Financial conflicts of interest and disclosure in clinical practice guidelines for bipolar disorder and major depressive disorder in Japan

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Article

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Abstract

Clinical practice guidelines (CPGs) are essential for standardizing patient care based on evidence-based medicine. However, the presence of financial conflicts of interest (COIs) among CPG authors can undermine their credibility. This cross-sectional analysis of disclosed payments from pharmaceutical companies assesses the prevalence and magnitude of personal payments for lecturing, consulting, and writing to CPGs for bipolar disorder and major depressive disorder in Japan between 2016 and 2020. This study found that 93.5% of authors received payments over a five-year period, with total payments exceeding $4 million. The median payment per author was $49,422 (interquartile range: $7,792 – $111,567), with a notable concentration of payments among a small number of authors, including the CPG chairperson. Despite these extensive financial relationships, only a fraction of authors disclosed their COIs in the CPGs. These large amounts of personal payments were made by pharmaceutical companies manufacturing new antidepressants and sleeping aids listed in the CPGs. The findings highlight deviations from international COI management standards and suggest a need for more stringent COI policies for psychiatry CPGs in Japan.

Introduction

Clinical practice guidelines (CPGs) have been increasingly used as a tool to endorse evidence-based medicine for healthcare professionals in their clinical practice[1, 2]. CPGs are developed based on the best available evidence and include recommendations for diagnosis and treatment of specific diseases. Nevertheless, the integrity and recommendations of CPGs are frequently compromised by conflicts of interest (COIs) between the guideline authors and the pharmaceutical industry, spanning various medical specialties. In the field of psychiatry, there is substantial documentation of ghostwriting by pharmaceutical industry[3] and widespread financial COIs between CPG authors and pharmaceutical companies[4–7]. Furthermore, studies showed that financial COIs are associated with a propensity for CPGs to make recommendations favorable to the healthcare industry[4, 8]. This underscores the necessity for rigorous management of financial COIs among CPG authors, particularly in psychiatry[6, 9, 10].

To enhance the transparency of financial relationships between healthcare professionals and pharmaceutical companies, members of the Japan Pharmaceutical Manufacturers Association have voluntarily disclosed their financial interactions with healthcare professionals and organizations[11]. Subsequent research using this disclosed information has revealed that the vast majority of CPG authors in Japan received personal payments during the CPG development across various medical specialties[11–21]. However, the specifics of these financial relationships between pharmaceutical companies and Japanese CPG authors in psychiatry remain largely unexplored. Considering the patterns observed in previous studies, we hypothesized that financial COIs are widespread among psychiatry CPG authors in Japan.
This cross-sectional analysis evaluated the extent and prevalence of financial interactions between pharmaceutical companies and authors of CPGs for major depressive disorder and bipolar disorder in Japan. The Japanese Society of Mood Disorders is responsible for the development of the sole CPGs for these conditions, namely Treatment Guideline I: Bipolar Disorder[22] and Treatment Guideline II: Major Depressive Disorder[23]. At the time of this study, the latest versions were published in June 2020 and July 2019, respectively.

The Japan Pharmaceutical Manufacturers Association, representing over 70 major pharmaceutical companies, mandates the disclosure of payments for lectures, consultancy, and writing to healthcare professionals, listing the recipients' names on company websites since 2013[24–26]. Despite annual updates and removal of previous years' data by these companies, the Medical Governance Research Institute has independently collected and disclosed this payment data on its public online database from 2016 to 2020, detailing individual physician and company contributions[27]. As the pharmaceutical companies have not individually disclosed other categories of non-research payments such as travel and accommodation fees, food and beverage fees, and royalties and ownership payments, this study incorporated all personal payments for lectures, consultancy, and writing from pharmaceutical companies to the psychiatry CPG authors from 2016 to 2020, following the approach of prior studies[28–31].

The study calculated the proportion of CPG authors receiving personal payments and assessed per-author payment amounts, including median, interquartile range, mean, and standard deviation. Payments were converted from Japanese yen to U.S. dollars using the 2020 average monthly exchange rate of 106.8 yen per $1. Data extraction and analyses were executed using Python 3.9.12 (Python Software Foundation, Beaverton, OR, USA), Microsoft Excel, version 16.0 (Microsoft Corp., Redmond, WA, USA), and Stata version 17.0 (StataCorp, College Station, TX, USA).

During the preparation of this work, the authors used ChatGPT version 4.0 to check and correct grammatical and spelling errors. After using this tool, the authors carefully reviewed and edited the content as needed and takes full responsibility for the content of the publication.

As a retrospective analysis of publicly available data, this study was classified as non-human subjects research and did not require institutional review board approval. The methodology adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline.

Results
The study included 29 authors for the bipolar disorder CPG and 42 for the major depressive disorder CPG, with 25 individuals contributing to both. Consequently, 46 unique CPG authors were analyzed (Table 1). Disclosure of financial COIs within the CPGs was self-reported solely by the writing authors. All authors (100%, 4 out of 4) associated with the bipolar disorder CPG and 85.7% (12 out of 14) with the major depressive disorder CPG declared financial COIs with pharmaceutical companies.

A significant majority, 43 authors (93.5%), received personal payments for lectures, consulting, and writing from pharmaceutical companies between 2016 and 2020 (Table 2). The cumulative personal payments amounted to $4,043,436 from 55 pharmaceutical companies over this period. The median payment per author was $49,422 (IQR: $7,792 – $111,567), and the mean payment was $87,901 (SD: $111,270), indicating a skewed distribution where a few authors received disproportionately high payments. Notably, 15 authors (32.6%) received in excess of $100,000 over five years. The chairperson of the guideline development committee received the highest total payment of $506,108 for lecturing, consulting, and writing from pharmaceutical companies during this time. Payments for lecturing constituted $2.7 million (65.8% of the total), with consulting and writing making up 25.8% ($1.0 million) and 8.3% ($337,255), respectively.

Annual analysis revealed a decline in total payments to CPG authors from $959,503 in 2016 to $697,170 in 2020 (Table 2). Correspondingly, the median annual payment per author decreased from $11,865 (IQR: $1,773 – $24,498) in 2016 to $2,693 (IQR: $0 – $22,968) in 2020. The proportion of authors receiving payments also fell from 91.3% in 2017 to 73.9% in 2020, yet a majority still received at least one personal payment annually.

Payments from the top 5 and 10 pharmaceutical companies constituted 53.3% ($2.2 million) and 83.1% ($3.4 million) of the total payments, respectively (Table 3). Sumitomo Pharma was the most generous, contributing $695,031 (17.2%), followed by Eisai (10.1%, $408,323), MSD (8.8%, $357,526), Otsuka Pharmaceutical (8.8%, $354,638), and Takeda Pharmaceutical (8.3%, $337,370). Among these, MSD, Pfizer Japan, and Meiji Seika notably reduced their non-research payments from 2016 to 2020, whereas Eisai increased its payments from $45,779 in 2016 to $151,856 in 2020.

Table 4 presents the types of financial COIs self-reported by the CPG authors within each respective guideline. Among the six categories extracted from the CPG disclosures, compensation for lecturing was the most frequently declared (100% for the bipolar disorder CPG and 78.6% for the major depressive disorder CPG). This was followed by scholarship donations and participation in pharmaceutical company advisory boards. The lack of a specified declaration period precluded the assessment of the accuracy of each CPG author's self-reported COI status against the payment data released by the pharmaceutical companies.

**Discussion**

This cross-sectional analysis of publicly disclosed payment data from pharmaceutical companies provides a detailed examination of the extent and prevalence of financial COIs among authors of the
Japanese Society of Mood Disorders' Treatment Guideline I: Bipolar Disorder[22] and Treatment Guideline II: Major Depressive Disorder[23]. These CPGs are considered by physicians the authoritative and trustworthy sources for the treatment of bipolar disorder and major depressive disorder in Japan[32]. To the best of our knowledge, this is the first in-depth study to analyze the financial relationships between psychiatry CPG authors and pharmaceutical companies in Japan using disclosed payment data. The findings reveal that a significant majority (93.5%) of CPG authors received personal payments for lecturing, consulting, and writing, with a total sum of $4.0 million between 2016 and 2020. The median payment per author was $49,422, with a minority, including the CPG chairperson, receiving substantial sums. Nearly all authors involved in writing the CPGs self-reported financial COIs with pharmaceutical companies. Notably, the bulk of personal payments to CPG authors came from companies that manufacture antidepressants and sleeping pills in Japan. However, other CPG authors did not publicly disclose their financial COIs with these companies. When compared to previous studies and international COI policies for CPG authors, these findings raise concerns for physicians, patients, policymakers, and other stakeholders within and beyond Japan.

The study highlights that over 93% of the authors of CPGs for bipolar disorder and major depressive disorder had financial relationships with pharmaceutical companies. Given the publication dates of the CPGs between 2019 and 2020, these financial relationships likely occurred during the development of the CPGs. This high percentage of authors receiving personal payments aligns with findings from other specialties within Japan[11–14, 16–19, 21, 33–36], where the proportion of CPG authors with personal payments ranged from 86.4% in cardiology[37] to 94.6% in hematology[13].

In contrast, research from other developed countries, such as the United States, reports lower proportions of CPG authors with financial COIs. For instance, 67% of authors for the DSM-5 mood disorders section disclosed financial COIs with the healthcare industry[9]. Additionally, a study by Cosgrove et al. found that only 18% of major depressive disorder CPG authors across eight countries had financial COIs with pharmaceutical companies[4, 10]. In Canada, half of the authors of the CPG for depressive disorder developed by the Canadian Network for Mood and Anxiety Treatments reported financial COIs with the healthcare industry[38]. Other specialties in the United States also showed lower percentages, with 53% of gastroenterology CPG authors[39] and 59.3% of urology CPG authors receiving personal and/or research payments[40]. Moreover, Mooghali et al. reported that 73.7% of physician CPG authors in the United States received personal and/or research payments from healthcare companies[41].

Furthermore, this investigation revealed that a select group of CPG authors, including the chairperson, received substantial personal payments from pharmaceutical companies. Only authors involved in writing the CPGs were mandated to declare their financial COIs, while other contributors did not publicly disclose any financial COIs with these companies. These results indicate that authors of Japanese CPGs for bipolar disorder and major depressive disorder clearly violate international COI policies on CPG development in several respects. The U.S. National Academy of Medicine’s 2011 report and the Guidelines International Network advocate for a majority of CPG authors to be free from financial COIs[1, 2]. These policies also stipulate that the chairperson of CPG development should not hold any COIs[1, 2].
The Guideline Panel Review Working Group's criteria for red flags, as published in the British Medical Journal in 2013, indicate that financial COIs held by a CPG chairperson and multiple authors are significant concerns for the trustworthiness of the CPGs[42]. The prevalence of COIs exceeding 93% in this study is not a marginal discrepancy but a significant deviation from these standards, casting doubt on the objectivity and reliability of the guidelines.

Moreover, the study uncovered that substantial payments were made by pharmaceutical companies marketing new antidepressants and sleep aids in Japan. For example, Sumitomo Pharma, the top paying company, manufactures lurasidone (brand name: Latuda), approved for bipolar disorder and schizophrenia in 2020, and co-promotes venlafaxine hydrochloride (brand name: Effexor) with Pfizer Japan since 2018. MSD, another major payer, produces suvorexant (brand name: Belsomra), the world’s first orexin receptor antagonist. Otsuka Pharmaceutical is noted for one of the major manufacturers of atypical antipsychotic medications such as aripiprazole (brand name: Abilify) and brexpiprazole (brand name: Rexulti) which are the most widely prescribed atypical antipsychotic drugs in Japan[43]. Despite these financial ties between the CPG authors and the pharmaceutical companies, the Japanese Society of Mood Disorders actively endorses adherence to these CPGs[44, 45]. Considering that the CPGs for bipolar disorder and major depressive disorder include pharmacotherapy recommendations involving drugs from these companies, it is imperative to address the close financial relationships between CPG authors and the pharmaceutical industry. We strongly recommend the Japanese Society of Mood Disorders to enforce more transparent and stringent COI management strategies in the CPG development process for bipolar disorder and major depressive disorder, ensuring the integrity and credibility of these guidelines.

Limitations

This study is subject to several limitations. Primarily, the study focus on CPGs for bipolar disorder and major depressive disorder in Japan would limit the generalizability of our findings to other medical fields or countries. Additionally, the payment data were derived from a secondary source, the Medical Governance Research Institute's database, which contains payment information from member companies of the Japan Pharmaceutical Manufacturers Association for the period 2016–2020[25, 46]. Absent legal mandates for precise payment disclosures in Japan, the potential for inaccuracies or underreporting in the database cannot be discounted. Furthermore, the voluntary nature of these disclosures means that financial interactions between CPG authors and non-disclosing pharmaceutical entities may remain undetected. Nevertheless, given that the member companies account for 80% of the market share for drugs and medical products in Japan[47], the impact of financial relationships between the CPG authors and uncovered companies would be minimized.

Conclusions

More than 93% of the authors of the Treatment Guidelines for Bipolar Disorder and Major Depressive Disorder developed by the Japanese Society of Mood Disorders received personal payments for the
reimbursement of their lecturing, consulting, and writing activities from the pharmaceutical companies manufacturing related drugs. The total amounts of personal payments to the CPG authors were more than $4.0 million over the five years. Nevertheless, the financial COIs were only declared by the limited group of CPG authors. Further transparent and rigorous COI management strategies must be warranted in the Japanese Society of Mood Disorders.

**Declarations**

**Author contribution:**

A.M. contributed to data collection, resource, software, formal analysis, visualization, supervision, and study administration. All authors (A.M., H.K., and Y.S.) contributed to study conceptualization, methodology, writing the original draft, and reviewing the draft.

**Conflicts of interest:**

The authors declare that there were no conflicts of interest for this study.

**Funding sources:**

The authors declare that there were no funding sources for this study.

**IRB Statement**

As this study was a retrospective analysis of publicly available data and met the definition of non-human subjects research, no institutional board review and approval were required. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline.

**Declaration of generative AI in scientific writing**

During the preparation of this work, the authors used ChatGPT version 4.0 to check and correct grammatical and spelling errors. After using this tool, the authors carefully reviewed and edited the content as needed and takes full responsibility for the content of the publication.

**Data availability statement:**

All data used in this study is available from Yen For Docs database run by Medical Governance Research Institute (https://yenfordocs.jp/) and each pharmaceutical companies belonging to the Japan Pharmaceutical Manufacturers Association.

**Acknowledgments**

The authors appreciate Ms Megumi Aizawa for her dedicated support of my research project. During the preparation of this work, the authors used ChatGPT version 4.0 to check and correct grammatical and
spelling errors. After using this tool, the authors carefully reviewed and edited the content as needed and takes full responsibility for the content of the publication.

References


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Tables

Table 1. Demographic characteristics of clinical practice guideline authors for bipolar disorder and major depressive disorder
### Table 2. Summary of personal payments from pharmaceutical companies to psychiatry clinical practice guideline authors between 2016 and 2020

<table>
<thead>
<tr>
<th>Variables</th>
<th>Guideline disease category</th>
<th>Overall</th>
</tr>
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<td></td>
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<td>Major depressive disorder</td>
</tr>
<tr>
<td></td>
<td>29</td>
<td>42</td>
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<td>Role of guideline authors</td>
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<tr>
<td>Writing authors</td>
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<td>14 (33.3)</td>
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<tr>
<td>Supporting authors</td>
<td>5 (17.2)</td>
<td>11 (26.2)</td>
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<tr>
<td>Guideline development committee authors</td>
<td>20 (69.0)</td>
<td>17 (40.5)</td>
</tr>
<tr>
<td>Number of authors with self-declared conflicts of interest, n (%)(^a)</td>
<td>4 (100)</td>
<td>12 (85.7)</td>
</tr>
</tbody>
</table>

\(^a\) Conflicts of interest were only declared by writing authors.

Table 2. Summary of personal payments from pharmaceutical companies to psychiatry clinical practice guideline authors between 2016 and 2020.
<table>
<thead>
<tr>
<th>Variables</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>Total amounts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total amount of payments, $</td>
<td>959,503</td>
<td>873,288</td>
<td>769,649</td>
<td>743,826</td>
<td>697,170</td>
<td>4,043,436</td>
</tr>
<tr>
<td>Mean payments per author (standard deviation), $</td>
<td>20,859 (27,155)</td>
<td>18,985 (24,259)</td>
<td>16,732 (24,649)</td>
<td>16,170 (21,256)</td>
<td>15,156 (22,221)</td>
<td>87,901 (111,270)</td>
</tr>
<tr>
<td>Median payments per author (interquartile range), $</td>
<td>11,865 (1,773 – 24,498)</td>
<td>10,239 (1,517 – 25,058)</td>
<td>2,294 (521 – 6,465)</td>
<td>4,476 (531 – 26,830)</td>
<td>2,693 (0 – 22,968)</td>
<td>49,422 (7,792 – 111,567)</td>
</tr>
<tr>
<td>Maximum, $</td>
<td>120,927</td>
<td>100,635</td>
<td>114,153</td>
<td>107,553</td>
<td>94,362</td>
<td>506,108</td>
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</table>

Authors with payments (N=46), n (%)

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<th>Any payments</th>
<th>40 (87.0)</th>
<th>42 (91.3)</th>
<th>36 (78.3)</th>
<th>38 (82.6)</th>
<th>34 (73.9)</th>
<th>43 (93.5)</th>
</tr>
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<td>24 (52.2)</td>
<td>23 (50.0)</td>
<td>20 (43.5)</td>
<td>22 (47.8)</td>
<td>19 (41.3)</td>
<td>33 (71.7)</td>
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<tr>
<td>&gt;$50,000</td>
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<td>4 (8.7)</td>
<td>2 (4.4)</td>
<td>3 (6.5)</td>
<td>23 (50.0)</td>
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<td>1 (2.2)</td>
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<tr>
<td>&gt;$250,000</td>
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<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>3 (6.5)</td>
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Japanese yen (¥) were converted to US dollars ($) using the 2020 average monthly exchange rate of ¥106.8 per $1.

Table 3. Payment amounts by top 10 companies.
<table>
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<th>Variables</th>
<th>Payment amounts (%)</th>
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<td>Total amounts of payments</td>
<td>959,503</td>
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<td>873,288</td>
<td>(100)</td>
</tr>
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<td></td>
<td>769,649</td>
<td>(100)</td>
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<td></td>
<td>743,826</td>
<td>(100)</td>
</tr>
<tr>
<td></td>
<td>697,170</td>
<td>(100)</td>
</tr>
<tr>
<td></td>
<td>4,041,648</td>
<td>(100)</td>
</tr>
<tr>
<td>Top 10 companies making the largest payment amounts</td>
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<tr>
<td>Sumitomo Pharma</td>
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<td>127,847</td>
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<td>(2.5)</td>
</tr>
<tr>
<td></td>
<td>155,356</td>
<td>(3.8)</td>
</tr>
</tbody>
</table>

Table 4. Financial conflicts of interest self-declared by the guideline authors
<table>
<thead>
<tr>
<th>Disclosure category</th>
<th>Bipolar disorder (N=4)</th>
<th>Major depressive disorder (N=14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Speaking compensation</td>
<td>4 (100)</td>
<td>11 (78.6)</td>
</tr>
<tr>
<td>Scholarship donation</td>
<td>3 (75.0)</td>
<td>6 (42.9)</td>
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<tr>
<td>Consulting payments</td>
<td>0 (0)</td>
<td>4 (28.6)</td>
</tr>
<tr>
<td>Collaborative research funds</td>
<td>1 (25.0)</td>
<td>2 (14.3)</td>
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<tr>
<td>Advisory board</td>
<td>2 (50.0)</td>
<td>1 (7.1)</td>
</tr>
<tr>
<td>Contracted research funds</td>
<td>1 (25.0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Legends: Proportion of authors reporting conflicts of interest were number of authors reporting conflicts of interest to the total number of writing authors.