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Authors

Ziai, Kasra
Sahyouni, Ronald
Moshtaghi, Omid
et al.

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An Analysis of the Open Payment Database in Neurotology

Kasra Ziai, MD^{1*}, Ronald Sahyouni, MS^{1,2*}, Omid Moshtaghi, MS¹, Kimberly Vu¹, Khodayar Goshtasbi¹, Yaser Ghavami, MD¹, Lauren Lee¹, Harrison W. Lin, MD¹, and Hamid R. Djalilian, MD^{1,2}

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Abstract

Since the introduction of the Sunshine Act in 2010 and Open Payments Database (OPD) in 2013, a significant amount of data has been collected on physicians and the payments received through ties with pharmaceutical and medical device companies. To date, a study within the field of otology and neurotology using data from the 2015 OPD has not been conducted. As such, we assessed the validity and accuracy of OPD information for otologists and neurotologists (O&Ns). Of the 126 physicians listed as O&Ns in the OPD, 25 were actually general otolaryngologists, and 1 was a cardiologist. In addition, 88 O&Ns were misclassified by the OPD as general otolaryngologists. A total of 1156 payments, summing \$1,966,204, were made to O&Ns as a whole, with 646, 507, and 3 payments classified as general, research, and ownership/investment interests, respectively. Analysis of OPD data for O&Ns demonstrates a significant financial relationship between O&N physicians and industry, as well as noteworthy inaccuracies in the OPD that likely affect other subspecialties.

Keywords

Sunshine Act, Open Payments Database, open payment database, otology, neurotology, payments

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Substantial financial ties between pharmaceutical/medical device industry and surgical specialties are not uncommon, with 94% of US physicians receiving some form of benefit from an external company.¹ The implementation of the Sunshine Act in 2010 mandated reporting of all payments made to physicians through medical device, pharmaceutical, and technology companies. In 2013, the Centers for Medicare & Medicaid Services (CMS) established the Open Payments Database (OPD) to store payment information for increased transparency and identification of conflicts of interest.²

Within otolaryngology, data from 2013 to 2014 have been analyzed and stratified according to region, subspecialty, sponsor, and payment amount, with otologists and neurotologists (O&Ns) demonstrated to accrue the highest mean payment from pharmaceutical companies.^{3,4} However, OPD analysis of payments to neurosurgeons demonstrated a 62% concordance rate among neurosurgeons listed in the OPD and actual practicing neurosurgeons.³ A similar study within otolaryngology using the 2015 OPD has not been conducted. As such, we aim to assess the financial relationship between O&Ns and industry, as well as the validity and accuracy of OPD information for O&Ns.

Methods

With institutional review board (IRB) exemption, payment information (in US dollars) was downloaded from the CMS OPD.² This data set detailed all payments made to O&Ns and teaching hospitals by manufacturers and group purchasing organizations (GPOs) in 2015. The resulting 11.9 million records were separated into general payments, research payments, and ownership and investment interest.

The list of O&Ns in the OPD was cross-referenced to an O&N list from the American Neurotology Society (ANS) and American Otological Society (AOS). O&Ns not found in either the ANS and AOS lists, but listed as O&N specialists in the OPD, were identified through the American Board of Otolaryngology's website and Google search engine. Data were nonparametric and SPSS version 22 (SPSS, Inc, an

¹Division of Neurotology and Skull Base Surgery, Department of Otolaryngology–Head and Neck Surgery, University of California, Irvine, California, USA

²Department of Biomedical Engineering, University of California, Irvine, California, USA

*These authors contributed equally to this work.

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Corresponding Author:

Hamid R. Djalilian, MD, Division of Neurotology and Skull Base Surgery, Department of Otolaryngology–Head and Neck Surgery, University of California Irvine, 19182 Jamboree Road, Otolaryngology-5386, Irvine, CA 92697, USA.

Email: hjdjalili@uci.edu

Table 1. Overview of Payments (in US Dollars) to Otolologists and Neurotologists in 2015.

Payment Category	No. of Payments	Mean	Median	Standard Deviation	Minimum	Maximum	Range	Sum
General	646	286	62	1134	0.52	11,893	11,893	184,184
Research	507	2621	308	6094	2.50	40,000	39,998	1,328,956
Ownership/investment interest	3	151,021	25,275	236,976	3423.00	424,366	420,943	453,064

IBM Company, Chicago, Illinois) was used for data synthesis.

Results

Data Accuracy

In total, 126 physicians were listed as O&Ns in the OPD. ANS/AOS lists of O&Ns consisted of 561 physicians. Cross-referencing the OPD with ANS and AOS lists demonstrated that 26 of 126 OPD-classified O&Ns were misclassified (25 general otolaryngologists, 1 cardiologist), and 88 O&Ns were misclassified as general otolaryngologists in the OPD.

Payment Overview

Of 561 O&Ns, 188 (33.5%) received some form of compensation. A total of 1156 payments were made to O&Ns as a whole, with the total, mean, standard deviation, and median being \$1,966,204, \$10,458, \$49,271, and \$220, respectively (**Table 1**).

General Payments

The total number of general payments to O&Ns was 646 (**Table 2**), with the total, mean, standard deviation, and median reported in **Table 1**. Eleven companies contributed general payments to O&Ns. Cochlear Corp. accounted for 75.4% (\$139,028) of all general payments, followed by DePuy Synthes Sales (\$19,578), Acclarent (\$11,294), and Sophono (\$10,055). These 4 companies accounted for 97.7% of all general payments (**Figure 1A**). In addition, Cochlear Corp. paid \$143,843 (40% to only 3 institutions), Advanced Bionics LLC paid \$523,909 (87.4% to only 3 institutions), and Med-El Corp. made \$47,944 (57% to only 3 institutions) in general payments to teaching hospitals.

Of the 646 payments, 444 (68.7%) were cash/cash equivalent, and 202 (31.3%) were in-kind items and services. Food and beverage was the most common category (538 payments, 83.2%), followed by travel and lodging (**Table 2**).

Research Payments

Research payments totaled 507 payments, with the total, mean, standard deviation, median, and range reported in **Table 1**. Seven drug/device manufacturers contributed research payments to O&Ns. Cochlear Corp. accounted for 70% (\$930,760) of total payments, with Acclarent (\$192,878) and Advanced Bionics LLC (\$141,720) accounting for 25.2% (**Figure 1B**). In-kind items and services comprised 55% of

Table 2. Breakdown of General Payments (in US Dollars) to Otolologists and Neurotologists in 2015.

	No. (%) of Payments
Total	646 (100)
Food/beverage	538 (83)
Travel/lodging	77 (12)
Consulting fee	23 (4)
Compensation for serving as faculty or speaker for a nonaccredited/noncertified continuing education program	4 (1)
Compensation for services other than consulting	2 (<1)
Grant	1 (<1)
Entertainment	1 (<1)

payments, with cash/cash equivalent comprising 45%. A total of 282 payments were for equipment for research support, 124 for study support, 60 for IRB fees, 5 for clinical research fees, and 36 unspecified. Cochlear Corp. paid \$504,084 (59% of which went to 3 institutions), Advanced Bionics LLC paid \$303,789 (77% to 3 institutions), and Med-El Corp. made \$111,377 (67% of which went to 1 institution) in research payments to teaching hospitals.

Ownership and Investment Interest

This payment category is defined as “value of ownership or investment interests that a physician . . . held in an applicable manufacturer or GPO.” A total of 3 ownership and investment interests for O&Ns were identified, summing \$453,064.

Discussion

There is a significant financial relationship between O&Ns and industry, with substantial dollar amounts dedicated to “research” support from cochlear implant companies. A total of 20.6% of physicians listed as O&Ns in the OPD were not O&Ns, and 88 O&Ns were misclassified by the OPD as general otolaryngologists. These 88 misclassified physicians received 46.8% of total payments accumulated by all O&Ns per the OPD. The significant financial relationship between physicians and industry, as well as the misclassification and misrepresentation of payments by the OPD, likely affects specialties outside of otolaryngology.

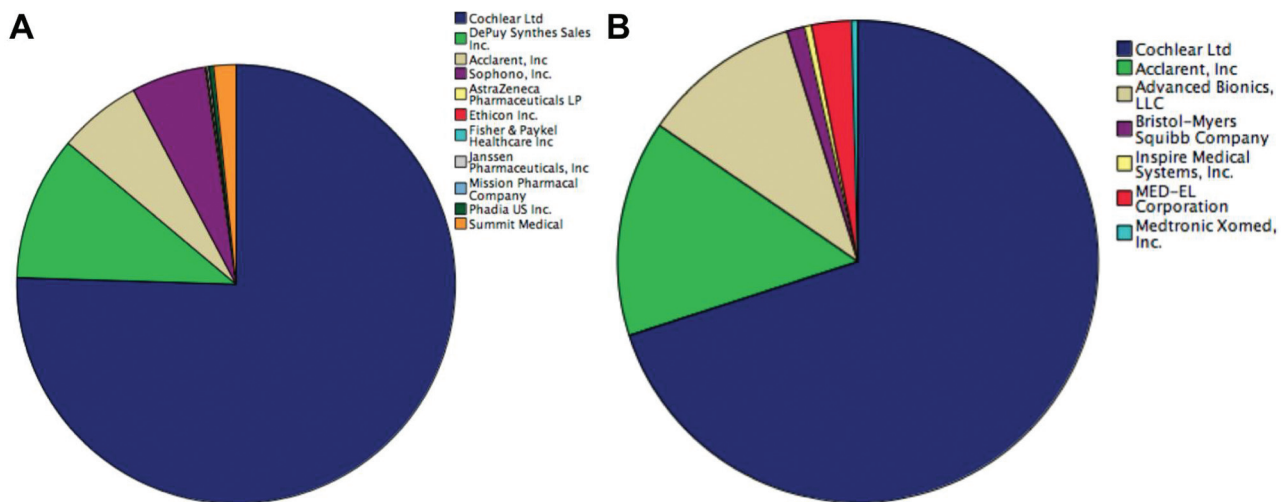


Figure 1. (A) General payments (in US dollars) by drug/device companies and (B) research payments by drug/device companies to otologists and neurotologists in 2015.

This study was feasible due to the small size of the O&N field, which allowed for manual cross-referencing and verification of all O&Ns with professional databases against the OPD. A total of 33.5% of ANS/AOS-verified O&Ns were compensated, compared to 48.1% of general otolaryngologists.⁴ Whether this discrepancy reflects a fundamental difference in clinical/surgical practices between subspecialties or simply erroneous data reporting remains to be clarified.⁵⁻⁷ Furthermore, an association between money received by otolaryngologists from industry and the regularity they use specific equipment has been demonstrated.⁸ Our analysis of research payments demonstrated that 95.2% of payments were made by only 3 medical device companies. This study was inherently limited in accuracy due to its reliance on reported data in the OPD and likely suffers from reporter bias as the data reported in the OPD may not accurately reflect the true financial relationship between physicians and industry. Further investigation into the influence that research funding from device companies has on device usage is warranted.

Conclusion

Analysis of OPD payment data for O&Ns demonstrates a significant financial relationship between physicians and industry, with noteworthy inaccuracies that likely affect specialties and subspecialties outside of otolaryngology.

Author Contributions

Kasra Ziai, substantial contributions to the conception and design of the work, drafting the work and revising it critically for important intellectual content, final approval of the version to be published, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy and integrity of any part of the work are appropriately investigated and resolved; **Ronald Sahyouni**, substantial contributions to the conception and design of the work, drafting the work and revising it critically for important intellectual content, final approval of the version to be

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Disclosures

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