
THE ORTHOPAEDIC FORUM

Inconsistencies Between Physician-Reported Disclosures at the AAOS Annual Meeting and Industry-Reported Financial Disclosures in the Open Payments Database

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Background: The purpose of this study was to determine the rate and type of inconsistencies between disclosures self-reported by physicians at a major academic meeting in the United States and industry-reported disclosures in the Open Payments database for a concordant time period.

Methods: Disclosures for every first and last author from the United States with a medical degree of a podium or poster presentation at the 2014 American Academy of Orthopaedic Surgeons (AAOS) Annual Meeting were collected and were compared with the disclosures reported in the Open Payments database to determine if any inconsistencies were present and, if so, within which category.

Results: In total, 1,925 total AAOS presenters were identified, and 1,113 met the inclusion criteria. Based on AAOS disclosures, 432 (39%) should have been listed within the Open Payments database. There were 125 presenters (11%) who reported an AAOS disclosure and thus should have been included in the Open Payments database, but were not included. An additional 259 presenters (23%) had ≥ 1 AAOS disclosures that were not reported or were improperly categorized in the Open Payments database. Inconsistencies were more common for authors who had significantly more poster presentations ($p < 0.001$), podium presentations ($p = 0.01$), total presentations ($p < 0.001$), and AAOS disclosures ($p < 0.001$) and a significantly higher value of payments in the Open Payments database ($p < 0.001$).

continued

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Conclusions: In this sample, there was a 35% rate of inconsistency between physician-reported financial relationships for presenters at the AAOS Annual Meeting and industry-reported relationships published in the Open Payments database.

Relationships between industry and physicians are very common in the United States, with up to 94% of physicians self-reporting some form of a relationship with industry¹. Physician-industry relationships can create a risk of bias in research study designs, experimental technique, and result interpretation and may affect treatment decisions in patient care²⁻¹⁸. However, physicians are in the best position to provide valuable innovations in design and safety that are mutually beneficial for patients, physicians, and industry¹. Many safeguards exist to protect utilization of physician-developed products, including contractual elimination of royalty streams for products used by the developer and elimination of royalty generation by hospitals where their patients are treated. The adequacy of conflict disclosure remains unclear. Certainly, conflicts can be perceived to alter clinical decision-making. There remains great interest from regulators, physician organizations, and patients in increasing transparency to mitigate the risks associated with these financial relationships between physicians and industry, while continuing to allow collaboration when it produces value¹⁹⁻²¹.

The Physician Payments Sunshine Act (PPSA) was established in 2010 as part of the Affordable Care Act to improve the transparency of physician-industry relationships in the United States. The PPSA mandates that all drug, medical device, and biologics companies annually report financial payments to physicians and teaching hospitals to the U.S. Centers for Medicare & Medicaid Services (CMS). Companies were required to begin collecting data on August 1, 2013, and the first set of data was released by the CMS and was published on their Open Payments web site on September 30, 2014²². The Open Payments database is the largest database of its kind, with more than 12,000 orthopaedic surgeons in the database and 58,000 industry financial payments published among them²³. Since 1985, the American Academy of Orthopaedic Surgeons (AAOS) has required presenters at its Annual Meeting to disclose financial conflicts of interest, including relationships with industry. These relationships are also listed in the publicly available AAOS Orthopaedic Disclosure Program database. Within this database, presenters are required to disclose the company and type of relationship, but not the financial value.

The purpose of this study was to determine the rate and type of inconsistencies between disclosures self-reported by physicians at a major academic meeting, the 2014 AAOS Annual Meeting, and industry-reported financial relationships that are published in the Open Payments database for a concordant time period. Our secondary purpose was to determine predictors of inconsistencies. We hypothesized that there would be a high rate of inconsistencies and that having more disclosures would be predictive of having an inconsistency.

Materials and Methods

AAOS 2014 Annual Meeting Data

The AAOS 2014 Annual Meeting was held from March 11 to March 15, 2014, in New Orleans, Louisiana. All attendees at the Annual Meeting who were authors of presentations or course lectures, board members, or committee members were mandated to “submit all financial relationships with industry occurring within the past 12 months” to the AAOS Orthopaedic Disclosure Program database²⁴. All disclosures listed in the AAOS Orthopaedic Disclosure Program as of October 1, 2013, were published in the final program of the 2014 Annual Meeting²⁴. Authors were required to disclose each financial relationship that they have in 1 of 9 categories (Table I). Those with no financial disclosures were required to submit that they had no financial disclosures.

Basic biographical information and disclosures for every first author and last author of a poster or podium presentation at the 2014 Annual Meeting were collected. Authors were categorized as podium presenter, poster presenter, or presenter of both a podium and a poster. For each author, academic degree, state of practice, and specialty data were collected. The self-reported disclosure data for the authors were collected from the Annual Meeting program according to the categories listed in Table I. The number of disclosures within each category and the name of the company for each disclosure were identified. If the same company was disclosed in separate categories by the same author, each was counted as a separate disclosure. A total number of disclosures were then calculated for each author.

Open Payments Data

The PPSA requires that all “applicable manufacturers” of drugs, devices, biologics, and medical supplies covered by Medicaid, Medicare, or the Children’s Health Insurance Program (CHIP) report to CMS “payments or other transfers of value” greater than \$10 to “covered recipients.” “Covered recipients” include physicians defined as a doctor of medicine or osteopathy, dentist, podiatrist, optometrist, or chiropractor who practice in the United States. The database categorizes payments into 3 major categories: general payments, research, and ownership and investment interest. Within general payments, payments are further subdivided into 1 of 13 categories (Table I).

The Open Payments database was accessed on December 15, 2015. Authors of podium or poster presentations who had a medical degree and were from the United States were included in the analysis. International presenters and those without a medical degree were excluded as these individuals would not be included within the Open Payments database. First authors and last authors of poster and podium presentations who met the inclusion criteria were identified by name in the Open Payments database. When there were several physicians with the same name, the author who presented at the AAOS Annual Meeting was further identified based on his or her state of practice and his or her labeled specialty as orthopaedic surgery in the Open Payments database.

Data collected from the Open Payments database included the total value of general payments, the total value of research payments, the total amount invested, and the total value of interest for a concordant time period. For each subcategory of general payments, the name of each unique company reporting a payment in that category was recorded, and the total number of companies that reported a payment for that disclosure category was calculated. The same methodology was applied to the research payments and value of the investment and interest payment categories.

TABLE I Corresponding AAOS and Open Payments Disclosures Categories

AAOS Disclosure Category*	Open Payments Database Disclosure Category†
Royalties	Royalty or license
Speaker's bureau or paid presentations	1. Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program 2. Compensation for serving as faculty or as a speaker for a non-accredited and noncertified continuing education program 3. Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program 4. Honoraria
Paid consultant	Consulting fees
Other financial or material support	1. Charitable contribution 2. Education 3. Entertainment 4. Food and beverage 5. Gift 6. Travel or lodging

*Categories excluded from the analysis were employee, unpaid consultant, stock or stock options, research or institutional support as principal investigator, and royalties and financial or material support from publishers. †Categories excluded from the analysis were grant, research, and ownership and investment interest.

Comparison of Disclosures and Statistical Methods

For each individual, it was then determined whether he or she should have been included within the Open Payments database on the basis of the presence of an AAOS disclosure under one of the following categories: royalties, speaker's bureau or paid presentations, paid consultant, or other financial or material support. These 4 AAOS categories were included in the analysis because they directly corresponded to a disclosure category in the Open Payments database (Table I). The AAOS disclosure categories of employee, unpaid consultant, and publishing royalties were excluded because they did not directly correspond to a disclosure category in the Open Payments database. Stock and research disclosures were also not included because the CMS had previously reported that the published information in their corresponding categories of "total value of research payments," "total amount invested," and "total value of interest" was incomplete as of December 15, 2015²⁵.

The number of individuals who should have been included in the Open Payments database but were excluded was then calculated. For each individual included in the Open Payments database, his or her AAOS disclosures were compared with the disclosures reported in the Open Payments database to determine if any inconsistencies were present and, if so, within which category. An inconsistency was defined as when a disclosure was reported by a physician in the AAOS Orthopaedic Disclosure Program, but was not present in the Open Payments database. In these comparisons, the AAOS was used as the gold standard against which the Open Payments data were judged. The number of individuals who were inappropriately excluded from the Open Payments database was then combined with the number of individuals with inconsistencies to determine the overall inconsistency rate.

The rate of AAOS disclosures and the inconsistency rate were then compared between regions, between specialties, with poster presentations, with podium presentations, with both poster and podium presentations, and with the presence or absence of an AAOS disclosure using chi-square tests. The number of AAOS disclosures and the value of payments reported within the Open Payments database were then compared between those with and without AAOS disclosures and those with and without inconsistencies using Mann-Whitney U tests after determining the data to be non-normally distributed

using the Kolmogorov-Smirnov test. Those variables that were significantly different between those with and without AAOS disclosures were then included in a binary logistic regression analysis. A similar analysis was conducted between those with and without inconsistencies.

Results

In total, 1,925 total AAOS presenters were identified and 1,113 presenters were included in the analysis based on the exclusion criteria (Fig. 1). Although all included had an MD, only 25

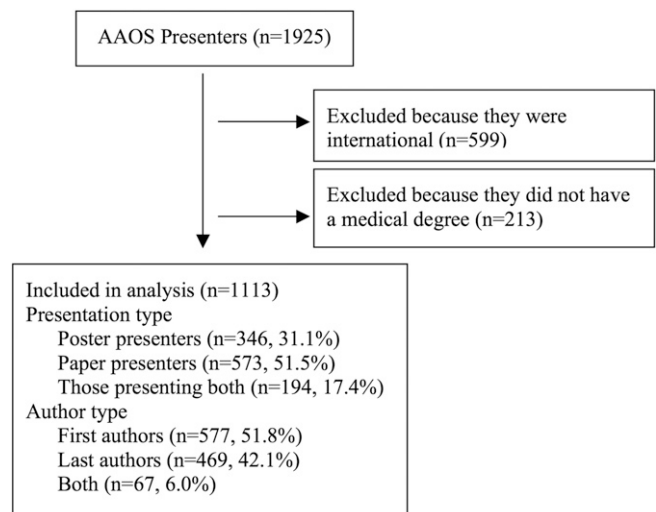


Fig. 1
Flowchart diagram demonstrating the application of inclusion and exclusion criteria.

TABLE II Inconsistencies Between the Open Payments Database and the AAOS Disclosure Database*

Variable	AAOS Disclosure Rate	P Value	Inconsistency Rate	P Value
Region of the United States		0.410		0.249
Midwest	41%		30%	
Northeast	47%		36%	
South	42%		29%	
West	43%		33%	
Specialty		0.437		0.014
Spine	48%		39%	
Foot and ankle	42%		38%	
Adult reconstruction	48%		38%	
Hand	44%		36%	
Shoulder and elbow	45%		33%	
Sports	42%		30%	
Trauma	39%		25%	
Tumor	34%		25%	
Pediatrics	37%		21%	
Practice management	36%		21%	
Presentation type		<0.001		<0.001
Podium	43%		32%	
Poster	38%		26%	
Both	61%		51%	
Author order		<0.001		<0.001
First	24%		16%	
Last	66%		50%	
Both	64%		49%	
Presence of an AAOS disclosure	NA	NA		<0.001
No			0%	
Yes			89%	

*NA = not applicable.

(2%) also had a PhD and only 8 (1%) also had an MBA. Of those included, 346 (31%) were presenting only a poster, 573 (51%) were presenting only a podium, and 194 (17%) were presenting both. Of those included, 577 (52%) were designated as a first author only, 469 (42%) were designated as a last

author only, and 67 (6%) were designated as both on separate projects.

Of those included, 488 (44%) had an AAOS disclosure and 526 (47%) were in the Open Payments database. The distribution of disclosures in the AAOS Orthopaedic Disclosure

TABLE III Comparison of Authors with and without Inconsistencies Between the AAOS and Open Payments Databases

Variable	Without Inconsistencies*	With Inconsistencies*	Total*	P Value
No. of poster presentations	0.5 (0.4 to 0.6)	0.8 (0.7 to 0.9)	0.6 (0.5 to 0.7)	<0.001
No. of podium presentations	0.85 (0.76 to 0.93)	1.0 (0.9 to 1.1)	0.9 (0.8 to 1.1)	0.01
Total no. of presentations	1.35 (1.3 to 1.4)	1.8 (1.7 to 2.0)	1.5 (1.4 to 1.6)	<0.001
Total no. of AAOS disclosures	0.4 (0.2 to 0.5)	5.6 (5.1 to 6.0)	2.1 (1.7 to 2.4)	<0.001
Value in Open Payments (\$)	17,587 (-11,828 to 47,002)	75,340 (37,970 to 112,711)	36,423 (4,093 to 68,752)	<0.001

*The values are given as the mean, with the 95% confidence interval in parentheses.

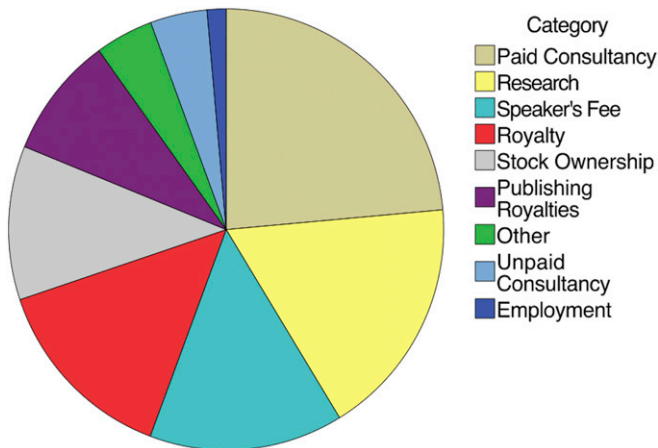


Fig. 2

Fig. 2 Pie chart demonstrating the distribution of the AAOS disclosures.

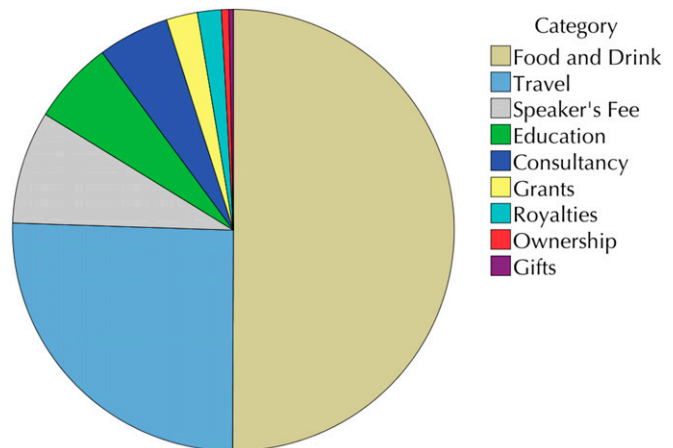


Fig. 3

Fig. 3 Pie chart demonstrating the distribution of the Open Payments disclosures.

Program is summarized in Figure 2, and the distribution of disclosures in the Open Payments database is summarized in Figure 3.

Inconsistencies between the Open Payments database and the AAOS disclosures were common (Fig. 4). Based on AAOS disclosures, 432 (39%) of those included should have been listed within the Open Payments database, but 125 (11%) were inappropriately not included within the Open Payments database. There were 259 individuals (23%) listed within the Open Payments database who had some relationships published in the AAOS Orthopaedic Disclosure Program not listed. Overall, 384 (35%) had an inconsistency between the Open Payments database and AAOS disclosures. Based on AAOS disclosures, 119 (11%) had an inconsistency within royalty relationships being disclosed, 165 (15%) had an inconsistency within speaker's fees, 262 (24%) had an inconsistency within consultant fees, and 47 (4%) had an inconsistency within another financial relationship (Fig. 3).

Table II summarizes the differences and lack thereof in AAOS disclosure rates or inconsistency rates across regions, orthopaedic subspecialties, presentation type, and author order. The AAOS disclosure rate ($p < 0.001$) and inconsistency rate ($p < 0.001$) were significantly different between podium, poster, and combined presenters, with combined presenters having the highest disclosure and inconsistency rates and poster-only presenters having the lowest disclosure and inconsistency rates (Table II). The AAOS disclosure rate ($p < 0.001$) and inconsistency rate ($p < 0.001$) were significantly different between first authors, last authors, and authors of both types, with last authors having the highest disclosure and inconsistency rates and first authors having the lowest disclosure and inconsistency rates (Table II). Because AAOS disclosures were used as the gold standard, those with an AAOS disclosure were also significantly more likely to have an inconsistency ($p < 0.001$). Those with inconsistencies also had significantly more poster presentations ($p < 0.001$), podium presentations ($p = 0.01$), total presentations ($p < 0.001$), and

AAOS disclosures ($p < 0.001$) and a significantly higher value of payments in the Open Payments database ($p < 0.001$) (Table III).

When the factors that significantly differed between those with and those without AAOS disclosures were compared in a multivariable binary logistic regression model, first-author status, number of posters, and a higher overall value of payments within the Open Payments database were all independent predictors of AAOS disclosures (Table IV). A model constructed with these 3 variables alone could predict 75% of AAOS disclosures. When the factors that significantly differed between those with and those without inconsistencies were compared in a multivariable binary logistic regression model, the presence of an AAOS disclosure and the number of AAOS disclosures were independent predictors of inconsistency (Table IV). A model constructed with these 2 variables alone could predict 91% of inconsistencies.

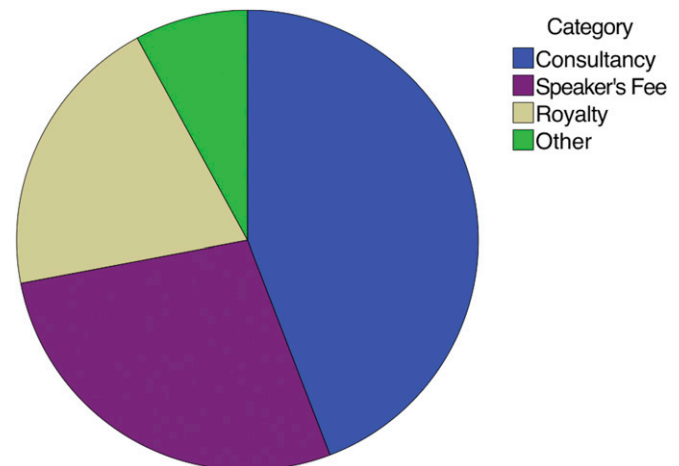


Fig. 4

Fig. 4 Pie chart demonstrating the distribution of inconsistencies between the AAOS and Open Payments databases (based on AAOS disclosures as the gold standard).

TABLE IV Multivariable Logistic Regression Model Statistics*

Variable	Odds Ratio†	P Value
With versus without AAOS disclosures		
First author	0.256 (0.140 to 0.467)	<0.001
No. of posters	1.341 (1.089 to 1.652)	0.006
Dollar value of payments in Open Payments	NA	<0.001
With versus without inconsistencies		
Presence of an AAOS disclosure	166.7 (40.00 to 1,000)	<0.001
No. of AAOS disclosures	1.634 (1.438 to 1.858)	<0.001

*NA = not applicable. †The values are given as the odds ratio, with the 95% confidence interval in parentheses.

Discussion

The most significant finding of our study is that 35% of the physicians had an inconsistency between what financial relationships they self-reported at the AAOS Annual Meeting and what relationships are reported by industry and published in the Open Payments database. When considering only those individuals who should have been listed in the Open Payments database based on their AAOS disclosures, 89% of physicians had a relationship that they disclosed in the AAOS Orthopaedic Disclosures Program not reported in the Open Payments database. Of the 432 AAOS presenters who should have been included in the Open Payments database based on their AAOS disclosures, only 11% had their self-reported disclosures directly match what is reported in the Open Payments database.

Previous studies have published discrepancy rates as high as 50% when comparing relationships reported by physicians with those reported by industry^{9,17,26-29}. Okike et al. compared payments reported by hip and knee prosthesis manufacturers with disclosures self-reported by physicians and found an overall inconsistency rate of 29%²⁶. Buerba et al. reported a similar inconsistency rate of 46% between payments reported by industry and disclosures self-reported at a national orthopaedic meeting²⁸. The results from the present study indicate that those with a greater sum of payments reported in the Open Payments database were more likely to have inconsistencies.

There are likely several contributing reasons for the high inconsistency rate between what is self-reported by physicians and what is published in the Open Payments database. First, there are errors in the large, complex Open Payments database. Prior to its initial release in September 2014, >39% of the data were de-identified because of potential inaccuracies²⁵. Despite a brief period in which physicians could review and could dispute the data, only 5% of physicians took advantage of this opportunity³⁰. It is unknown how many physicians were aware of the opportunity as it was not well publicized and the review period was short at 45 days^{25,31}. Second, there are many companies, such as private groups in development, that are not covered by CMS or CHIP and thus are not required to report to CMS. Third, the Open Payments database only reports mon-

etary relationships, while the AAOS Orthopaedic Disclosure Program also includes non-financial conflicts of interests. Fourth, inconsistencies could be related to differing rules and definitions or to misunderstandings of what relationships should be disclosed, which apply to disclosures by industry and by physicians alike. Disclosure guidelines also change often and physicians may be unaware of the change in policy. Prior to 2007, the AAOS required physicians to only report "relevant relationships," and many physicians may still interpret the current AAOS disclosure policy as such. Additionally, physicians may have differences in understandings of the reporting period of time that could have contributed to the discrepancies. Our findings indicate that the Open Payments database may not provide an accurate accounting of physician-industry relationships.

Inconsistencies were more common among spine subspecialists, authors with more presentations, last authors, and those with a greater value of payments in the Open Payments database. Last authors were more likely to have disclosures as they are often the more senior author; however, we were unable to determine whether time in practice was related to inconsistencies. The presence of an AAOS disclosure and the number of AAOS disclosures were the only 2 independent predictors of inconsistency. These results suggest that authors with more AAOS disclosures should be particularly attentive to the Open Payments database as they are at increased risk for inconsistencies within their Open Payments published record.

There were several limitations to this study, most notably the difference in reporting structures between the AAOS and Open Payments database. Unfortunately, the AAOS disclosure categories and the Open Payments database categories are not the same. This may have led to differences in the way that certain relationships were categorized. A second limitation was that, at the time of this study, the Open Payments Program published payments from August 1, 2013, to December 31, 2013. The AAOS disclosure time period is at least 12 months prior to October 1, 2013. This is a recognized limitation; however, these were the best possible data to compare at the time of this study and we believe that the effect of this time discrepancy was not likely to be substantial. The greatest

inconsistencies were seen with royalty payments (11%), speaker's fees (15%), and consultant fees (24%), all of which are typically, but not necessarily, long-term financial relationships. Fourth, we chose to use the AAOS disclosures as the gold standard to compare the Open Payments database against because it has been in existence since 1985 and its completeness has been previously studied²⁶. We recognize that neither the Open Payments database nor the AAOS disclosures are completely accurate representations of financial relationships for each physician.

The impact of the Open Payments database on the future of patients' health-care decisions, biomedical research, government regulators, and the relationships between physicians and industry remains to be seen, but could be substantial. Certainly, one outcome is that physicians receive less compensation for collaborating with industry because of the stigma that may be associated with such a relationship. Future regulations may also limit the amount of compensation that physicians receive for collaborating with industry. The "opportunity cost" of partnering with industry may be too high for the physician when compared with the potential personal and financial benefit of spending time in the clinic, in the operating room, performing research, or with family. Transparency and accurate reporting hopefully will not discourage fair and equitable compensation for the value added by physician collaboration. The high rate of inconsistency between the financial relationships listed in the Open Payments database and those reported by physicians hopefully encourages the individual clinician to review the Open Payments database for errors, including omissions of relationships. Physician societies, such as the AAOS, must decide whether to accept and to publish the disclosures that physicians report, the Open

Payments database report, or both. The high rate of inconsistency of the Open Payments database in its current form may steer physician societies away from publishing those data at this time.

Patients, industry, regulators, and physician societies and organizations will have to consider whether to rely on self-reported physician financial relationships or to transition to the Open Payments database. As these Open Payments data begin to be accessed, used, and publicized, all must be aware of the 35% inaccuracy rate within the database. Continued efforts by CMS and industry as well as further engagement of physicians with the database will hopefully improve the accuracy of the Open Payments database over time. ■

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