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Exploring financial relationships between board-certified cardiologists and pharmaceutical industry in Japan between 2016 and 2019: a descriptive analysis of personal payments to cardiologists

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Exploring financial relationships between board-certified cardiologists and pharmaceutical industry in Japan between 2016 and 2019: a descriptive analysis of personal payments to cardiologists

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Objective:
To evaluate the extent and trends of personal payments from pharmaceutical companies to cardiologists board-certified by the Japanese Circulation Society in Japan.

Design:
An observational analysis study using a publicly available database.

Setting:
The study focused on payments to cardiologists in Japan.

Participants
All 15,048 cardiologists who were board-certified by the Japanese Circulation Society as of 2021.

Primary and Secondary Outcome Measures:
The primary outcome measured was the extent of personal payments to cardiologists between 2016 and 2019. Secondary outcomes included the analysis of trends in these payments over the same period.

Results
Of all 15,048 board-certified cardiologists, 9,858 (65.5%) received personal payments totaling \$112,934,503 entailing 164,978 transactions between 2016 and 2019. The median payment per cardiologist was \$2,947 (IQR: \$1,022–\$8,787), with a mean of \$11,456 (SD: \$35,876). The Gini index was 0.840, indicating a highly concentration of payments to a small number of cardiologists. The top 1%, 5%, and 10% of cardiologists accounted for 31.6%, 59.4%, and 73.5% of all payments, respectively. There were no significant trends in the number of cardiologists receiving payments and payments per cardiologist from 2016 to 2019.

Conclusion
More than 65% of Japanese cardiologists received personal payments from the pharmaceutical companies over the four years. Although the payment value was relatively small for the majority of cardiologists, only a small number of cardiologists received the vast majority of payments.

Strengths and limitations of this study
All pharmaceutical companies affiliated with the Japan Pharmaceutical Manufacturers Association are required to disclose their payments related to lecturing, consulting, and manuscript drafting to individual physicians with the physicians’ names. These payment data have been collected by an independent research organization and the organization developed a publicly accessible, searchable payment database. This study used a comprehensive payment database containing personal payments to physicians from all pharmaceutical companies between 2016 and 2019. Our limitation is that the study did not cover financial relationships between the cardiologists and non JPMJA-affiliated companies. Our limitation is that the study did not cover other types of personal and research payments to the cardiologists.

Keywords:

Conflicts of interest, ethics, health policy, medical ethics, Japan, industry payments

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74 **Introduction**

75 Collaborations between physicians and pharmaceutical companies play a crucial role in
76 advancing healthcare innovation and improving patient care through joint research
77 efforts. However, such collaborations can also lead to financial conflicts of interest
78 (COIs) for physicians. Furthermore, physicians may engage in promotional activities or
79 be targeted for marketing by the companies [1,2], potentially biasing their decision-
80 making, including prescribing patterns and guideline recommendations [3,4]. These
81 COIs could bias physicians' decision-making including prescribing patterns and
82 guideline recommendations [3,5-13].

84 To improve transparency in these financial relationships, the Japan Pharmaceutical
85 Manufacturers Association (JPMA), the largest pharmaceutical trade organization in
86 Japan, implemented a policy in 2013 requiring its member companies to disclose
87 payments to physicians on their websites [14]. This data is then collected by an
88 independent research organization and journalists and has been voluntarily available on
89 a comprehensive searchable database since 2016. Previous research using this database
90 has revealed prevalent financial relationships between physicians and pharmaceutical
91 companies in Japan [15-23].

93 Among several specialists, cardiologists are among the most heavily targeted specialists
94 for marketing by pharmaceutical companies. Murayama et al. previously reported that
95 society executive board members of the Japanese Circulation Society received the
96 second highest mean payments of \$311,653, with the fourth highest median payments
97 of \$207,888 in personal payments for lecturing, consulting, and writing among 15
98 internal medicine subspecialty societies in Japan [16]. Another study found that authors
99 of the Japanese Society of Hypertension clinical guidelines received a mean of \$21,447
100 in personal payments in 2016 [24]. Additionally, Tringale et al. reported that
101 cardiologists received the highest median payments of \$862 from healthcare companies
102 of 26 specialties in the United States (US) [2]. Similarly, Murayama et al. reported that
103 cardiologists received \$725 in personal payments in the US in 2019 [1]. Despite the
104 likely presence of prevalent and substantial financial relationships between cardiologists
105 and pharmaceutical companies in Japan, no studies have been conducted to evaluate the
106 whole size and extent of financial relationships between cardiologists and
107 pharmaceutical companies. Utilizing a publicly accessible database, this study
108 investigated the extent and trends of personal payments from pharmaceutical companies
109 to all cardiologists in Japan.

111 **Methods**

112 *Study setting & participants*

113 Utilizing the publicly available payment database (<https://yenfordocs.jp/>), this analysis
114 examined all personal payments to all cardiologists from JPMA-affiliated
115 pharmaceutical companies from 2016 to 2019. We included all cardiologists board-
116 certified by the Japanese Circulation Society (JCS) as of September 2021. The JCS,
117 established in 1935, is the sole professional body board-certifying cardiologists since
118 1989. As of the specified date, we identified 15,048 board-certified cardiologists from
119 the JCS webpage.

Payment disclosure & payment source

All pharmaceutical companies affiliated with the JPMA are required to disclose their payments to physicians and healthcare organizations on the company webpages after 2013. However, most of companies regularly update their payment data each year and delete the data for previous years from the webpages. The publicly accessible, searchable payment database were developed by an independent research organization and journalists and contains payments to individual physicians from all pharmaceutical companies affiliated with the JPMA and several subsidiary companies disclosing payment data for lecturing, consulting, and writing fees after 2016. At the time of the data collection for this study, payment data in 2019 were the latest searchable data on the database. The JPMA only requires its member companies to disclose personal payments to individual physicians for lecturing, consulting, and writing services at individual physician level. More common payment categories such as meals, travel, accommodations, and other gifts are reported in aggregate, precluding individual-level analysis [25]. Therefore, we searched for the names of cardiologists and collected from the payment database only payments to cardiologists for lectures, consulting, and writing for this study.

Statistical analyses

We conducted descriptive analyses including mean and median payments per cardiologist and the proportion of cardiologists receiving payments. The concentration of payments among cardiologists was assessed using the Gini index, as in previous studies [26-28]. Furthermore, we examined trends in the number of cardiologists receiving payments and the payment amounts from 2016 to 2019 using generalized estimating equation (GEE) models. To adjust for highly skewed distribution of payments, we used a log-linked GEE model with a Poisson distribution for the number of cardiologists receiving payments and a negative binomial GEE model for payments per cardiologist, as conducted in previous studies [15,17,19,25,29]. For trend analysis, we adjusted for inflation, converting all payment values to 2019 Japanese yen value.

Ethical clearance

Given that all data used in this study were publicly available and met the definition of non-human subjects research, institutional review board approval was not required in Japan. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Results

Of the 15,048 eligible cardiologists board-certified by the JCS, 9,858 (65.5%) received at least one personal payment from pharmaceutical companies between 2016 and 2019 (Table 1). The total amount of these payments was \$112,934,503, entailing 164,978 payment transactions. For cardiologists who received at least one payment, the median amount per cardiologist was \$2,947 (interquartile range [IQR]: \$1,022–\$8,787), with a mean of \$11,456 (standard deviation [SD]: \$35,876) over the four-year period. The Gini

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index was 0.840 for personal payments per cardiologist, indicating that only a small proportion of cardiologists received the vast majority of these payments. Specifically, the top 1% (150 cardiologists), 5% (752 cardiologists), and 10% (1505 cardiologists) received 31.6%, 59.4%, and 73.5% of all personal payments, respectively. Only 0.5% (67 cardiologists) received more than \$200,000 payments and one cardiologist received 565 payments totaling \$782,015 over the four years.

Lecturing payments accounted for 88.6% of the total payments (\$100,067,695) in monetary value and 89.7% in the number of payments over the four years, with 64.5% (9,710) of cardiologists receiving at least one lecturing payment. Consulting and writing payments accounted for 8.0% (\$9.1 million) and 3.3% (\$3.8 million) in monetary value. The mean values per payment were \$1,243 for lecturing, \$1,236 for consulting, and \$915 for drafting services.

Of 83 pharmaceutical companies making payments to the cardiologists, Daichi Sankyo made the largest amounts of personal payments totaling \$26.4 million (23.4% of all payments), followed by Bayer (\$11.8 million; 10.4% of all payments), Boehringer Ingelheim Japan (\$8.8 million; 7.8% of all payments), Otsuka Pharmaceutical (\$8.3 million; 7.5% of all payments), Bristol Myers Squibb (\$5.7 million; 5.0% of all payments), and Takeda Pharmaceutical (\$5.2 million; 4.6% of all payments). The top 5 and 10 companies with the largest payment amounts were responsible for 54.2% (\$61.2 million) and 71.3% (\$80.5 million) of all payments over the four years.

The total annual payments to cardiologists were from \$27.4 million in 2016 to \$28.8 million in 2017 (Table 2). Of all cardiologists, 46.4% to 47.4% of cardiologists received at least one personal payment each year. Median annual payments slightly increased from \$1,226 (IQR: \$511–\$3,247) in 2016 to \$1,354 (IQR: \$613–\$3,335) in 2019. The GEE models showed that there were no significant trends in the number of cardiologists receiving personal payments (relative annual average percentage change [RAAPC]: 0.3% [95% confidence interval: -0.2% to 0.8%], $p=0.23$) and payments per cardiologist (RAAPC: 0.6% [95% confidence interval: -0.7% to 1.8%], $p=0.39$) between 2016 and 2019.

Discussion

Our study revealed that 65.5% of all board-certified cardiologists in Japan received personal payments for activities such as lecturing, consulting, and writing from pharmaceutical companies between 2016 and 2019. The total amount of these payments exceeded \$112.9 million, equivalent to approximately 12.3 billion Japanese yen over this four-year period. Although the level of these payments remained stable throughout the study period, a disproportionately small group of cardiologists received the majority of these payments. To the best of our knowledge, this is the first study to explore the comprehensive financial interactions between pharmaceutical companies and cardiologists in a country other than the US [1,2].

Contrary to findings in the US, where approximately three-quarters of cardiologists reportedly received various personal payments, including compensation, honoraria, travel fees, royalties, and food and beverage payments from pharmaceutical and medical

device corporations [1,2], our research in Japan indicates that a mere half of the board-certified cardiologists annually received financial recompense for lecturing and consulting from the pharmaceutical companies. Although the study findings were consistent with previous studies in Japan [15,17-19,25], this lower percentage of cardiologists in Japan receiving such payments than those in the US would substantially underrepresent the actual degree of their financial engagements with the healthcare companies, given that our study was limited to compensation payments to individual cardiologists and did not encompass other prevalent payment categories or payments from medical device companies, despite that cardiologists frequently utilized medical equipment and devices such as implantable cardioverter-defibrillators, cardiac catheters, and stents.

Although the majority of cardiologists received only modest amounts of payments relative to their overall income as cardiologists, the impact of these payments should not be underestimated. Previous studies in the United States have demonstrated that even small payments to cardiologists from medical device and pharmaceutical companies are significantly associated with increased usage of percutaneous coronary interventions, stent placements [4], and prescriptions for oral anticoagulants and antiplatelet drugs [4]. Nonetheless, given the absence of studies exploring the associations between payments to cardiologists and their clinical practices, future research is warranted to investigate the impact of industry payments on the clinical practices of cardiologists in Japan.

Additionally, we found that only a small number of cardiologists received the vast majority of personal payments. As we elucidated, the average payments to JCS executive board members [16] and cardiology guideline authors [24] were substantially larger than those received by the board-certified cardiologists on average. These physicians, often referred to as key opinion leaders, are frequently targeted by pharmaceutical and medical device companies [23,30], due to their authoritative and influential positions. Given their significant influence on other cardiologists, it is crucial to properly manage COIs among these influential cardiologists. However, previous studies have indicated significant undeclared and underreported COIs between these physicians and pharmaceutical companies in Japan [16,23,24,30]. Additionally, the policies for managing COIs in Japan are less rigorous and transparent compared to those in other developed countries [23,30]. The study findings further underscore the critical need for effective management of financial COIs among influential cardiologists in Japan.

This study has several limitations. Potential inaccuracies in the payment data reported by companies and in the database may exist. Moreover, the omission of certain types of payments, including meals, travel expenses, and gifts, which are not readily available in Japan, likely leads to a substantial underestimation of the magnitude and proportion of financial relationships between cardiologists and pharmaceutical companies in Japan. Furthermore, as the study encompassed only payments from JPMA-affiliated companies, it may not fully represent the entire range of financial interactions between cardiologists and pharmaceutical companies not affiliated with the JPMA and medical device companies.

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In conclusion, our study demonstrates that more than 65% of cardiologists certified by the Japanese Circulation Society received personal payments related to lecturing, consulting, and writing from pharmaceutical companies between 2016 and 2019. These payments were concentrated among a small group of cardiologists. Future studies should explore the influence of these payments to cardiologists on their clinical practice in Japan.

Declarations

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. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflicts of interest:

The authors have no conflicts of interest for this study.

Funding statement:

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

Ethics approval 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.

Patient consent statement

Not applicable

Permission to reproduce material from other sources

Not applicable

Clinical trial registration

Not applicable

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 take full responsibility for the content of the publication.

Author contribution:

A.M.: conceptualization; methodology; resource; software; formal analysis; investigation; writing - original draft; writing - review & editing; visualization; study administration

K.H.: conceptualization; methodology; resource; software; formal analysis; investigation; writing - review & editing

Y.S.: conceptualization; methodology; resource; formal analysis; investigation; writing - original draft; writing - review & editing

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Table 1. Summary of personal payments to board-certified cardiologists

Variables	Value
Total amounts of payments	
Payment values, \$	112,934,503
Number of payments, No.	164,978
Payments per cardiologist	
Mean (standard deviation) ^a	
Payment values, \$	12,649 (35,012)
Number of payments, No.	16.7 (33.9)
Median (interquartile range) ^a	
Payment values, \$	2,947 (1,022 – 8,787)
Number of payments, No.	7.0 (2.0 – 17.0)
Maximum ^a	
Payment values, \$	782,015
Number of payments, No.	575.0
Gini index	0.840
Cardiologists with specific amounts of payments (N=15,048), n (%)	
No payment	5,190 (34.5)
Any payments	9,858 (65.5)
\$1-\$1,000	2,318 (15.4)
\$1,001-\$10,000	5,314 (35.3)
\$10,001-\$50,000	1,825 (12.1)
\$50,001-\$100,000	225 (1.5)
\$100,001-\$200,000	109 (0.7)
\$200,001 or more	67 (0.5)
Payment categories	
Lecturing payments	
Monetary value (%), \$	100,067,695 (88.6)
Number of payments (%), No.	148,012 (8.0)
Number of cardiologists receiving payments (%), n	9,710 (64.5)
Consulting payments	
Monetary value (%), \$	9,084,765 (89.7)
Number of payments (%), No.	11,814 (8.0)
Number of cardiologists receiving payments (%), n	3,561 (23.7)
Writing payments	
Monetary value (%), \$	3,782,044 (3.3)
Number of payments (%), No.	5,152 (3.1)
Number of cardiologists receiving payments (%), n	2,300 (15.3)

Legends: ^a Payments per cardiologist were calculated among cardiologists who received one or more payments, as 34.5% of cardiologists did not receive any payments over the five years.

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Table 2. Trend in personal payments from pharmaceutical companies to board-certified cardiologists between 2016 and 2019.

Variables	2016	2017	2018	2019	Average relative yearly change between 2016 and 2019 (95% CI), %
Total payments					
Monetary value, \$	27,358,539	28,757,456	28,090,504	28,728,005	–
Number of payments, No.	40,527	41,822	40,572	42,057	–
Payments per cardiologist					
Monetary value, \$					
Mean (standard deviation)	3,917 (10,883)	4,068 (11,314)	3,938 (10,416)	4,082 (10,764)	0.6 (-0.7 to 1.8)
Median (interquartile range)	1,226 (511–3,247)	1,328 (511–3,372)	1,320 (511–3,270)	1,354 (613–3,335)	
Maximum	248,198	221,104	173,339	211,955	
Gini index	0.865	0.862	0.858	0.858	
Number of payments, No.					
Mean (standard deviation)	5.8 (10.1)	5.9 (10.4)	5.7 (9.7)	6.0 (10.0)	0.8 (-0.1 to 1.7)
Median (interquartile range)	3.0 (1.0–6.0)	3.0 (1.0–6.0)	3.0 (1.0–6.0)	3.0 (1.0–6.0)	
Maximum	189.0	160.0	155.0	162.0	
Gini index	0.810	0.808	0.802	0.805	
Physicians with payments (%) (N=15,048), n	6,984 (46.4)	7,070 (47.0)	7,133 (47.4)	7,038 (46.8)	0.3 (-0.2 to 0.8)

Abbreviation: 95% confidence interval (95% CI). *p<0.01. **p<0.001.

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	4-5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	n/a
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5
		(b) Describe any methods used to examine subgroups and interactions	5
		(c) Explain how missing data were addressed	n/a
		(d) If applicable, describe analytical methods taking account of sampling strategy	5
		(e) Describe any sensitivity analyses	n/a
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	5
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	5
		(b) Indicate number of participants with missing data for each variable of interest	n/a
Outcome data	15*	Report numbers of outcome events or summary measures	5-6
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	5-6

		(b) Report category boundaries when continuous variables were categorized	n/a
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6
Discussion			
Key results	18	Summarise key results with reference to study objectives	6-7
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	7
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	6-8
Generalisability	21	Discuss the generalisability (external validity) of the study results	7-8
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	8

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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**Retrospective analysis of non-research payments to board-certified cardiologists
from pharmaceutical industry in Japan from 2016 to 2019**

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Abstract

Objectives: To evaluate the extent and trends of personal payments from pharmaceutical companies to cardiologists board-certified by the Japanese Circulation Society.

Design: A retrospective analysis study using data from a publicly available database

Setting: The study focused on payments to cardiologists in Japan.

Participants: All 15,048 cardiologists who were board-certified by the Japanese Circulation Society as of 2021.

Primary and Secondary Outcome Measures: The primary outcome was the extent of personal payments to cardiologists in 2016–2019. Secondary outcomes included the analysis of trends in these payments over the same period.

Results: Of all 15,048 board-certified cardiologists, 9,858 (65.5%) received personal payments totaling \$112,934,503 entailing 165,013 transactions in 2016–2019. The median payment per cardiologist was \$2,947 (interquartile range, \$1,022–\$8,787), with a mean of \$11,456 (standard deviation, \$35,876). The Gini index was 0.840, indicating a high concentration of payments to a small number of cardiologists. The top 1%, 5%, and 10% of cardiologists received 31.6%, 59.4%, and 73.5% of all payments, respectively. There were no significant trends in the number of cardiologists receiving payments or number of payments per cardiologist during the study period.

Conclusions: More than 65% of Japanese cardiologists received personal payments from pharmaceutical companies over the 4-year study period. Although the payment amount was relatively small for the majority of cardiologists, a small number of cardiologists received the vast majority of the payments.

Strengths and limitations of this study

- All pharmaceutical companies affiliated with the Japan Pharmaceutical Manufacturers Association (JPMA) are required to disclose their payments made for lecturing, consulting, and manuscript drafting to individual physicians with the physicians' names.
- These payment data were collected by an independent research organization, which developed a publicly accessible and searchable payment database.
- This study used data from a comprehensive payment database containing personal payments to physicians from all pharmaceutical companies in 2016–2019.
- One study limitation was that it did not include financial relationships between the cardiologists and non-JPMA-affiliated companies.
- Another study limitation is that it did not detail other types of personal and research payments made to the cardiologists.

Keywords:

Conflicts of interest, ethics, health policy, industry payments

Introduction

Collaborations between physicians and pharmaceutical companies play a crucial role in advancing healthcare innovation and improving patient care through joint research efforts. However, such collaborations can also create financial conflicts of interest (COIs) for physicians. Furthermore, physicians may engage in companies' promotional or marketing activities^{1 2}, potentially biasing their decision-making efforts including prescribing patterns and guideline recommendations^{3 4}. These COIs could bias physicians' decision-making including prescribing patterns and guideline recommendations^{3 5-17}.

To improve the transparency of these financial relationships, the Japan Pharmaceutical Manufacturers Association (JPMA), the largest pharmaceutical trade organization in Japan, implemented a policy in 2013 requiring its member companies to disclose payments made to physicians on their websites¹⁸. These data are then collected by an independent research organization and journalists and has been voluntarily available on a comprehensive searchable database since 2016. Previous research using this database revealed prevalent financial relationships between physicians and pharmaceutical companies in Japan¹⁹⁻³⁰.

Cardiologists are among the most heavily targeted specialists by pharmaceutical companies. A previous study reported that society executive board members of the Japanese Circulation Society (JCS), the most influential cardiology society in Japan, received the second highest mean payment totaling \$311,653, with the fourth highest median payment of \$207,888 for lecturing, consulting, and writing among 15 internal medicine subspecialty societies in Japan²⁰. Another study found that authors of the Japanese Society of Hypertension clinical guidelines received a mean \$21,447 in personal payments in 2016³¹. The JCS itself received a total of \$10.2 million in donations and sponsorship payments from pharmaceutical companies in 2016–2020, the second highest total amount among 34 major professional medical societies in Japan^{32 33}. Tringale et al. reported that cardiologists received the highest median payment (\$862) among 26 specialties in the United States (US)². Similarly, another study reported that cardiologists received a median \$725 in personal payments in the US in 2019¹. Despite the likely presence of prevalent and substantial financial relationships between cardiologists and pharmaceutical companies in Japan, no studies have evaluated the size and extent of financial relationships between cardiologists and pharmaceutical companies. Utilizing a publicly accessible database, this study investigated the extent and trends of personal payments made by pharmaceutical companies to all cardiologists in Japan in 2016–2019.

Methods

Study setting & participants

Utilizing the publicly available payment database (<https://yenfordocs.jp/>), this retrospective analysis examined all personal payments made to all cardiologists from JPMA-affiliated pharmaceutical companies in 2016–2019. We included all cardiologists board-certified by the JCS as of September 2021. The JCS, established in 1935, has been the sole professional body to board-certify cardiologists since 1989. As of the specified date, we identified 15,048 board-certified cardiologists on the JCS webpage.

Payment disclosure & payment source

In Japan, all JPSMA-associated pharmaceutical companies are required to disclose their payments made to physicians and healthcare organizations on their company webpages after 2013. As of January 2020, 73 (70.2%) of the 104 pharmaceutical companies manufacturing prescription drugs in Japan were affiliated with the JPSMA. Prescription drugs manufactured by these JPSMA-affiliated companies accounted for 94.0% (\$101.0/\$107.4 billion) of all drug costs in Japan in 2020³⁴. However, most of these companies regularly update their payment data each year and delete the data for previous years from their webpages³⁵. The publicly accessible and searchable payment database, which was developed by an independent research organization and journalists, contains payments to individual physicians from all JPSMA-affiliated pharmaceutical companies and several subsidiary companies disclosing payment data for lecturing, consulting, and writing fees after 2016. At the time of the data collection for this study, payment data in 2019 were the latest available. The JPSMA requires its member companies to disclose personal payments to individual physicians for lecturing, consulting, and writing services at individual physician level only. More common payment categories such as meals, travel, accommodations, and other gifts are reported in aggregate^{2 35-37}; thus, an individual-level analysis was not possible. Therefore, we searched for the names of cardiologists and collected from the payment database only those payments made to them for lecturing, consulting, and writing services.

Identifying payments to cardiologists

After extracting payments to physicians whose names matched those of board-certified cardiologists, we excluded those payments made to individuals who were not actually cardiologists by cross-referencing affiliation and practice location data from the JCS with the recipients' affiliation and specialty data from the payment database. When identifying a cardiologist was challenging using only the payment database and the information from the JCS, we conducted additional searches for the physicians' names and affiliations and reviewed relevant webpages (e.g., hospitals, universities, clinics) of the physicians' affiliations to verify that they were the eligible cardiologists as previously explained^{22 29 38 39}. Payments made to physicians who were not confirmed board-certified cardiologists through these steps were excluded from the study.

Statistical analyses

We conducted descriptive analyses including mean and median payments per cardiologist and the proportion of cardiologists receiving payments. The concentration of payments among cardiologists was assessed using the Gini index as in previous studies^{36 40 41}.

Next, we examined trends in the number of cardiologists receiving payments and their amounts in 2016–2019 using generalized estimating equation (GEE) models. To adjust for the highly skewed distribution of payments, we used a log-linked GEE model with a Poisson distribution for the number of cardiologists receiving payments and a negative binomial GEE model for payments per cardiologist as in previous studies^{19 21 23 42 43}. Linear regression models were used to examine the yearly trends in the total payment amounts and numbers. For the trend analysis, inflation was adjusted by converting all

payment values to 2019 Japanese yen⁴⁴. Subsequently, the Japanese yen values were converted to US dollars using the 2019 average monthly exchange rate of ¥109.0 per \$1.

Furthermore, we analyzed the characteristics of the top 100 cardiologists who received the largest total amounts of payments over the 4-year period. For the top 100 cardiologists who received the largest total amounts, we collected information regarding their involvement in the creation of clinical practice guidelines issued by the JCS in 2015–2022, their status as executive board members of the JCS, and their position at their affiliation as of September 2021 when we extracted the cardiologists' names from the JCS as previously noted^{20 42 45}.

Ethical clearance

Given that all data used in this study were publicly available and met the definition of non-human-subject research in Japan, institutional review board approval was not required. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology guideline.

Patient and public involvement

No patients and/or the public were involved in the design, conduct, reporting, or dissemination plans of this study.

Results

Summary statistics of personal payments to board-certified cardiologists

Of the 15,048 eligible cardiologists board-certified by the JCS, 9,858 (65.5%) received at least one personal payment from a pharmaceutical company in 2016–2019 (Table 1). The total amount of these payments was \$112,934,503, entailing 165,013 payment transactions. For cardiologists who received at least one payment, the median amount was \$2,947 (interquartile range [IQR], \$1,022–\$8,787), with a mean of \$11,456 (standard deviation [SD]: \$35,876) over the 4-year period. The Gini index was 0.840 for personal payments per cardiologist, indicating that only a small proportion of cardiologists received the vast majority of the payments. Specifically, the top 1% (150 cardiologists), 5% (752 cardiologists), and 10% (1505 cardiologists) received 31.6%, 59.4%, and 73.5% of all personal payments, respectively. Over the 4-year period, only 0.5% (67 cardiologists) received payments exceeding \$200,000, while one cardiologist received 565 payments totaling \$782,015.

Lecturing payments accounted for 88.6% of the total payments (\$100,067,695) in value and 89.7% in the number of payments over the 4-year period, with 64.5% (9,710) of cardiologists receiving at least one lecturing payment. Consulting and writing payments accounted for 8.0% (\$9.1 million) and 3.3% (\$3.8 million) of the overall value. The mean value per payment was \$769 (SD, \$1,296) for consulting payments, \$733 (SD, \$340) for writing payments, and \$676 (SD, \$341) for speaking payments.

Payments made by pharmaceutical companies

Of 83 pharmaceutical companies making payments to the cardiologists, Daichi Sankyo made the largest payments (\$26.4 million [23.4% of all payments]), followed by Bayer

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6 207 (\$11.8 million [10.4% of all payments]), Boehringer Ingelheim Japan (\$8.8 million
7 208 [7.8% of all payments]), Otsuka Pharmaceutical (\$8.3 million [7.5% of all payments]),
8 209 Bristol Myers Squibb (\$5.7 million [5.0% of all payments]), and Takeda Pharmaceutical
9 210 (\$5.2 million [4.6% of all payments]). The top five and 10 companies with the largest
10 211 payment amounts were responsible for 54.2% (\$61.2 million) and 71.3% (\$80.5
11 212 million) of all payments over the 4-year period, respectively.
12 213

13
14 214 ***Personal payment trends to cardiologists, 2016–2019***

15 215 The total annual payments made to cardiologists ranged from \$27.4 million in 2016 to
16 216 \$28.8 million in 2017 (Table 2). Overall, 46.4%–47.4% of all cardiologists received at
17 217 least one personal payment each year. The median annual payment per cardiologist
18 218 increased slightly from \$1,226 (IQR, \$511–\$3,247) in 2016 to \$1,354 (IQR, \$613–
19 219 \$3,335) in 2019. The GEE models showed no significant trends in the number of
20 220 cardiologists receiving personal payments (relative annual average percentage change
21 221 [RAAPC], 0.3% [95% confidence interval, -0.2% to 0.8%], p=0.23) and payments per
22 222 cardiologist (RAAPC: 0.6% [95% confidence interval: -0.7% to 1.8%]; p=0.39) in
23 223 2016–2019. The linear regression models also showed no significant trends in the
24 224 annual total payment amounts and number of payments over the 4-year period.
25 225

26 226 ***Characteristics of top 100 cardiologists receiving largest total payments***

27 227 The top 100 cardiologists received a total of \$29.3 million, representing 25.9% of the
28 228 total personal payment amounts over the 4-year period. Of the top 100 cardiologists, 68
29 229 (68.0%) were authors of at least one cardiology clinical guideline developed by the JCS,
30 230 while 18 (18.0%) were executive board members of the JCS (Table 3). Sixty-eight
31 231 (68.0%) and six (6.0%) were full professors and associate or assistant professors at their
32 232 affiliated medical schools and universities, respectively, while 12 (12.0%) were
33 233 directors at their hospitals or clinics.
34 234

35 235 **Discussion**

36 236 Our study revealed that 65.5% of all board-certified cardiologists in Japan received
37 237 personal payments from pharmaceutical companies for activities such as lecturing,
38 238 consulting, and writing in 2016–2019. The total amount of these payments exceeded
39 239 \$112.9 million, equivalent to approximately 12.3 billion Japanese yen over the 4-year
40 240 period. Although the amounts of these payments remained stable throughout the study
41 241 period, a disproportionately small group of cardiologists received the majority of the
42 242 payments. Furthermore, these top-paid cardiologists were professors at their affiliated
43 243 medical schools and universities, participated in the creation of clinical practice
44 244 guidelines for cardiovascular diseases, and played leading roles at the JCS. To the best
45 245 of our knowledge, this is the first study to explore the comprehensive financial
46 246 interactions between pharmaceutical companies and cardiologists in a country other
47 247 than the US^{1 2 46}.
48 248

49 249 Contrary to findings in the US, where approximately three-quarters of cardiologists
50 250 reportedly received various personal payments, including compensation, honoraria,
51 251 travel fees, royalties, and food and beverage payments from pharmaceutical and medical
52 252 device corporations^{1 2}, our research in Japan indicates that approximately half of all
53 253 board-certified cardiologists annually received payments in the form of reimbursements
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for lecturing and consulting from pharmaceutical companies. Although the study findings were consistent with those of previous studies in Japan^{19 21-23 29 30 42}, this lower percentage of cardiologists receiving such payments in Japan versus the US would substantially underrepresent the actual degree of their financial engagements with the healthcare companies. Our study data were limited to compensation payments to individual cardiologists and did not encompass other prevalent payment categories or payments from medical device companies despite the fact that cardiologists frequently utilized medical equipment and devices such as implantable cardioverter-defibrillators, cardiac catheters, and stents.

Although the majority of cardiologists received only modest payments relative to their overall income, the impact of these payments should not be underestimated. Previous studies in the US demonstrated that even small payments to cardiologists from medical device and pharmaceutical companies are significantly associated with increased usage of percutaneous coronary interventions, stent placements⁴, and prescriptions for oral anticoagulants and antiplatelet drugs⁴. Nonetheless, given the absence of studies exploring the associations between payments to cardiologists and their clinical practices, future research is warranted to investigate the impact of industry payments on the clinical practices of cardiologists in Japan.

Interestingly, our trend analysis found no significant annual trends in personal payments to the cardiologists in 2016–2019, while previous studies in the US reported contrary findings^{1 47}. This finding may be related to fewer novel drugs being approved in Japan during the study period prior to the introduction of sacubitril/valsartan (brand name: Entresto), the first angiotensin receptor–neprilysin inhibitor manufactured by Novartis and marketed/promoted by Otsuka Pharmaceutical in Japan in August 2020. In contrast, in the US, sacubitril/valsartan was first approved for heart failure in 2015, leading to extensive marketing activities. These activities for sacubitril/valsartan resulted in payments to physicians exceeding \$50 million, representing the eleventh largest payment amount made to physicians in the US⁴⁸. In addition, despite a lack of detailed information for product names for which companies made payments to the cardiologists, the companies making largest payments to cardiologists in Japan were related to marketing for several direct oral anticoagulants (DOACs). Of the top five companies, four manufactured DOACs in Japan, including edoxaban (Daiichi Sankyo), rivaroxaban (Bayer), dabigatran etexilate (Boehringer Ingelheim), and apixaban (Bristol Myers Squibb). These DOACs were approved in the early 2010s, and the patents will expire within a few years. Thus, the companies would have less motivation to increase their marketing payments to cardiologists during the study period.

We found that only a small number of cardiologists received the vast majority of the personal payments. As we elucidated above, the average payments to JCS executive board members²⁰ and cardiology guideline authors^{31 45} were substantially larger than those received by the board-certified cardiologists. Additionally, the top-paid cardiologists were positioned in leading roles such as university professors, hospital directors, clinical practice guideline authors, and society executive board members. These physicians, often referred to as key opinion leaders, are frequently targeted by pharmaceutical and medical device companies^{27 49} due to their authoritative and

influential positions. Given their significant influence on other cardiologists, it is crucial that COIs among these influential cardiologists are properly managed. However, previous studies indicated significant undeclared and underreported COIs between physicians and pharmaceutical companies in Japan^{20 25-27 31 45 49-52}. Our previous study elucidated that more than 94% of authors of clinical practice guidelines for cardiovascular diseases received personal payments from pharmaceutical companies in Japan⁴⁵. Additionally, the policies used to manage COIs in Japan are less rigorous and transparent than those in other high-income countries^{27 45 49}. These study findings further underscore the critical need for the effective management of financial COIs among influential cardiologists in Japan.

This study had several limitations. Potential inaccuracies in the payment data reported by companies and in the database may exist. Moreover, the omission of certain types of payments, including meals, travel expenses, and gifts, which are not readily available in Japan, likely leads to a substantial underestimation of the magnitude and proportion of financial relationships between cardiologists and pharmaceutical companies in Japan. Furthermore, as the study encompassed only payments from JPMA-affiliated companies, it may not fully represent the entire range of financial interactions between cardiologists and JPMA-unaffiliated pharmaceutical companies or medical device companies.

In conclusion, our study demonstrated that more than 65% of cardiologists certified by the Japanese Circulation Society received personal payments from pharmaceutical companies related to lecturing, consulting, and writing services in 2016–2019. These payments were concentrated among a small group of cardiologists. Future studies should explore the influence of these payments on the clinical practice of cardiologists in Japan.

Declarations

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. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflicts of interest:

The authors have no conflicts of interest for this study.

Funding statement:

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

Ethics approval 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.

Patient consent statement

Not applicable

Permission to reproduce material from other sources

Not applicable

Clinical trial registration

Not applicable

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 take full responsibility for the content of the publication.

Author contribution:

A.M. contributed to data collection, resource, software, formal analysis, visualization, supervision, and study administration. All authors (A.M., K.H., and Y.S.) contributed to study conceptualization, methodology, writing the original draft, and reviewing the draft. A.M. is the guarantor of this study, accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

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Table 1. Summary of personal payments to board-certified cardiologists

Variables	Value
Total amounts of payments	
Payment values, \$	112,934,503
Number of payments, No.	165,013
Payments per cardiologist	
Mean (standard deviation) ^a	
Payment values, \$	12,649 (35,012)
Number of payments, No.	16.7 (33.9)
Median (interquartile range) ^a	
Payment values, \$	2,947 (1,022 – 8,787)
Number of payments, No.	7.0 (2.0 – 17.0)
Maximum ^a	
Payment values, \$	782,015
Number of payments, No.	576.0
Gini index	0.840
Cardiologists with specific amounts of payments (N=15,048), n (%)	
No payment	5,190 (34.5)
Any payments	9,858 (65.5)
\$1-\$1,000	2,318 (15.4)
\$1,001-\$10,000	5,314 (35.3)
\$10,001-\$50,000	1,825 (12.1)
\$50,001-\$100,000	225 (1.5)
\$100,001-\$200,000	109 (0.7)
\$200,001 or more	67 (0.5)
Payment categories	
Lecturing payments	
Monetary value (%), \$	100,067,695 (88.6)
Number of payments (%), No.	148,036 (89.7)
Mean value per payment (standard deviation), \$	676 (341)
Number of cardiologists receiving payments (%), n	9,710 (64.5)
Consulting payments	
Monetary value (%), \$	9,084,765 (89.7)
Number of payments (%), No.	11,815 (7.2)
Mean value per payment (standard deviation), \$	769 (1,296)
Number of cardiologists receiving payments (%), n	3,561 (23.7)
Writing payments	
Monetary value (%), \$	3,782,044 (3.3)
Number of payments (%), No.	5,162 (3.1)
Mean value per payment (standard deviation), \$	733 (340)
Number of cardiologists receiving payments (%), n	2,300 (15.3)

Legends: ^a Payments per cardiologist were calculated among cardiologists who received one or more payments, as 34.5% of cardiologists did not receive any payments over the four years.

Table 2. Trend in personal payments from pharmaceutical companies to board-certified cardiologists between 2016 and 2019.

Variables	2016	2017	2018	2019	Average relative yearly change between 2016 and 2019 (95% CI), %
Total payments					
Monetary value, \$	27,358,539	28,757,456	28,090,504	28,728,005	1.2 (-0.6 to 3.1)
Number of payments, No.	40,535	41,834	40,581	42,063	0.8 (-1.0 to 2.6)
Payments per cardiologist					
Monetary value, \$					
Mean (standard deviation)	3,917 (10,883)	4,068 (11,314)	3,938 (10,416)	4,082 (10,764)	0.6 (-0.7 to 1.8)
Median (interquartile range)	1,226 (511–3,247)	1,328 (511–3,372)	1,320 (511–3,270)	1,354 (613–3,335)	
Maximum	248,198	221,104	173,339	211,955	
Gini index	0.865	0.862	0.858	0.858	
Number of payments, No.					
Mean (standard deviation)	5.8 (10.1)	5.9 (10.4)	5.7 (9.7)	6.0 (10.0)	0.4 (-0.1 to 1.7)
Median (interquartile range)	3.0 (1.0–6.0)	3.0 (1.0–6.0)	3.0 (1.0–6.0)	3.0 (1.0–6.0)	
Maximum	189.0	160.0	155.0	162.0	
Gini index	0.810	0.808	0.802	0.805	
Physicians with payments (%) (N=15,048), n	6,984 (46.4)	7,070 (47.0)	7,133 (47.4)	7,038 (46.8)	0.3 (-0.2 to 0.8)

Abbreviation: 95% confidence interval (95% CI).

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588 Table 3. Characteristics of the top 100 cardiologists who received the largest total amounts of payments
589 from 2016 to 2019.
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Variables	Number of cardiologists
Participation in creation of cardiology clinical practice guidelines, n (%)	
Clinical practice guideline authors	66 (66.0)
Non-guideline author cardiologists	34 (34.0)
Board membership	
Executive board members	18 (18.0)
Non-board members	82 (82.0)
Positions at cardiologists' affiliations	
Full professor	68 (68.0)
Department director at a hospital	12 (12.0)
Hospital/clinic director	11 (11.0)
Associate or assistant professor	6 (6.0)
Other positions (e.g. chief advisor, consultant, and vice hospital director)	3 (3.0)

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STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3-4
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	3-4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3-5
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4-5
Bias	9	Describe any efforts to address potential sources of bias	n/a
Study size	10	Explain how the study size was arrived at	3
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4-5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5
		(b) Describe any methods used to examine subgroups and interactions	5
		(c) Explain how missing data were addressed	n/a
		(d) If applicable, describe analytical methods taking account of sampling strategy	5
		(e) Describe any sensitivity analyses	n/a
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	5
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	5
		(b) Indicate number of participants with missing data for each variable of interest	n/a
Outcome data	15*	Report numbers of outcome events or summary measures	5-6
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	5-6

		(b) Report category boundaries when continuous variables were categorized	n/a
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6
Discussion			
Key results	18	Summarise key results with reference to study objectives	6-7
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	6-8
Generalisability	21	Discuss the generalisability (external validity) of the study results	7-8
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	8

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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