Statistical significance was set at $P < .05$ for all comparisons (Prism 8, GraphPad, San Diego, USA). Values are presented as mean (interquartile range) given a nonparametric distribution of all payments.

Results

Included authors

Between January 2014 and December 2018, 2879 articles were published in *JoA* with 15,401 authors, and 268 articles were published in *Arthroplasty Today* with 1048 authors (Fig. 1). Three thousand six hundred twenty-eight authors from *JoA* and 410 authors from *Arthroplasty Today* met the inclusion criteria, with 11,773 and 638 authors excluded from the *JoA* and *Arthroplasty Today*, respectively.

Summary of financial relationships

Of the authors included, 2088 (57.6%) authors from *JoA* and 210 (51.2%) authors from *Arthroplasty Today* were found to have accurate COI statements (Table 1). There were 1540 (42.4%) authors from *JoA* and 200 (48.8%) authors from *Arthroplasty Today* found to have discrepancies between their disclosure and the OPD. The total amount of disclosed payments equaled $1,617,456,248 from *JoA* and $96,100,245 from *Arthroplasty Today* (Table 1). The total amount of undisclosed payments equaled $331,815,709 from *JoA* and $3,019,254 from *Arthroplasty Today* (Table 1). Of authors with financial conflicts disclosed, median values for disclosed COI per author were $141,939 [$23,801, $963,431.75], whereas the value for undisclosed conflicts of interest was significantly lower, $5040 [$876, $90,026] ($P \leq .001$).

Financial disclosure by relationship type

For both *JoA* and *Arthroplasty Today*, "Royalty or License" were the largest contributor of payments received. "Royalty or License" comprised $1.4 billion in *JoA* (Fig. 2) and $68 million in *Arthroplasty Today* (Fig. 3).

By amount, the lowest accurate disclosure rates in *Arthroplasty Today* were under education (28.6%, $96,846/$337,783), compensation for serving as faculty (47.1%, $35,219/$74,719), and honoraria (49.1%, $65,091/$132,454). Similarly, by amount, in *JoA* only 37.9% ($494,919/$1,307,363) of honoraria payments were disclosed and 46.1% ($1,062,852/$2,304,077) of education payments were disclosed. In both journals, the highest rates of accurate disclosure were in the categories of royalties and licenses (86.3%) and investments (90.5%). On a per-author basis, the lowest rates of accurate disclosure were in education (41.5%, n = 324/796), honoraria (40.5%, n = 79/195), and food and beverage (58.0%, n = 2188/3771).

Disclosure by payment amount

There were significant differences in the rates of disclosure by total amount received per author (Fig. 3a). Authors receiving total

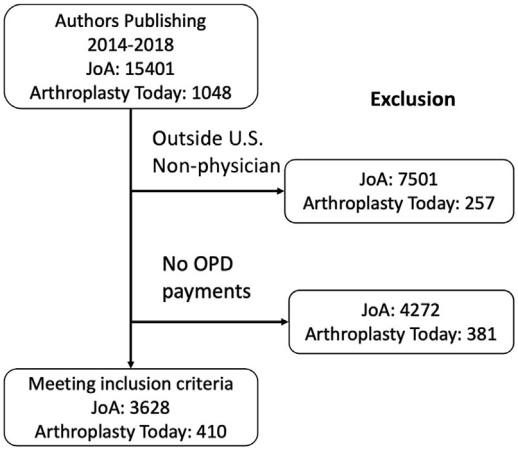

Figure 1. Arthroplasty conflict of interest search strategy and inclusion/exclusion criteria.

Table 1
Authors and value for disclosed and undisclosed arthroplasty conflicts of interest.

Variable	The Journal of Arthroplasty	Arthroplasty Today
Total number of articles	2879	268
Total number of authors	15,401	1048
Number of authors meeting inclusion criteria	3628	410
Authors with accurate disclosure statements (%)	2088 (57.6)	210 (51.2)
Authors with undisclosed conflicts of interest (%)	1540 (42.4)	200 (48.8)
Value of disclosed conflicts of interest in USD (%)	$ 96100428 (97.0)	$ 1617456248 (83.0)
Value of undisclosed conflicts of interest in USD (%)	$ 3019559 (3.0)	$ 331815709 (17.0)

payments >$1,000,000 were correctly disclosing 85.6% (554/647, $P < .001$ compared to all other groups) of the time. Those receiving payments between $100 and $999 were correctly disclosing 25.6% (162/632) of the time, significantly less than any other overall payment amounts ($P < .001$).

Additionally, on the individual payment level, there were significant differences in the rates of disclosure for payments (Fig. 3b). A total of 170,425 individual payments were received by all included authors. There was a significantly higher rate of disclosure for payments >$100,000 (85.9%, 4586/5340) compared with lower payment amounts, $P < .001$. Payments under $1000 were correctly disclosed 66.1% (66,094/99,946) of the time, significantly lower than all higher payment amounts ($P < .001$).

Disclosure by authorship position

There were significant differences in the rates of disclosure by authorship position (Fig. 4). There was no significant difference in rates of correct disclosure between first (305/700, 43.6%) and middle authors (1077/2057, 52.4%). Senior authors disclosed their financial COI correctly 72% (916/1281) of the time, significantly greater than first or middle authors ($P < .001$).

Discussion

Physician-industry relationships are crucial to advancing technology, education, and research in the field of arthroplasty, with the focus of improving the quality of patient care and outcomes. However, when evaluating the medical literature, it is necessary to understand the potential for bias related to conflicts of interest [7,18]. Accurate reporting of conflicts of interest provides important context for readers to critically assess the results and conclusions of a given study. This study reveals a high rate of underreporting conflicts of interest by authors publishing in the arthroplasty literature, which is comparable to the rate reported in the trauma [15], spine [14], and oncology literature [19], all fields with strong relationships with industry partners.

There is a significant difference in the reporting patterns of individuals who receive greater payments and those who receive smaller amounts, with those receiving more payments disclosing them at a significantly higher rate. This likely indicates that there is a lack of education or awareness that any payments or services received from a company could represent a potential COI with smaller payment amounts. Finally, senior authors were more likely to disclose conflicts of interest than first or middle authors, which may be related to larger payment amounts being disclosed at a higher rate or represent differences in awareness of the importance of conflicts of interest disclosure in early career physicians. Senior authors typically receive tax forms for payments from companies that they may have a relationship with. However, junior authors who attend dinners or courses are not given a tax statement. Providing a summary statement to junior authors from the company that the goods were provided may help junior authors disclose more accurately. For junior authors, the largest discrepancy appeared to be in the education and entertainment subcategory, and it is possible that these have no "actual or perceived" COI to junior authors. These findings suggest a critical need for senior authors to educate their junior colleagues regarding the importance of accurate financial disclosures.

In the arthroplasty surgery literature, the bulk of payments tend to be for royalties or license. Honoraria and education had the lowest rates of correct disclosures. Authors may not be aware categories such as honoraria and education are recorded by the OPD and fail to disclose payments in these categories accurately. While industry sponsorship of these programs appears innocuous, previous studies have suggested that small dollar payments such as compensation for meals or educational activities can influence practices [20]. Implant preference has also been associated with prior experience with that implant [5]. It is possible that many early-career physicians are unfamiliar with the OPD and fail to

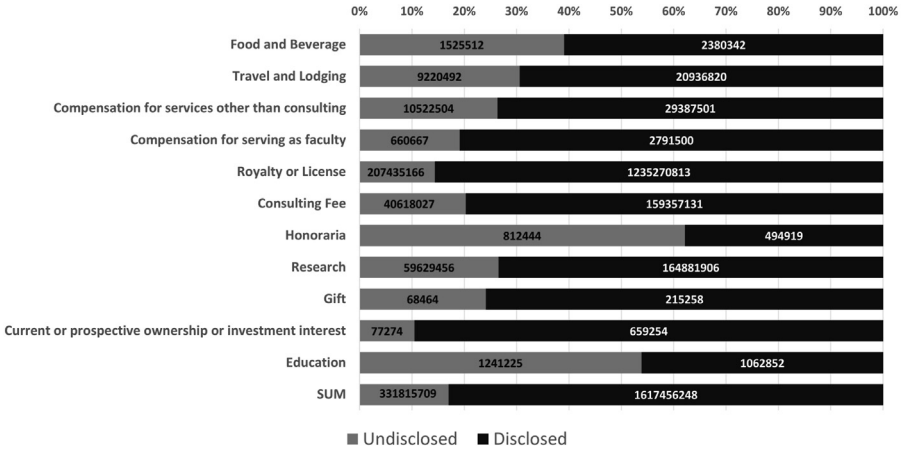

Figure 2. Journal of arthroplasty summary by payment type (amount in USD).

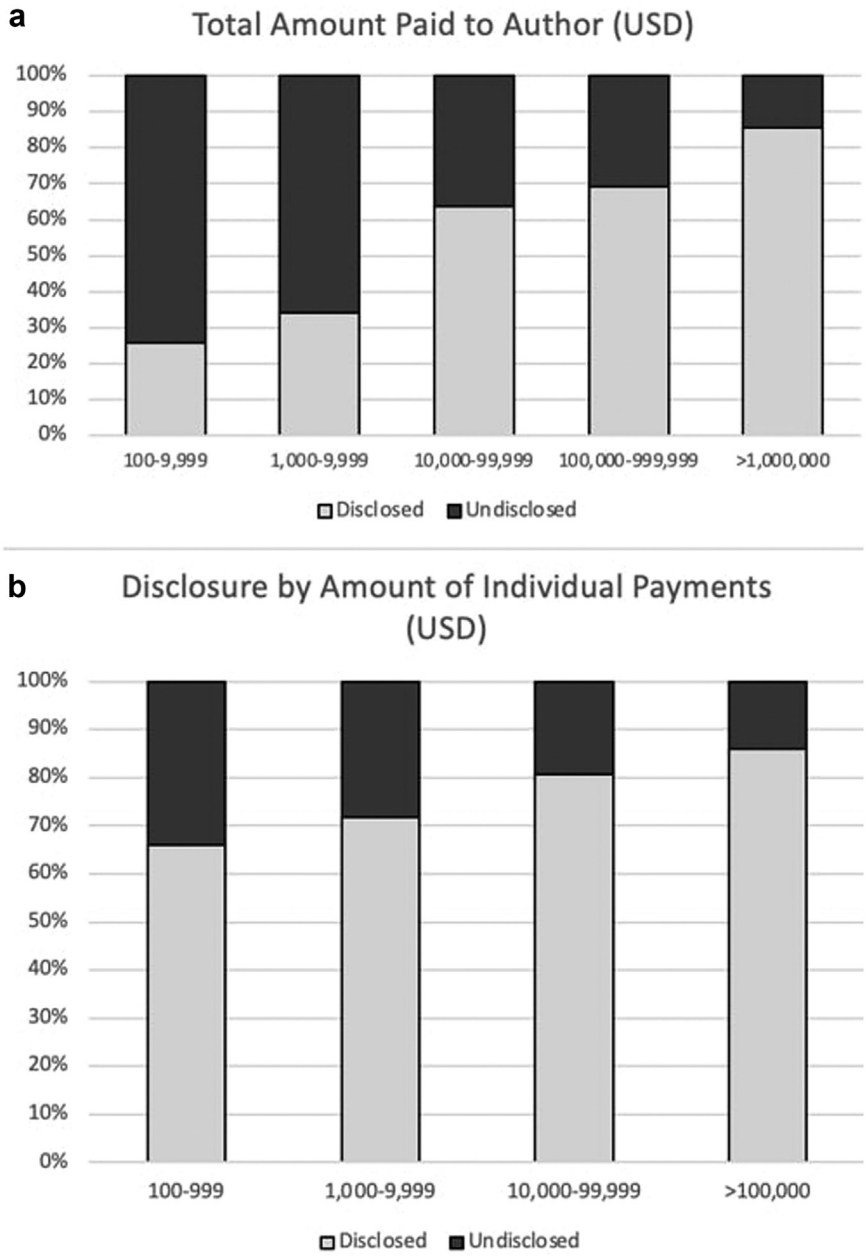

Figure 3. (a) Total amount paid to author (USD); (b) disclosure by amount of individual payments (USD).

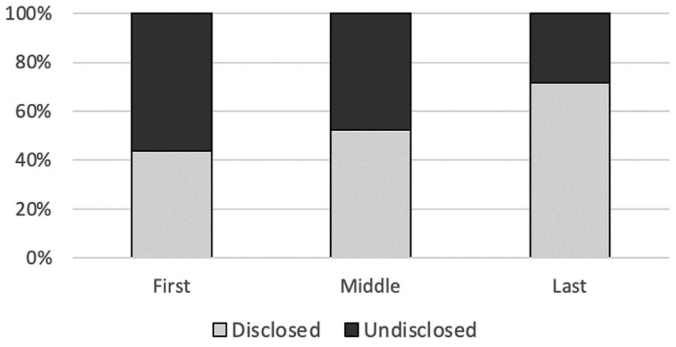

Figure 4. Disclosure of conflicts of interest by author position.

realize that involvement in educational activities is recorded and is important to disclose in a research setting. Additionally, senior members receiving royalties for teaching courses are likely to declare the income as education.

Most journals are now moving toward the use of standardized COI forms. However, the authors are unaware of any COI forms that verify with the OPD for physicians based in the United States. Active verification with the OPD would improve transparency in the field of arthroplasty surgery and help readers be aware of potential sources of bias in research. Verification with the OPD or determining disclosures solely based on the OPD without self-reporting could significantly improve accuracy of conflicts of interest and decrease errors by stigma from self-reporting conflicts of interest. Although verification in disclosures with the OPD would be a

significant improvement in COI reporting, utilizing the OPD would present some challenges. Since the OPD only includes US physicians, any payments made to authors that are not based in the US or that are not physicians (PhDs, medical students, and residents) would be unaccounted for. There is a growing need for a centralized system for reporting financial conflicts of interest within the orthopaedic community; this would not only improve transparency but also lead to easier submission of manuscripts in the orthopaedic literature.

Limitations of the current study include the shortcomings of the OPD, which may contain inaccurate and incomplete data. However, recent studies suggest the accuracy of reports in the general payments database in the OPD to be nearly 90% [17]. Contested listings in the OPD were specifically excluded from this study to limit inaccurate data that may have affected the results. In this study, all payments received were considered broadly relevant to the published article as the detail within the OPD does not allow for determination of relationship between a payment and a specific subject. This may result in a significant underestimation of the true rate of accurate disclosures. While some journals only require relevant disclosures, many require all disclosures, but this breakdown cannot be assessed based on the methodology used. However, this method has been used in similar studies evaluating inaccurate disclosures in the literature [12,14,21]. Furthermore, the OPD does not contain payments made to foreign authors, medical students, or nonphysician scientists. Therefore, we only included authors who have OPD listings, so values reported are only for those physicians who do have financial conflicts, which leads to an underestimation of the true rate of accurate disclosures and an overall underestimation of the total amount of money paid. Additionally, at some medical centers, royalty payments go directly to the institution. In these cases, the OPD would not have a listing of the financial relationship directly tied to a specific physician. This phenomenon may also affect our finding of the true rate of full disclosure. The analysis based on payment amount would also differ with various money cutoffs, and this breakdown was chosen somewhat arbitrarily. A lower value on the breakdown may be less likely to be reported, and this cannot be evaluated based on the current analysis. Lastly, there is an inability of the OPD to differentiate between individuals with the same name. While subspecialty and location were used in the current study to correlate individuals with OPD entries, it is possible that authors with the same name as another individual were incorrectly included in the analysis. This would lead to a small overestimation of the number of payments received as well as the rate of payment underreporting.

Conclusions

Overall, this study found a low rate of accurate COI reporting within the 2 main arthroplasty journals. Senior authors had accurate disclosures more frequently than middle or first authors, which suggests that the criteria for what constitutes a COI may be unclear for early-career physicians. Larger payments were more often disclosed, which suggests that many authors may not recognize these small payments as potential conflicts of interest. Therefore, there is a need to standardize the criteria of what comprises a COI and a need to make early-career physicians aware of these criteria.

Conflicts of interest

J. D. Shaw has stock options in Purgo Scientific LLC, receives other financial and material support from AO Spine NA, is an editorial board member of Operative Techniques in Orthopaedics, Elsevier; and is a board/committee member of Cervical Spine Research Society and Lumbar Spine Research Society. All other authors declare no potential conflicts of interest.

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CRediT authorship contribution statement

Robert T. Tisherman: Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Richard A. Wawrose:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Aditya M. Mittal:** Writing – review & editing, Methodology, Investigation, Data curation, Conceptualization. **Stephen R. Chen:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Joseph Chen:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Christopher J. Como:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration. **Malcolm Dombrowski:** Writing – review & editing, Supervision, Resources, Project administration. **Jeremy D. Shaw:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

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