Assessment of Financial Relationships between Otorhinolaryngologists and Pharmaceutical Companies in Japan between 2016 and 2019

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Saito received personal fees from Taiho Pharmaceutical Co. Ltd outside the scope of the submitted work. Regarding non-financial conflicts of interest among the study authors, all are engaged in ongoing research examining financial and non-financial conflicts of interest among healthcare professionals and pharmaceutical companies in Japan. The other authors have no example conflicts of interest to disclose.

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Author contributions:
Anju Murayama: Data collection, study concept and design, resource, statistical analysis, software, visualization, drafting of the manuscript, revising of the manuscript, and study supervision
Hiroaki Saito: Data collection, resource, drafting of the manuscript, revising of the manuscript, and reviewing of the manuscript
Sae Kamamoto: Study concept and design, drafting of the manuscript, and revising of the manuscript
Akihiko Ozaki: Data collection, reviewing of the manuscript

Abstract

Objective:
To evaluate the magnitude, prevalence, and trend of the financial relationship between Japanese otolaryngologists and pharmaceutical companies.

Methods
Using payment data publicly disclosed by 92 pharmaceutical companies, we examined magnitude, prevalence, and trend in personal payments made to otorhinolaryngologists board certified by the Japanese Society of Otorhinolaryngology-Head and Neck Surgery between 2016 and 2019 in Japan. Furthermore, differences in payments were evaluated by whether otolaryngologists were clinical practice guideline authors, society board member, and academic journal editor or not. Trend in payments were evaluated by generalized estimating equations.

Results
Of 8,190 otorhinolaryngologists, 3,667 (44.8 %) were paid a total of $13,873,562, in payments for lecturing, consulting, and writing by 72 pharmaceutical companies between 2016 and 2019. Median four-year combined payments per physician was $1,022 (interquartile range: $473–$2,526). Top 1%, 5%, and 10% of otorhinolaryngologists received 42.3% (95% confidence interval [95% CI]: 37.2–47.4%), 69.3% (95% CI: 65.9–72.8%), and 80.6% (95% CI: 78.3–82.9%) of overall payments, respectively. The median payments per physicians were significantly higher among otorhinolaryngologists authoring clinical practice guideline authors, society board member, and journal editors ($11,522), society board members ($22,261), and journal editors ($35,143) than those without. The payments and number of otorhinolaryngologists receiving payments remained stable between 2016 and 2019.

Conclusion
This study demonstrates that a minority but large number of otorhinolaryngologists received personal payments from pharmaceutical companies for the reimbursement of lecturing, consulting, and writing in Japan. Large amounts of these personal payments were significantly concentrated on a small number of leading otorhinolaryngologists.

Keywords:
conflict of interest; Japan; industry payments; otolaryngologist; ethics; health policy

Introduction
Although collaborations between industry and healthcare professionals can bring breakthroughs in medicine, several medical scandals and limited transparency in the financial relationships between healthcare professionals and pharmaceutical companies led to the concern for the undue influence of financial relationships on patient care. Since 2013, the Japan Pharmaceutical Manufacturers Association (JPMA), the largest pharmaceutical trade organization in Japan, has required all pharmaceutical companies belonging to the JPMA, whose share account for more than 80% of total sales for pharmaceutical products in Japan,[1] to disclose their payments made to healthcare professionals for lecturing, consulting, and writing, based on the JPMA
voluntary transparency guidance.\cite{2, 3} This voluntary payment disclosure by pharmaceutical companies enabled the evaluation of the detailed magnitude of the financial relationships between healthcare professionals and pharmaceutical companies in several specialties.\cite{4-8}

As shown in previous studies in the United States, there are large and prevalent financial transfers from pharmaceutical industries to otorhinolaryngologists for various purposes,\cite{9-13} as well as other specialty physicians.\cite{14-21} The payments from pharmaceutical companies often disproportionately concentrate on small numbers of physicians in leading and authoritative positions who are required to be independent and unbiased from any industries,\cite{4, 5, 22-26} namely key opinion leaders.\cite{27, 28} This trend would exist among Japanese otorhinolaryngologists, considering previous studies showing that there were substantial and prevalent financial relationships between leading otorhinolaryngologists and pharmaceutical companies in other specialties in Japan.\cite{4, 7, 29, 30} However, there was lack of assessment regarding the whole picture of the financial relationships between pharmaceutical companies and otorhinolaryngologists in Japan. Thus, this study aimed to evaluate the magnitude, prevalence, and trend in personal payments made to otorhinolaryngologists by pharmaceutical companies for the latest years in Japan.

**Methods**

**Study design and study participants**

This retrospective study examined the magnitude and trends in financial relationships between pharmaceutical companies and all otorhinolaryngologists board-certified by the Japanese Society of Otorhinolaryngology-Head and Neck Surgery (JSO-HNS). As the JSO-HNS did not disclose the name list of board-certified otorhinolaryngologists for the previous years, we considered all board-certified otorhinolaryngologists in 2021. The JSO-HNS, established in 1893, is the sole and most authoritative professional medical society certifying otorhinolaryngologists in the field of otorhinolaryngology and head and neck surgery in Japan. The JSO-HNS has contributed to training otorhinolaryngologists, funded clinical trials and basic research, published many clinical practice guidelines for otorhinolaryngological diseases, and issued the English-language academic journal (*Auris Nasus Larynx*). This study defined leading otorhinolaryngologists as board-certified otorhinolaryngologists authoring clinical practice guidelines, board members of JSO-HNS, and editorial members of *Auris Nasus Larynx*.

**Data collection**

As the JSO-HNS did not disclose the name list of board-certified otorhinolaryngologists for the previous years, the name, practicing region and prefecture of all board-certified otorhinolaryngologists in 2021 were extracted from the official webpage of the JSO-HNS (http://www.jibika.or.jp/members/nintei/senmon/senmon-kensaku.html). Furthermore, we collected the name of all clinical practice guideline authors issued and reviewed by the JSO-HNS between 2015 and 2020 (including one year before and after the payment period), the JSO-HNS board members in 2018-2019 and 2020-2021, and editorial members of the *Auris Nasus Larynx* in April 2022. For data collection of society board members, we previously collected the name list of JSO-HNS in 2018-2019 and 2020-2021.\cite{25} As the *Auris Nasus Larynx* did not publicly provide the name list of editorial board members in previous years, we collected the latest editorial members of *Auris Nasus Larynx* in April 2022.

The payments concerning lecturing, consulting, and writing paid to the board-certified otorhinolaryngologists were extracted from a total of 92 pharmaceutical companies belonging to the JPMA between 2016 and 2019. The period of payment data collection was determined by our availability of data collection. The companies have published and updated the payment data each year on their company webpages. The payment data for all companies belonging to the JPMA were collected from 2016 and as of May 2022, the payment data of 2019 were the latest analyzable data in Japan. Payment categories were described in our previous study and the JPMA transparency guideline.\cite{3, 31} The detailed procedure of payment collection was noted previously.\cite{5, 7, 29}

**Analysis**
First, payment data were descriptively analyzed. Payments per physician were also calculated only for physicians receiving payment each year, as in other previous studies.[7, 12, 14, 32] Second, the payment concentration was evaluated by the shares of the payment values held by the top 1%, 5%, 10%, and 25% of the otorhinolaryngologists and the Gini coefficient at the physician level. The Gini index ranges from 0 to 1, and the greater the Gini index, the greater the disparity in the distribution of payments.[4, 7, 33] Third, we calculated descriptive statistics and evaluated payment differences among the leading otorhinolaryngologists, including guideline authors, society board members, journal editors, and other otorhinolaryngologists. The differences in payments by each variable were evaluated by Chi-square and Fisher exact tests for the proportion of otorhinolaryngologists receiving payments and by Mann-Whitney U test for payment values per otorhinolaryngologist. Furthermore, the linear log-linked Poisson regression model was used to assess the association between relative risk of payment receipt and the otorhinolaryngologist characteristics. To account for the skewed distribution of payment values, negative binomial regression model was employed to evaluate the association between relative monetary value of payments per physician and the otorhinolaryngologist characteristics. Finally, we evaluated the trends in payments per physician and number of physicians receiving payments between 2016 and 2019 by the population-averaged generalized estimating equation (GEE) with the panel data of the annual payments. As the payment distribution was highly skewed (Supplemental Material 1), the negative binomial GEE model for the payment values per physician and linear log-linked GEE model with Poisson distribution for the number of otorhinolaryngologists with payments were selected.[7, 34] The payment values were converted from Japanese yen (¥) to US dollars ($) using the 2019 average monthly exchange rates of ¥109.0 per $1. All analyses were conducted using Microsoft Excel, version 16.0 (Microsoft Corp) and Stata version 15 (StataCorp).

Ethical approval

The Ethics Committee of the Medical Governance Research Institute approved this study (approval number: MG2018-04-20200605; approval date: June 5, 2020). As this retrospective analysis only included publicly available information, informed consent was waived by the ethics committee.

Patient and public involvement

No patient involved.

Results

Overall and per-otorhinolaryngologist payments

At the time of this study, we identified 8,190 otorhinolaryngologists board certified by the JSO-HNS. Of the 8,190 otorhinolaryngologists, 3,667 (44.8 %) were paid a total of $13,873,562, entailing 22,076 contracts in payments for lecturing, consulting, and writing by 72 pharmaceutical companies between 2016 and 2019. (Table 1) Median payments per physician were $0 (interquartile range [IQR]: $0 – $851) for overall otorhinolaryngologists. For otorhinolaryngologists receiving payments, median payments per physician was $1,022 (IQR: $473–$2,526), while average payments were $3,783 (standard deviation [SD]: $14,349). The median payment contracts and number of companies making payments per physician were 3.0 (IQR: 1.0–6.0) and 2.0 (IQR: 1.0–4.0) over the four years, respectively. One otorhinolaryngologist received a maximum payment of $490,081 and 332 payment contracts.

Table 1. Summary of personal payments from pharmaceutical companies to board-certified otorhinolaryngologists between 2016 and 2019

<table>
<thead>
<tr>
<th>Variables</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payment values, $</td>
<td>13,873,562</td>
</tr>
<tr>
<td>Instances, n</td>
<td>22,076</td>
</tr>
<tr>
<td>Companies, n</td>
<td>72</td>
</tr>
<tr>
<td>Average per physician (SD)</td>
<td></td>
</tr>
</tbody>
</table>
### Variables

<table>
<thead>
<tr>
<th></th>
<th>Payment values, $</th>
<th>Instances, n</th>
<th>Companies, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median per physician (IQR)</td>
<td>3,783 (14,349)</td>
<td>6.0 (13.6)</td>
<td>3.0 (3.0)</td>
</tr>
</tbody>
</table>

|                           | 1,022 (473-2,526) | 3.0 (1.0-6.0) | 2.0 (1.0-4.0) |

<table>
<thead>
<tr>
<th>Range</th>
<th>Payment values, $</th>
<th>Instances, n</th>
<th>Companies, n</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>28-490,081</td>
<td>1.0-332</td>
<td>1.0-27.0</td>
</tr>
</tbody>
</table>

### Category of payments

<table>
<thead>
<tr>
<th>Category</th>
<th>Payment value, $ (%)</th>
<th>Instances, n (%)</th>
<th>Physicians, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lecturing</td>
<td>11,968,045 (84.8)</td>
<td>18,714 (84.8)</td>
<td>3373 (41.2)</td>
</tr>
<tr>
<td>Consulting</td>
<td>1,075,487 (7.8)</td>
<td>2,121 (9.6)</td>
<td>1112 (13.6)</td>
</tr>
<tr>
<td>Writing</td>
<td>701,495 (5.1)</td>
<td>1,075 (4.9)</td>
<td>494 (6.0)</td>
</tr>
<tr>
<td>Other</td>
<td>128,534 (0.9)</td>
<td>168 (0.8)</td>
<td>113 (1.4)</td>
</tr>
</tbody>
</table>

Abbreviations: SD (standard deviation), IQR (interquartile range)

**Payments by category and payment concentration**

Payments for lecturing occupied for 86.3% of overall monetary values ($11,968,045) and 84.8% of overall payment contracts (18,714 contracts) between 2016 and 2019. Of 8,190 eligible otorhinolaryngologists, 3,373 (41.2%), 1,112 (13.6%), and 494 (6.0%) received one or more compensation payments for lecturing, consulting, and writing from the pharmaceutical companies over the four years, respectively.

While majority of otorhinolaryngologists did not receive any payments from the pharmaceutical companies over the four years, top 1%, 5%, 10%, and 25% of otorhinolaryngologists received 42.3% (95% confidence interval [95% CI]: 37.2–47.4%), 69.3% (95% CI: 65.9–72.8%), 80.6% (95% CI: 78.3–82.9%), and 94.8% (95% CI: 94.1–95.5%) of overall payments, respectively. (Supplemental Material 2) The Gini coefficient for four-year combined payments per physician was 0.889, indicating that the payments disproportionately concentrated on small numbers of otorhinolaryngologists.

**Payments to leading otorhinolaryngologists: clinical practice guideline authors, society board members, and academic journal editors**

We identified a total of 139 individual authors from eight clinical practice guidelines accredited or authorized by the JHO-HNS between 2015 and 2020. (Table 2) Of the 139 authors, 101 (72.7%) authors were board-certified otorhinolaryngologists and 94 (69.3%) received one or more personal payments for lecturing, consulting, and writing compensations. A total of $2,435,239 (17.6% [2,435,239 out of $13,873,562] of
overall personal payments from the companies) were made to 94 otorhinolaryngologists authoring clinical practice guidelines. The aggregated payment per physician was significantly higher among otorhinolaryngologists authoring clinical practice guidelines than that of otorhinolaryngologists not involved in authoring guidelines ($11,522 [IQR: $3,090–$32,390] vs $0 [IQR: $0–$817], p<0.001).

All 36 board members of the JSO-HNS during the 2018-2019 and 2020-2021 period were board-certified otorhinolaryngologists. Of 36 board-certified otorhinolaryngologists with the JSO-HNS board membership, 34 (94.4%) received a total of $1,234,715 (8.9% of overall payments) and a median payment of $22,261 (IQR: $4,537–$50,331) per physician. (Table 2) Both the proportion of otorhinolaryngologists receiving payments (94.4% vs 44.6%, p<0.001) and the payments per physician ($22,261 [IQR: $4,537–$50,331] vs $0 [IQR: $0–$817], p<0.001) were significantly higher for the otorhinolaryngologists positioned as the JSO-HNS board member than those without board membership.

There were 20 Japanese editors of the *Auris Nasus Larynx* and among them, 19 editors were board-certified otorhinolaryngologists. All 19 (100%) board-certified otorhinolaryngologists who are editors of the *Auris Nasus Larynx* received payments with $774,171 (5.6% of overall payments) in total and $35,143 (IQR: $7,733–$50,373) in median per-physician payments from pharmaceutical companies. (Table 2)

The multivariable Poisson regression model showed that clinical practice guidelines authorship, JSO-HNS board membership, and editorial membership in the academic journal were significantly associated with 1.96 (95% CI: 1.82–2.12) times, 1.47 (95% CI: 1.10–1.79) times, and 1.21 (95% CI: 1.11–1.33) times higher likelihood to accept personal payments from pharmaceutical companies than those without authorships or memberships. (Table 2) The multivariable negative binomial regression model indicated that clinical practice guidelines authorship and JSO-HNS board membership were positively associated with 13.04 times (95% CI: 9.55–17.79) times and 8.57 (95% CI: 3.04–24.17) times higher monetary values in personal payments, while editorial membership in the academic journal was negatively associated with payment values.

Table 2. Payments to the board-certified otorhinolaryngologists with leading roles between 2016 and 2019

<table>
<thead>
<tr>
<th>Physician with payments</th>
<th>Physician with payments</th>
<th>Payment per physician $</th>
<th>Payment per physician $</th>
<th>Payment per physician $</th>
<th>Relative payments</th>
<th>Relative payments</th>
<th>Relative payments</th>
<th>Pay value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (%)</td>
<td>P value</td>
<td>Number (%)</td>
<td>P value</td>
<td>Number (%)</td>
<td>P value</td>
<td>Number (%)</td>
<td>P value</td>
<td>Number (%)</td>
</tr>
<tr>
<td>Clinical practice guideline</td>
<td>Non-guideline author otorhinolaryngologists</td>
<td>Otorhinolaryngologists authoring guideline</td>
<td>3,573</td>
<td>&lt;0.001</td>
<td>1,414 (8,751)</td>
<td>0 (0–817)</td>
<td>&lt;0.001</td>
<td>Ref.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The total annual payments from the pharmaceutical companies ranged from $3,356,647 in 2016 to $3,615,634 in 2017. A total of 1,988 (24.3%) otolaryngologists in 2019 to 2,129 (26.0%) otolaryngologists in 2018 received more than one personal payment from the companies in a single year. (Table 3) Median annual payments per physician were $511 (IQR: $307–$1,188) in 2016 to $619 (IQR: $473–$1,328) in 2019, while average annual payments per physician were $1,663 (SD: $5,505) to $1,761 (SD: $5,518). There were no significant annual changes in total payments, payments per physician, and the number of otolaryngologists receiving payments. A sensitivity analysis, limiting payments from 63 companies whose payment data were available throughout the four years, also confirmed that there were no significant annual changes in total payments, payment per physician, and the number of otolaryngologists with payments between 2016 and 2019.

Table 3. Trend of personal payments from pharmaceutical companies to board-certified otolaryngologists between 2016 and 2019

<table>
<thead>
<tr>
<th>Physician with payments $</th>
<th>Payment per physician $</th>
<th>Payment per physician $</th>
<th>Payment per physician $</th>
<th>Relative payments</th>
<th>Relative payments</th>
<th>Relative payments</th>
<th>Ref.</th>
<th>Ref.</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-board members</td>
<td>3633 (44.6)</td>
<td>1,550 (9,109)</td>
<td>0 (0–831)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>Ref.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Board membership</td>
<td>34 (94.4)</td>
<td>34.298 (44,388)</td>
<td>22.261 (4,537–50,331)</td>
<td>1.47</td>
<td>8.57</td>
<td>(3.04–24.17)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Journal editorial membership $</td>
<td>3,648 (44.7)</td>
<td>1,603 (9,365)</td>
<td>0 (0–851)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>Ref.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-editor otohinalaryngologists</td>
<td>19 (100)</td>
<td>40,746 (46,059)</td>
<td>35,143 (7,733–50,373)</td>
<td>1.21</td>
<td>0.54</td>
<td>(0.38–0.77)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Editor otohinalaryngologists</td>
<td>22 (100)</td>
<td>(46,059)</td>
<td>(7,733–50,373)</td>
<td>1.11</td>
<td>0.77</td>
<td>(0.38–0.77)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: SD (standard deviation), IQR (interquartile range), 95% CI (95% confidence interval)

a The difference in proportion of otorhinolaryngologists with payments was evaluated by the chi-square test and fisher exact test.

b The difference in payments per otorhinolaryngologist was evaluated by the Mann–Whitney U test for two groups.

c The interaction between continuous variable society board membership and journal editorial membership were included in multivariable regression models. The relative risk for the interaction was 0.81 (95% CI: 0.63–1.03) and relative monetary value for the interaction was 2.29 (95% CI: 0.63–8.38).

The JSO-HNS required clinical practice guideline authors to declare their financial conflicts of interest (FCOIs) with the industry, and the authors disclosed their FCOIs in the guidelines. Meanwhile, there was no FCOI disclosure among the JSO-HNS board members and the academic journal editors.
<table>
<thead>
<tr>
<th>Variables</th>
<th>Payment year</th>
<th>Payment year</th>
<th>Payment year</th>
<th>Payment year</th>
<th>Average yearly change (95%CI), %</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All pharmaceutical companies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total payments, $</td>
<td>3,356,647</td>
<td>3,615,634</td>
<td>3,463,336</td>
<td>3,437,945</td>
<td>-0.26 (-2.06-2.59)</td>
<td>0.84</td>
</tr>
<tr>
<td>Average payments per physician (SD), $</td>
<td>1,663 (5,505)</td>
<td>1,761 (5,518)</td>
<td>1,627 (4,319)</td>
<td>1,729 (4,249)</td>
<td>0.27 (-2.72-3.35)</td>
<td>0.86</td>
</tr>
<tr>
<td>Median payments per physician (IQR), $</td>
<td>511 (307-1,188)</td>
<td>511 (307-1,209)</td>
<td>613 (411-1,211)</td>
<td>619 (473-1,328)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range of payments per physician, $</td>
<td>28-164,556</td>
<td>94-151,906</td>
<td>92-91,580</td>
<td>92-82,038</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physicians with payments, n (%)</td>
<td>2,019</td>
<td>2,053</td>
<td>2,129</td>
<td>1,988</td>
<td>-0.083 (-1.34-1.19)</td>
<td>0.90</td>
</tr>
<tr>
<td>Gini index</td>
<td>0.923</td>
<td>0.922</td>
<td>0.910</td>
<td>0.913</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical companies with 4-years payment dataa</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total payments, $</td>
<td>3,315,057</td>
<td>3,608,993</td>
<td>3,417,689</td>
<td>3,358,464</td>
<td>-0.18 (-3.06-2.70)</td>
<td>0.90</td>
</tr>
<tr>
<td>Average payments per physician (SD), $</td>
<td>1,653 (5,491)</td>
<td>1,758 (5,509)</td>
<td>1,616 (4,290)</td>
<td>1,714 (4,219)</td>
<td>-0.18 (-3.14-2.87)</td>
<td>0.91</td>
</tr>
<tr>
<td>Median payments per physician (IQR), $</td>
<td>511 (307-1,188)</td>
<td>511 (307-1,209)</td>
<td>613 (409-1,211)</td>
<td>613 (473-1,306)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range of payments per physician, $</td>
<td>28-163,610</td>
<td>94-151,906</td>
<td>92-90,161</td>
<td>92-82,038</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physicians with payments, n (%)</td>
<td>2,005</td>
<td>2,053</td>
<td>2,115</td>
<td>1,959</td>
<td>-0.37 (-1.63-0.90)</td>
<td>0.56</td>
</tr>
<tr>
<td>Gini index</td>
<td>0.923</td>
<td>0.922</td>
<td>0.911</td>
<td>0.914</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Abbreviations: standard deviation (SD); interquartile range (IQR); and the United States (US)

a There were 9 companies without payment data through the four years and were excluded from the trend analysis.

Payments by company

Total payments by company were described in Figure 1. Kyorin Pharmaceutical paid the largest personal payments to the board-certified otorhinolaryngologists in total, accounting for 12.6% ($1,745,682 out of $13,873,561) of overall payments. Similarly, payments from Taiho Pharmaceutical and Mitsubishi Tanabe Pharma, the second and third largest paying companies, accounted for 12.3% ($1,705,181) and 12.3% ($1,704,126) of overall payments, respectively. The payments from the top ten companies occupied 73.3% of overall personal payments between 2016 and 2019. Most companies made personal payments for the purpose of lecturing to the board-certified otorhinolaryngologists.

Discussion

This study demonstrates that a minority but large number of otorhinolaryngologists received personal payments from pharmaceutical companies for the reimbursement of lecturing, consulting, and writing in Japan. Large amounts of these personal payments were significantly concentrated on a small number of otorhinolaryngologists with leading positions such as clinical practice guideline authors, society board members, and academic journal editors in the field of otorhinolaryngology. We observed that the personal financial relationships between the otorhinolaryngologists and pharmaceutical companies had remained stable over the four years in Japan. Our findings show significant similarities and differences compared to previous studies assessing this issue in Japan and other developed countries.

First, this large sample-sized longitudinal observational study elucidated that 44.8 % of all board-certified otorhinolaryngologists received a median personal payment of $1,022 from the pharmaceutical companies. Previous studies in Japan reported that there was an increasing trend in physicians receiving payments from pharmaceutical companies in terms of the number of physicians with payments and payments per physician.[7, 8, 29, 34] Proportion of physicians with payments and median four-year personal payments were from 62.0% in pulmonology[34] to 70.6% in medical oncology[8] and $2,210 in pulmonology[34] to $3,183 in infectious diseases, respectively.[29] Smaller payments made to otorhinolaryngologists observed in this study were consistent with many previous studies in the United States.[9-11, 14, 35] Pathak et al. found that US otorhinolaryngologists received the second lowest personal payments in surgical specialties between 2014 and 2015,[11] Cvetanovich et al.[35] and Rathi et al.[9] reported that the trend of lowest payments made to the otorhinolaryngologists persisted since the launch of the Open Payments Program in 2013. Fewer expensive and novel drugs and the large number of otorhinolaryngologists could contribute to the lower payment values both in Japan and the US.

Second, we observed that the personal financial relationships between the otorhinolaryngologists and pharmaceutical companies remained stable over the four years at both low monetary payment values and number of otorhinolaryngologists with payments. In contrast to our findings, Morse et al. previously observed that there was an increasing trend in personal payments among the US otorhinolaryngologists between 2014 and 2016,[10] while the increasing trend was not observed in 2017.[12] Meanwhile, even lower personal payments to otorhinolaryngologists significantly influence otorhinolaryngologists’ clinical practice, such as increasing brand-name prescripions,[36] prescribing more brand-name intranasal corticosteroids over generic alternatives,[37] and performing more controversial treatment, sinus balloon catheter dilation.[38, 39] Accumulating evidence strongly suggests that personal payments made by pharmaceutical companies significantly distort physicians’ prescribing patterns which were potentially harmful to patients,[36, 38, 40-46] increase healthcare costs,[40, 47, 48] and lower patients’ trust in physicians,[49-51] while many physicians have denied the influence and justified their personal financial relationships with industries.[52-54]

In addition, our study directly demonstrated that large amounts of personal payments significantly concentrated on only a small number of otorhinolaryngologists positioned in authoritative and public roles, such as
clinical practice guideline authors, society board members, and academic journal editors. High concentration of payments on leading physicians, namely key opinion leaders, are pervading in medicine worldwide.[22-24, 26, 28] Moynhian et al. elucidated that 72% of board members of ten US professional medical societies in the highest financial burden disease areas accepted a median of $6,026 in personal payments from pharmaceutical and medical devices companies between 2013 and 2018.[23] Similarly, Saito et al. reported that 86.9% of the board member from 19 major Japanese professional medical societies received a median per-physician payment of $7,486 in 2016.[25] Also, there are prevalent and large FCOIs among clinical practice guideline authors and journal editors in many developed countries.[4, 6, 55-63] Furthermore, many of these financial relationships between leading physicians and pharmaceutical companies are undisclosed to the public and underreported.[5, 23, 30, 61, 64, 65] As we found that the JSO-HNS did not disclose FCOIs among the board members and academic journal editors. Unlike leading physicians conducting clinical trials and research sponsored by the industry, such leading physicians as clinical practice guideline authors, society board members, and academic journal editors are necessary to manage and, if possible, be free from financial interest with the industry, as their financial interest with industry conflict with their primary interest. Currently, FCOIs among clinical practice guideline authors are strictly managed by many guideline developing organizations: minority of guideline authors with FCOIs involve in guideline development, all FCOIs for the past three years are declared and disclosed by guideline authors, and the guideline chairperson is required to be free from any FCOIs with industry.[66-68] Several academic journals such as the Annals of Emergency Medicine, the official journal of the American College of Emergency Physicians, and Journal of Urology, the official journal of the American Urological Association, disclose the editors’ FCOIs on journal webpages.[61] Transparency and rigorous managements are necessary in financial relationships between pharmaceutical companies and leading otorhinolaryngologists with authoritative and public positions.

Limitations

This study included several limitations. First, there would be underestimated payments made by non-member companies of JPMA to the otorhinolaryngologists. However, as the member companies accounted for 80.8% of total pharmaceutical sales in Japan in 2018,[1] such underestimation of payments could be minimized by including data from all member companies. Second, the pharmaceutical companies were not required to disclose other categories of payments such as meals, beverages, travel, and stock ownerships at an individual level, according to the JPMA guidance.[3] This could have led to underestimations of the extent and prevalence of overall financial relationships between otorhinolaryngologists and industries. Third, this study included otorhinolaryngologists as of November 2021, as the JSO-HNS did not disclose the name list of otorhinolaryngologists for previous years. Therefore, this study would have included otorhinolaryngologists who were not certified during the study period. Fourth, the payment magnitude and trend may not be applicable to other countries.

Conclusion

Although a minority of otorhinolaryngologists board-certified by the Japan Society of Otolaryngology-Head and Neck Surgery stably received personal payments from pharmaceutical companies for the reimbursement of lecturing, consulting, and writing between 2016 and 2019, large amounts of payments significantly concentrated on a relatively small number of otorhinolaryngologists. Leading otorhinolaryngologists such as clinical practice guideline authors, society board members, and academic journal editors significantly accepted far larger personal payments than those who were not.

Ethical approval

The Ethics Committee of the Medical Governance Research Institute approved this study (approval number: MG2018-04-20200605; approval date: June 5, 2020). As this retrospective analysis only included publicly available information, informed consent was waived by the ethics committee.

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interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.


Figure 1. Payment trends by company

Total payments made to all board-certified otorhinolaryngologists for lecturing, consulting, and writing between 2016 and 2019 by each company.

Supplemental Material 1. Distribution of payment values per physician
Supplemental Material 2. Payment concentration