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Running Head: Evaluation of COI of PsA Practice Guidelines

Title: Evaluation of Financial and Non-financial Conflicts of Interest and Quality of Evidence underlying Psoriatic Arthritis Clinical Practice Guidelines–Analysis of Personal Payments from Pharmaceutical Companies and Authors' Self-citation Rate in Japan and the United States

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Abstract

Objective

To assess financial conflict of interest (FCOI) and non-financial conflicts of interest (NFCOI) among psoriatic arthritis clinical practice guideline (PsACPG) authors in Japan and US, and to evaluate the quality of evidence and strength of recommendations of PsACPG.

Methods

We performed a retrospective analysis using payment data from major Japanese pharmaceutical companies and the US Open Payments Database from 2016 to 2018. All authors of PsACPG issued by Japanese Dermatological Association (JDAPsACPG) and American College of Rheumatology (ACRPsACPG) were included.

Results

Of 23 CPG authors in Japan, 21 (91.3%) received at least one payment, with the combined total of $3,335,413 between 2016 and 2018. Regarding 25 US authors, 21 (84.0%) received at least one payment, with the combined total of $4,081,629 during the same period. The 3-year combined average payment per author was $145,018 (standard division [SD]: $114,302) in Japan and $162,825 (SD: $259,670) in US. 18 (78.3%) JDAPsACPG and 12 (48.0%) ACRPsACPG authors had undisclosed FCOI worth $474,663 and $218,501, respectively. The percentage of citations with at least one CPG author relative to total citations were 3.4% in Japan and 33.6% in US. 71.4% and 88.8% of recommendations for psoriatic arthritis in JDA and ACR were supported by low or very low quality of evidence.

Conclusion

More rigorous cross-checking of information disclosed by pharmaceutical companies and self-reported by physicians, and more stringent and transparent COI policies are necessary.

Significance and Innovations

- 21 (91.3%) JDAPsACPG and 21 (84.0%) ACRPsACPG authors received at least one payment, with the combined total of $3,335,413 and $4,081,629 between 2016 and 2018.
- 18 (78.3%) JDAPsACPG and 12 (48.0%) ACRPsACPG authors had undisclosed FCOI worth $474,663 and $218,501, respectively.
- 71.4% and 88.8% of recommendations for psoriatic arthritis in JDA and ACR were supported by low or very low quality of evidence.
- More rigorous cross-checking of information disclosed by pharmaceutical companies and self-reported by physicians, and more stringent and transparent COI policies are necessary.

Introduction

Clinical practice guidelines (CPG) help healthcare professionals deliver patient-centered care based on the most rigorous scientific evidence and expert opinion available [1]. However, financial conflicts of interest (FCOI) and non-financial conflicts of interest (NFCOI) can unduly influence CPG development, including bias in treatment recommendations and descriptions[2-4]. Therefore, all CPG authors and contributing organizations are universally expected to manage the FCOI and NFCOI rigorously.[1,5-7]

In addition, recent studies have explored the impact of NFCOI, such as self-citations, on CPG recommendations, which can exceed that of FCOI[7-10]. International Committee of Medical Journal Editors (ICMJE) states NFCOI as "conflicts, such as personal relationships or rivalries, academic competition, and intellectual beliefs"[28] and recommends reporting NFCOI in their COI form. NFCOI is potentially difficult to evaluate, however, the self-citation rate can be used to evaluate NFCOI objectively. Also, self-citation is reported to be mainly caused by confirmation bias or the authors' desire to improve their own academic standing.[11] Thus, we chose self-citation as an index to assess FCOI in this research. Indeed, our previous study found that Japanese otolaryngology CPG authors self-cited 27.9% to 47.6% of all citations within CPG.[10]

CPG authors for diseases in which new or high-cost drugs are used tend to have significant FCOI with pharmaceutical companies.[12,13] Particularly, remarkable progress has been achieved in the treatment of psoriatic arthritis (PsA) over the past three decades[14] with the launch of several novel biological drugs such as risankizumab,[15] secukinumab,[16] brodalumab,[17] and adalimumab.[18] Therefore, appropriate COI management is necessary in both Japan and US to develop a trustworthy PsACPG.

Since the COIs of CPG authors have been reported in multiple countries,[19-25] comparing directly how FCOI and NFCOI is managed in different countries is important for all stakeholders, including healthcare professionals, patients, and CPG authors. However, our previous study has been the only study that evaluated the FCOI of CPG authors in both Japan and US, or NFCOI by self-citation rates in CPG.[10] In addition, these two countries have taken different approaches to FCOI regulation, including or beyond the CPG authors. Therefore, in this study, we aimed to evaluate the prevalence and magnitude of FCOI and NFCOI with pharmaceutical companies among PsACPG authors in Japan and US and to clarify how a disparity in the approaches would affect the extent of the COI and its proper disclosure.

Methods

Study Setting

We conducted cross-sectional analysis to examine the FCOI and NFCOI of PsACPG authors in Japan and US. All authors of the Japanese PsACPG published by the Japanese Dermatological Association (JDA) on December 20, 2019 (JDAPsACPG),[25] and the US PsACPG published by the American College of Rheumatology (ACR) on November 30, 2018 (ACRPsACPG),[26,27]were considered. JDA has 12,080 members as of March 2019 and is considered as the leading medical society for clinical dermatology in Japan. ACR is the most authoritative rheumatology society in US, founded in 1934, with more than 7,700 healthcare professionals, and has developed many CPGs for arthritis and rheumatic diseases. The CPG issued by JDA are influential in Japan, and the CPG issued by ACR is influential in US and several other countries.

Data collection & payment source

Data of author names, gender, affiliations, positions, individual COI statements, cited publications, quality of evidence (QOE), and strength of recommendations was extracted from the CPGs.

The quality of CPGs may be devalued when there are many self-citations by its authors[10], and the self-citation rate has been used as an objective evaluable item for NFCOI in recent years. To assess the extent of NFCOI from self-citation in JDAPsACPG and ACRPsACPG, all citations were extracted. Authors' names were extracted from PubMed and by manual Google searches.

To analyze FCOI of all JDAPsACPG authors, we used payment data published between 2016 and 2018 for all 83 companies belonging to the Japan Pharmaceutical Manufacturers Association. This research focused on personal payments and excluded research payments, since in Japan, the name, institution, and position of the author or researcher who received the research payment is not disclosed, which makes assessing research payments difficult. The period of observation was the fiscal year of 2016 to 2018 with variations among the companies,[26] as the JDAPsACPG was published on December 20, 2019, and the JDA requires CPG authors to report COI for the past three years. We extracted data on individual payments for lecturing, writing, and consultancy, as in our previous studies.[10,12,27] The extracted data includes recipient names, monetary

amount, payment category, and pharmaceutical company name. For each person named in the database we checked to find and remove all duplicates, as described previously.[12]

Similarly, to evaluate FCOI among the ACRPsACPG authors, the US Open Payments Database was used. Since only US physicians were covered, ACRPsACPG authors with MD and affiliated with US organizations were included in the payment search, as described previously[28,29]. The extraction period was set at three years from before the first online publication on November 30, 2018.[30] Payment data for all categories of general payments such as speaking, consulting, meals, and travel expenses from pharmaceutical companies between November 30, 2015, and November 29, 2018, were extracted from this database. Personal payments such as lecturing, writing, and consulting were paid directly to CPG authors by pharmaceutical companies, and considering this nature of payments, personal payments are likely to have a greater impact on authors' work in developing CPG and making CPG recommendations than research payments. Thus, this study focused on the general payments. Further payments made by medical device companies were excluded from the Open Payments data to ensure consistency with the Japanese data, which only covers pharmaceutical companies.[31]

Data Analysis

We reviewed and compared COI policies developed by JDA[32], ACR[33], US National Academy of Medicine[1], Japanese Association of Medical Sciences[34], and Guidelines International Network[5]. The COI policy by Japanese Association of Medical Sciences[34], National Academy of Medicine[1], and Guidelines International Network[5] were considered as international and domestic standard COI policies as of October 28, 2021.

Additionally, descriptive analysis of demographic, self-citation, and payment data was conducted. To evaluate NFCOI, median and interquartile range (IQR) of self-citations to total citations in the CPG were calculated, following our previous study.[10] To assess the accuracy of self-reported FCOI, we compared authors' self-reported FCOI with database-based COI and calculated the number of cases, payments, and undisclosed authors for each of the disclosed and undisclosed FCOI. As indicated by each CPG, the period of collation was set to two years between 2017 and 2018 for JDAPsACPG and one year between 30 November 2017 and 29 November 2018 for ACRPsACPG. Furthermore, since the authors of the JDAPsACPG stated in the CPG that they were following the COI policy of the Japanese Association of Medical Sciences, payments

exceeding 500,000 yen (¥) (US$4,682)/year/company were reported as FCOI. (Supplementary Table S1)
The calculations were based on payments in Japanese yen for the JDAPsACPG and in US dollars for the ACRPsACPG. Japanese yen were converted into US dollars using 2016, 2017 and 2018 average monthly exchange rates of ¥108.8, ¥112.1 and ¥110.4 per $1, respectively. All statistical analyses were performed using Microsoft Excel, version 16.0 (Microsoft Corp), and Stata version 15 (Stata Corporation) by A.M. and H.M.

In evaluating the CPG recommendations, QOE were initially presented on a three-point scale (A: high; B: low; and C: very low) in the JDAPsACPG and on a four-point scale (high; moderate; low; and very low) in the ACRPsACPG following the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. (Supplementary Table S2)[35-37] Both JDA and ACRPsACPG classified strength of recommendation into two groups: class 1 (strong) recommendations and class 2 (weak or conditional) recommendations.

Ethical clearance

The Ethics Committee of the Medical Governance Research Institute approved this study. Informed consent from study participants was not required as all data were publicly available.

Results

A total of 23 JDAPsACPG authors and 36 ACRPsACPG authors were identified. The characteristics of the JDAPsACPG authors were male (78.3%), physician (100%), and specializing in dermatology (52.2%) (Table 1). Meanwhile, among the 36 ACRPsACPG authors, 16 (44.4%) were male, 28 (77.8%) had medical licenses, and 19 (52.8%) specialized in rheumatology and 4 (11.1%) in dermatology. In addition, nine PsA patients reviewed the evidence and provided input on their values and preferences before recommendations were formulated in the ACRPsACPG, but they were not included as ACRPsACPG authors. There were no patients involved during the JDAPsACPG development.

Regarding FCOI, 14 (60.9%) JDAPsACPG authors and 18 (50.0%) ACRPsACPG authors voluntarily declared FCOI with pharmaceutical companies in each CPG. Both chairpersons of JDAPsACPG and ACRPsACPG disclosed FCOI with pharmaceutical companies in the CPG.

Of 36 ACRPsACPG authors, 25 (69.4%) were eligible for the US Open Payments Database search. 21 (91.3%) JDAPsACPG authors and 21 (84.0%) ACRPsACPG authors received $3,335,413 and $4,081,629 personal payments in total for the three years (Table 2). The average and median personal payments were $145,018 (standard deviation (SD): $116,871) and $123,876 (IQR: $30,129–$243,227) for the JDAPsACPG authors, and $162,825 (SD: $259,670) and $58,826 (IQR: $877–189,900) for the ACRPsACPG authors. Limiting payments to lecturing, writing, and consulting fees reported in the US Open Payments Database, which authors are also required to report under the ACR's COI policy, 17 (65.4%) ACRPsACPG authors received a mean of $130,102 (SD: $216,238) and a median of $39,375 (IQR: $0-149,441). The chairpersons of the JDAPsACPG and ACRPsACPG received personal payments of $123,876 and $8,170, respectively, over a three-year period. In addition, the personal payments that must be reported according to each society's COI policy for CPG were $1,226,298 and $1,235,527 for JDAPsACPG and ACRPsACPG authors, respectively. Among them, 18 (78.3%) of JDAPsACPG and 12 (48.0%) of ACRPsACPG authors had undisclosed payments of $474,663 (38.4%) and $218,501 (17.7%), respectively (Table 2).

Of 11 ACRPsACPG authors who were not eligible for US Open Payments Database search, 5 declared FCOI with pharmaceutical companies in the ACRPsACPG. Therefore, a total of 26 (72.2%) ACRPsACPG authors had FCOI with pharmaceutical companies verified by the US Open Payments Database or self-declared COI in the ACRPsACPG.

We identified 354 and 137 different citations in JDAPsACPG and ACRPsACPG, respectively. The number of authors with self-citations was 18 (78.2%) in JDAPsACPG and 11 (31.6%) in ACRPsACPG. Further, 12 (3.39%) citations in JDAPsACPG and 46 (33.6%) citations in ACRPsACPG were self-cited by the authors of each CPG. The median number of self-cited articles per author were 2 (0.56%) citations in the JDAPsACPG and 0 in the ACRPsACPG. In the JDAPsACPG, three-quarters of the self-cited articles were about observational studies, whereas in the ACRPsACPG, 52.2% (24 of 46) of the self-cited articles were clinical trials, most of which were randomized controlled studies (23 of 24). (Table3) Even though the percentage of self-citations in ACRPsACPG was lower than that in JDAPsACPG, the self-cited trials in ACRPsACPG had a direct impact on the recommendations of the CPG, and the authors' non-financial COI was not disclosed in ACRPsACPG.

As for underlying evidence, there were 32 clinical questions (PICOs) and 42 recommendations in the JDAPsACPG, and 72 PICOs and 80 recommendations in the ACRPsACPG. Among 42 JDAPsACPG recommendations, 10 (23.8%) and 20 (47.6%) were graded as low and very low QOE, respectively. Also, of 80 ACRPsACPG recommendations, 31 (38.8%) and 40 (50%) were low and very low QOE, respectively. (Table 4) There were nine (21.4%) and five (6.3%) strong recommendations in the JDA and ACRPsACPG, respectively. In JDAPsACPG, 50.0% of strong recommendations were based on low or very low QOE, while in ACRPsACPG, there were no strong recommendations based on low or very low QOE. In addition, of the 32 PICOs in the JDAPsACPG, only two (6.3%) compared one intervention to another, whereas in the ACRPsACPG, all were comparison questions (Supplementary Table S3)[36,38].

Regarding the comparison of COI policies between the two medical societies, both JDA and ACR required CPG authors to declare and disclose nearly the FCOI compared to Guidelines International Network and National Academy of Medicine COI policies, while neither JDA nor ACR adequately considered the NFCOI of CPG authors in the comprehensive category (Supplementary Table S1). ACR did not require CPG authors to declare small payments, while JDA required authors to declare gifts and compensation more than $459 (¥50,000). Furthermore, despite the current global and US standard COI policies such as Guidelines International Network, National Academy of Medicine, and ACR, requiring CPG authors to declare all FCOI regardless of the payment amount, there was a monetary threshold for reporting FCOI for CPG authors in Japan. The ACR only required declaration of FCOI covering one year before and during CPG development. Although JDA required CPG authors to declare their FCOI for the past three years of CPG development, JDAPsACPG disclosed them for two years, between January 1, 2017 and December 31, 2018. One of the novel approaches of the ACRCPG was to predetermine CPG authors with diverse backgrounds, including race, gender, and specialty, so that recommendations would be well-balanced between clinical, academic, and patient preferences.

Discussion

We assessed FCOI and NFCOI among PsACPG authors in Japan and US, finding that most authors had substantial FCOI with pharmaceutical companies before and during the work on CPG development. There were significant discrepancies between authors' self-reported and company-reported FCOI among the CPG authors. Further, several references were self-cited by the CPG authors without the declaration of NFCOI. In

addition, 71.4% and 88.8% of recommendations for PsA in JDA and ACR were supported by low or very low quality of evidence. Both JDA and ACR COI policies on CPG development had several blind spots in regulating how COIs are managed, compared to the international COI policies issued by the National Academy of Medicine and Guidelines International Network. There were important similarities and differences in COI reported by JDAPsACPG and ACRPsACPG authors.

Surprisingly, we found that 91.3% and 81.0% of the authors in JDAPsACPG and ACRPsACPG received an average of $48,339 ($145,018 for the three years) and $54,422 ($163,265 for the three years) in annual personal payments, respectively. The average dermatologist annual income in the US is $ 361,700 as of April 26, 2022[39], thus the amount ACRPsACPG received accounted for 45.0% of the average annual income. On the other hand, the rate of the amount JDAPsACPG received to the average annual income of Japanese dermatologists could not be calculated because the average income amount for Japan was not available. Both the prevalence and monetary value were much larger than reported in relation to other medical specialties in Japan[10,12,39-44] and the US. As we noted previously, the prevalence and average annual personal payments from pharmaceutical companies to Japanese CPG authors ranged from 78.2% in oncology[27] to 100.0% in hepatology[43] and from $10,565 in oncology to $33,490 in hepatology,[43] respectively. Similarly, Wayatt et al. reported that 49.4% of the authors of five ACR CPG received an average annual personal payment of $40,824.[28] 81.6% of American Academy of Dermatology CPG authors received $27,901 in average general payments per year.[29] In other specialties, the prevalence of CPG authors with FCOI and average annual personal payments were 59.3% and $18,413 in urology;[45] 61.1% and $2,347 in hematology;[44] 80% and $3,970 in otolaryngology;[46] and 86% and $10,011 in oncology.[47] It is true that influential doctors such as clinical practice guideline authors tend to receive various types of payments from pharmaceutical companies and that it is difficult to conduct research without funding from pharmaceutical companies. However, our current research mainly focuses on personal payments from pharmaceutical companies such as lecture fees and consulting fees. These payments are recognized as pocket money and are not used for research. Thus, it is questionable that the observed relationships are something evitable. Overall, the disparity in the approaches toward FCOI regulations between Japan and US appears not to have affected the extent of the FCOI and its disclosure.

The patterns of self-citation between JDAPsACPG and ACRPsACPG differed remarkably. While more than three-fourths of JDAPsACPG authors self-cited their articles, and the articles were primarily observational studies, nearly one-third of the ACRPsACPG authors self-cited their articles, and more than half of the articles were randomized controlled trials. As the CPG authors mainly comprised content experts and high QOE such as results from randomized controlled trials were an essential source for rigorous CPG development, self-citations of clinical trials could be justified. However, NFCOI include authorship of original studies and review articles directly influencing CPG recommendations. Thus, although JDA and ACR did not consider and manage authorship and other forms of NFCOI in their policies, they might want to consider a comprehensive definition and rigorous management with full disclosure of NFCOI.

Notably, 80.9% and 88.8% of the latest recommendations in JDAPsACPG and ACRPsACPG were supported by low, very low, or no QOE, respectively. This data should be interpreted cautiously given that perceived quality of evidence depends upon various factors including the question/recommendation in the guideline. This is higher than in a study by Duarte-Garcia et al., highlighting that 50.0% of all ACRCPG recommendations as of 2017 were based on expert opinions, case studies, and standard of care and further that 50.0% of strong recommendations were based on such low QOE. Although the percentage of low QOE in ACRPsACPG is consistent with the previous study, there was no strong recommendation based on low or very low LOE in the latest ACRPsACPG issued in 2018. Meanwhile, one-third of the JDAPsACPG strong recommendations were based on low or very low QOE. Surprisingly, although a Japanese methodology expert specializing in the Appraisal of Guidelines for Research and Evaluation methodology participated in JDAPsACPG development, 93.8% of the JDAPsACPG PICO were unidirectional questions whether an intervention is effective in PsA treatment or not. On the other hand, there was one study reporting that participation of methodologists in the CPG authors led to rigorous COI management; formulation of sufficient PICO comparing each intervention; rigorous grading of evidence; and modest strength of recommendations.[48] However our findings indicate that merely including methodology experts does not necessarily guarantee the rigorous development of a high-quality CPG in Japan.

Nonetheless, this study did not reveal any relationship among the extent of FCOI, the strength of recommendation and quality of evidence. Recommendations of clinical practice guidelines could be biased when only low-quality evidence is available, and

when there is COI between clinical guideline authors and specific commercial entities. Thus, it is important to discuss these elements all together in one paper to understand how COI would affect clinical practice. Consequently, we intended to do so in this paper as well. However, since JDA and ACR did not disclose the name list of authors making each recommendation, we could not analyze the relationship among them in this work. We call for a publication of the list of authors making each recommendation to grasp implications of COI in clinical practice guidelines.

Moreover, the current JDA and ACR COI policies deviated in some important ways from the global standard COI policies such as National Academy of Medicine and Guidelines International Network. Although ACR required CPG authors to declare COI from one year before CPG development, many societies currently set a three-year look-back period for COI declaration[7]. Also, definitions of NFCOI in the current JDA and ACR COI policies were limited or non-existent. In 2020, Wayatt et al. recommended that ACR ensure full disclosure with more stringent COI policies, including disclosing more types of FCOI, not limiting the list of associated companies, adhering to National Academy of Medicine COI policy, and using the US Open Payment Database to cross-check COI reported by the CPG authors[28]. Similarly, Murayama et al. recommended that JDA should also use the payment database for the cross-checks in 2020[12]. In the field of nephrology, Improving Global Outcome CPG routinely examine the adherence of National Academy of Medicine standards. Also, Guidelines International Network published the checklist for rigorous CPG development. However, there were no revisions to the COI policies of both JDA and ACR, and no alternative strategies of COI management and CPG development were identified as of October 28, 2021. Thus, JDA and ACR ought to increase the transparency and rigor of their COI policies.

Lastly, this study does not reveal any relationship between the strength of recommendation and quality of evidence. Previous research has shown that there was some possibility for COI of guideline authors with pharmaceutical companies to influence on guideline recommendations by using more drugs and that recommendations tend to be more inappropriate in expert-consensus based approach than in evidence-based approach even if which were based on low quality evidence[2]. Therefore, the consensus-based guidelines have been shown to produce more recommendations that violate medical principles than evidence-based guidelines. However, this study cannot show the existence of a causal relationship between them.

Our study had several limitations. First, our Japanese payment database was compiled manually by collecting data from each pharmaceutical companies' webpage. Despite careful and repeated checks, we could not eliminate the possibility of human error in data compilation and management, as explained elsewhere[10,40,42]. Second, due to the different methodology for grading evidence and strength of recommendations between JDA and ACR, direct comparison of recommendations was impossible. Third, pharmaceutical companies in Japan were not required to disclose payments other than for lecturing, writing, and consulting with individual name of recipients, which contrasts with a greater scope of payments covered by Open Payments. Further our payment database did not include payments from pharmaceutical companies not belonging to the JPMA, because these companies had no obligation to disclose payment data. Thus, the payments to the JDAPsACPG authors should have been underreported due to the lack of payment from all companies. However, this study would elucidate the magnitude of significant FCOI between JDAPsACPG authors and major pharmaceutical companies. Finally, the time lag between the COI disclosure and publication of the guideline may have led to a disparity between the disclosure and actual financial relationships, which may explain a part of the non-disclosed conflicts. As a countermeasure, the guidelines should mention the detailed date of the COI disclosure and the date of the COI disclosure should be close to the publication date as much as possible.

In conclusion, we found that majority of the authors of PsACPG issued by JDA and ACR received substantial personal payments from the pharmaceutical companies before and during CPG development, several CPG authors self-cited their articles without the disclosure of NFCOI, and most of the recommendations were based on low or very low quality of evidence. Although the COI policies used by JDA and ACR are clearly inadequate, no significant revisions have been made for the last three years.

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Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

Table 1. Demographic characteristics of Japanese Clinical Practice Guideline authors for psoriatic arthritis in 2019

Variables	Japan	United States
Sex, n (%)		
Male	18 (78.3)	16 (44.4)
Female	5 (21.7)	20 (55.6)
Job type, n (%)		
Physicians and researchers with MD	23 (100.0)	28 (77.8)
Researchers without MD	0 (0.0)	3 (8.3)
Physician Assistant	0 (0.0)	1 (2.8)
Physical Therapist	0 (0.0)	1 (2.8)
Research Analyst	0 (0.0)	1 (2.8)
Patient/patient representative	0 (0.0)	1 (2.8)
Society staff	0 (0)	1 (2.8)
Affiliation, n (%)		
University	20 (87.0)	24 (66.7)
Professor	15 (65.2)	15 (41.7)
Non-professor	5 (21.7)	9 (25.0)
General hospitals and teaching hospitals	3 (13.0)	4 (11.1)
Other institutes including research organizations, patient organizations, and societies	0 (0.0)	8 (22.2)
Specialty, n (%)		
Dermatology	11 (52.2)	4 (11.1)
Clinical immunology/Rheumatology	4 (17.4)	23 (52.8)
Orthopedics	2 (8.7)	0 (0.0)
Radiology	2 (8.7)	0 (0.0)
Obstetrics and gynecology	2 (8.7)	0 (0.0)
Pediatrics	1 (4.3)	0 (0.0)
Public health/Clinical epidemiology/Methodology	1 (4.3)	5 (13.9)
Other specialties including a patient, a patient representative, and a society staff	0 (0.0)	4 (11.1)
Type of involvement, n (%)*		
Writing Committee/Core panel	16 (69.6)	5 (13.9)**
Literature review panel	NA	5 (13.9)
Voting panel	NA	16 (44.4)

Cooperation/Expert panel	7 (30.4)	10 (27.8)**

Abbreviations: IQR, interquartile range; NA: not applicable

* There was no description on contribution to ACRPsACPG development for one author.

** One ACRPsACPG author was appointed to both the Core panel and the Literature Review panel in duplicate.

Table 2. Characterization of personal payments from pharmaceutical companies to the authors of clinical practice guideline for psoriatic arthritis issued by the Japan Dermatology Association and American College of Rheumatology

Variables	Japan	United States
Self-declared COI		
Type of involvement, n (%)		
Writing Committee/Core panel	12 (75.0)	3 (60.0)
Literature review panel	NA	0 (0)
Voting panel	NA	6 (42.9)
Cooperation/Expert panel	2 (28.6)	9 (90.0)
Total number of authors with COI	14 (60.9)	18 (50.0)
Database-based COI		
Number of eligible authors for payment database search, n (%)	23 (100)	25 (69.4)
Total amount of payments, $	6,024,309	4,070,626
Mean per author (SD), $	145,018 (114,302)	162,825 (259,670)
Median per author (IQR), $	123,876 (46,010–242,194)	58,826 (877–189,900)
Authors with payments (n (%))		
Any payments	21 (91.3)	21 (84.0)
≧ $10,000	19 (82.6)	15 (60.0)
≧ $50,000	17 (73.9)	14 (56.0)
≧ $100,000	16 (69.6)	9 (36.0)
≧ $150,000	9 (39.1)	7 (28.0)
≧ $300,000	3 (13.0)	5 (20.0)
≧ $600,000	0 (0.0)	2 (8.0)
Type of payments, $ (%)		
Lecturing	2,480,352 (74.4)	1,261,961 (31.0)
Consulting	591,499 (17.7)	1,947,205 (47.8)
Writing	252,047 (7.6)	NA
Travel and accommodation	NA[a]	697,692 (17.1)
Meal	NA[a]	105,618 (2.6)
Honoraria	NA	43,385 (1.1)
Education	NA[a]	14,765 (0.4)
Other	10,797 (0.3)	NA
Discrepancy between self-declared and database-based financial COI		
Self-declared COI		
Total number of cases, n (%)	80 (54.8)	389 (79.2)
Total amounts of payment, $ (%)	760,357 (61.6)	1,017,025(82.3)
Database-based undisclosed COI		
Total number of cases, n (%)	66 (45.2)	102 (20.8)
Total amounts of payment, $ (%)	474,663 (38.4)	218,501(17.7)
Number of authors with undisclosed COI, n(%)	18 (78.3)	12 (48.0)

Japanese yen (¥) were converted to U.S. dollars ($) using the 2017 average monthly exchange rate of ¥112.1 per $1 and 2018 average exchange rate of ¥110.4 per $1.

[a] Personal payments concerning travel and accommodation, meal, and education were not disclosed by the pharmaceutical companies as to the individual names of the recipients in Japan.

Abbreviations: SD, standard deviation; IQR: interquartile range; NA: Not available

Table 3. Breakdown of the citations in clinical practice guidelines for psoriatic arthritis in Japan and the United States

Variables	Japan	United States
Total citations, n	354	137
Language of publications		
English	342 (96.6)	137 (100)
Japanese	12 (3.4)	0 (0.0)
Number of authors with self-citation, n (%)	18 (78.2)	11 (31.6)
Number of self-cited articles, n (%)		
Total	12 (3.39)	46 (33.6)
Median number of self-citations per author	2 (0.56)	0 (0.0)
Interquartile range of self-citations per author	0–3 (0.28–0.85)	0–1 (0.0–0.73)
Range of self-citations per author	0–7 (0–1.98)	0–17 (0–12.4)
Publication type of self-citated articles		
Clinical trial articles	0 (0.0)	24 (52.2)
Observational study articles	9 (75.0)	8 (17.4)
Review articles	1 (8.3)	3 (6.5)
Systematic reviews and meta-analysis articles	0 (0)	1 (2.2)
Clinical and other guidelines	1 (8.3)	10 (21.7)
Consensus conference report	1 (8.3)	0 (0.0)

Table 4. Evidence level and strength of recommendation underlying clinical practice guidelines for psoriatic arthritis in Japan and the United States

Level of evidence	Strength of recommendation			Total
	Class 1 (strong)	Class 2 (weak and conditional)	Ungraded	
Japan, n (%)*				
A (high)	6 (14.3)	1 (2.4)	1 (2.4)	8 (19.0)
B (low)	1 (2.4)	4 (9.5)	5 (11.9)	10 (23.8)
C (very low)	2 (4.8)	9 (21.4)	9 (21.4)	20 (47.6)
Ungraded	0 (0)	0 (0)	4 (9.5)	4 (9.5)
Total	9 (21.4)	14 (33.3)	19 (45.2)	42
United States, n (%)**				
High	0 (0)	0 (0)	0 (0)	0 (0)
Moderate	5 (6.3)	4 (5.0)	0 (0)	9 (11.3)
Low	0 (0)	31 (38.8)	0 (0)	31 (38.8)
Very low	0 (0)	40 (50.0)	0 (0)	40 (50.0)
Total	5 (6.3)	75 (93.8)	0 (0)	80

*Japanese Dermatological Association categorized quality of evidence into three: A (high); B (low); and C (very low)

**American College of Rheumatology categorized quality of evidence into four: high; moderate; low; and very low.