# **BMJ Open** Cross-sectional analysis of pharmaceutical payments to Japanese board-certified gastroenterologists between 2016 and 2019

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#### To cite: Murayama A,

Kamamoto S. Kawashima M. et al. Cross-sectional analysis of pharmaceutical payments to Japanese board-certified gastroenterologists between 2016 and 2019. BMJ Open 2023;13:e068237. doi:10.1136/ bmjopen-2022-068237

 Prepublication history and additional supplemental material for this paper are available online. To view these files. please visit the journal online (http://dx.doi.org/10.1136/ bmjopen-2022-068237).

Received 12 September 2022 Accepted 04 April 2023



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#### ABSTRACT

**Objectives** Limited evidence is available regarding the financial relationships between gastroenterologists and pharmaceutical companies in Japan. This study analysed the magnitude, prevalence and trends of personal payments made by major pharmaceutical companies to board-certified gastroenterologists in Japan in recent vears.

**Design** Cross-sectional analysis

Setting and participants Using payment data publicly disclosed by 92 major pharmaceutical companies, this study examined the non-research payments made to all board-certified gastroenterologists by the Japanese Society of Gastroenterology.

Primary and secondary outcome measures The primary outcomes were payment amounts, the prevalence of gastroenterologists receiving payments, yearly trends in per-gastroenterologist payment values and the number of gastroenterologists with payments. Additionally, we evaluated the differences in payments among influential gastroenterologists, including clinical practice guideline authors, society board member gastroenterologists and other general gastroenterologists.

Results Approximately 52.8% of all board-certified gastroenterologists received a total of US\$89 151 253, entailing 134249 payment contracts as the reimbursement for lecturing, consulting and writing, from 84 pharmaceutical companies between 2016 and 2019. The average and median payments per gastroenterologist were US\$7670 (SD: US\$26 842) and US\$1533 (IQR: US\$582-US\$4781), respectively. The payment value per gastroenterologist did not significantly change during the study period, while the number of gastroenterologists with payments decreased by -1.01% (95% CI: -1.61% to -0.40%, p<0.001) annually. Board member gastroenterologists (median: US\$132 777) and the guideline authoring gastroenterologists (median: US\$106 069) received 29.9 times and 17.3 times higher payments, respectively, than general gastroenterologists (median: US\$284).

**Conclusion** Most gastroenterologists received personal payments from pharmaceutical companies, but only very few influential gastroenterologists with authority accepted substantial amounts in Japan. There should be transparent and rigorous management strategies for financial conflicts of interest among gastroenterologists working in influential positions.

# STRENGTHS AND LIMITATIONS OF THIS STUDY

- $\Rightarrow$  This is the first cross-sectional study to evaluate the extent, prevalence and trends of personal payments for lectures, consultations and writing to all gastroenterologists from pharmaceutical companies in Japan.
- $\Rightarrow$  We considered all board-certified gastroenterologists from the Japanese Society of Gastroenterology and collected payment data from all pharmaceutical companies belonging to the Japan Pharmaceutical Manufacturers Association (JPMA).
- $\Rightarrow$  The concentration of personal payments to influential gastroenterologists, such as clinical practice guideline authors and society board member gastroenterologists, was assessed.
- $\Rightarrow$  Our study did not include payments for other purposes such as meals, travel, and accommodation, research, royalties, licences, or payments from pharmaceutical companies not belonging to the JPMA.

# INTRODUCTION

data mining, Al training, and Repeated medical scandals and accumulating evidence suggest that financial relationships between pharmaceutical companies and healthcare professionals influence health-<u>0</u> These care professional behaviours.<sup>1–4</sup> concerns jeopardise the trust in pharmaceutical companies and evoke motivation to demand greater transparency in financial relationships worldwide.<sup>56</sup> In Japan, all pharmaceutical companies belonging to the Japan Pharmaceutical Manufacturers Association (JPMA), the largest pharmaceutical trade organisation in Japan, were mandated to disclose their payments to healthcare professionals and healthcare organisations on each company webpage since 2013.<sup>7</sup> This payment disclosure by pharmaceutical companies enabled the exploration of financial relationships between healthcare professionals and

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pharmaceutical companies with detailed payments in several specialties.<sup>8-13</sup>

Similar to other specialties,<sup>14–17</sup> gastroenterology has attracted significant financial attention from the global pharmaceutical industry. The global market size of gastroenterology diseases is estimated to continue growing from US\$37.6 billion in 2022<sup>18</sup> due to a growth in the number of patients and the introduction of various novel treatments.<sup>19 20</sup> Multiple studies conducted in the USA found that there were pervasive financial relationships between pharmaceutical companies and gastroenterologists.<sup>21–23</sup> Gangireddy et al found that 12743 US gastroenterologists and hepatologists received a median of US\$398 in general payments from pharmaceutical and device companies.<sup>24</sup> Nusrat et al reported that 88.9% of board-certified gastroenterologists in the USA received one or more general payments from the industry in 2016.<sup>25</sup> They also found that gastroenterologists authoring clinical practice guidelines were likelier to make more personal payments than other general gastroenterologists.<sup>25</sup>

Japan is no exception. Our previous studies in Japan elucidated the strong financial relationships between gastroenterologists and pharmaceutical companies, and these relationships were even stronger among high-class gastroenterologists. For example, guidelines for hepatitis C issued by the Japan Society of Hepatology received US\$46033 between 2016 and 2017.<sup>26</sup> Considering that gastroenterology (21608 board-certified gastroenterologists in 2019) is the largest among 23 internal and surgical subspecialties in Japan, followed by cardiology (14944 board-certified cardiologists) and pulmonology (6657 board-certified pulmonologists) and that the personal payments made by pharmaceutical companies to gastroenterologists influence their prescription patterns<sup>235</sup> understanding the characteristics of financial relationships between gastroenterologists and pharmaceutical companies is of particular importance.

However, little is known about the full landscape of financial relationships between Japanese gastroenterologists and pharmaceutical companies. This study aimed to elucidate the prevalence, magnitude and trend of personal payments from pharmaceutical companies to board-certified gastroenterologists in Japan in recent years.

#### **METHODS**

#### Study design and participants

This cross-sectional study assessed the payments made by pharmaceutical companies to Japanese board-certified gastroenterologists. We included all board-certified gastroenterologists by the Japanese Society of Gastroenterology (JSG) in Japan as of November 2021. The JSG, established in 1898, is the largest and most prestigious professional society for gastroenterologists in Japan. The JSG has developed many clinical practice guidelines for digestive diseases and has contributed to the training and certification of gastroenterologists in Japan since the launch of the gastroenterologist certification programme in 1988. As of February 2022, the JSG required physicians to meet several requirements, such as being a board-certified physician, surgeon or radiologist; completing specialised training for digestive diseases under the guidance of a board-certified instructor at an accredited hospital; having published academic articles; or presenting at an academic conference for digestive diseases.

#### **Data collection**

The full names of all board-certified gastroenterologists are publicly disclosed at the prefectural level on the official webpage of the JSG (https://www.jsge.or.jp/about/ 9 meibo\_senmon) and updated daily. Our data were extracted on 15 December 2021. To evaluate the personal payments among leading gastroenterologists, such as clinical practice guideline authors and society's board in members, compared with those of general gastroenterologists, the names and affiliations of all the latest board members with gastroenterology certification and authors with gastroenterology certification of clinical practice guidelines issued by the JSG between 2016 and 2021 were collected, as previous studies showed that leading physiollected, as previous studies showed that leading physi-ans such as board members<sup>27–30</sup> and clinical practice uideline authors<sup>4 11 25 31–36</sup> received substantial personal ayments from pharmaceutical companies. Payments concerning lecturing, writing and consulting cians such as board members<sup>27–30</sup> and clinical practice guideline authors<sup>4</sup> <sup>11</sup> <sup>25</sup> <sup>31–36</sup> received substantial personal payments from pharmaceutical companies.

paid to board-certified gastroenterologists were extracted from all 92 pharmaceutical companies that disclosed te payment data according to JPMA guidelines<sup>37</sup> between 2016 and 2019. As several pharmaceutical companies were disaffiliated from the JPMA or joined the JPMA recently, they did not have publicly disclosed payment data for a over 4 years. We then removed payments made to people **E** with duplicate names, as previously noted.<sup>8 38</sup> When we identified two or more gastroenterologists with the same names, we differentiated them by manually searching on Google and checking the official websites of the hospitals and organisations to where they belong, as previously noted.<sup>8</sup> All pharmaceutical companies belonging to the JPMA are required to disclose payments concerning lecturing, writing and consulting with the individual names of the payment recipients. Payment categories, such as meals, travel and accommodations, are disclosed in aggregated amounts and could not be analysed individually for each gastroenterologist. Further payments for lecturing, writing and consulting are generally paid directly to physicians from pharmaceutical companies & and in larger amounts than payments for other categories.<sup>7 21</sup> As of March 2022, the payments made in 2019 were the latest available and analysable data in Japan. Thus, considering the nature of personal payments, this study analyses personal payments for lecturing, writing and consulting between 2016 and 2019.

#### **Statistical analyses**

First, descriptive analyses of payment values and the number of payments were performed for individual

Second, the payment concentration among gastroenterologists was evaluated using the shares of payment values held by the top 1%, 5%, 10% and 25% of gastroenterologists. We also calculated the Gini index as an indicator of payment maldistribution. The Gini index ranges from 0 to 1, and the greater the Gini index, the greater the disparity in the distribution of payments on a gastroenterologist basis.<sup>10 15 39</sup>

Third, using panel data on payments for each gastroenterologist between 2016 and 2019, the trends in payment values per gastroenterologist and the prevalence of gastroenterologists with payments were evaluated using population-averaged generalised estimating equations (GEE). As the payment distribution was highly skewed (online supplemental material 1), a negative binomial GEE model with robust standard errors for the payment values per gastroenterologist and a linear GEE log-linked model with a binomial distribution for the prevalence of gastroenterologists with payments were used. The average annual change was reported as a relative percentage. Thus, the estimates can be interpreted as the annual change in payment values per gastroenterologist and the prevalence of gastroenterologists with payments. Trends were reported based on payments from all data-collected companies with payment data for the 4years between 2016 and 2019.

Finally, we evaluated the payment values per gastroenterologist according to whether they served on the ISG board or authored the ISG clinical practice guidelines. To examine the uneven distribution of payments by role for the guidelines, we divided gastroenterologists into three groups, 'non-guideline author gastroenterologist', 'guideline author' and 'the chairperson of guidelines'. The difference in payments between the groups was evaluated using the Mann-Whitney U test for two groups and the Kruskal-Wallis H test for three or more groups. The differences between every pair of groups were assessed using the Mann-Whitney U test with Bonferroni correction. Furthermore, the modified log-linked Poisson regression model with binomial distribution<sup>40</sup> examined the association of payment receipt with gastroenterologist board membership and/or participation in clinical guideline development using a relative risk ratio as the outcome measure. A multivariable negative binomial regression model<sup>8</sup> was used to evaluate the association between payment values, gastroenterologists' board membership and participation in clinical guideline development.

Payment values were converted from Japanese yen (¥) to US\$ using 2019 average monthly exchange rates of ¥109.0 per US\$1. All analyses were performed using Microsoft Excel for Microsoft 365 MSO V.2202 (Microsoft Corp.) and Stata V.15 (StataCorp).

# **Open access**

# Patient and public involvement

No patients and the public were directly involved in this study.

# RESULTS

#### **Overview and per-gastroenterologist payments**

We identified 22018 gastroenterologists who were board certified by the ISG as of 15 December 2021. Among the 22018 gastroenterologists, 11623 (52.8%) received **D** payments between 2016 and 2019. The total payment amount was US\$89 151 253, entailing 134249 payment contracts from 84 pharmaceutical companies over 4 years. Payments for lecturing were the largest (US\$77 940 406; 87.4%), most frequent (US\$119910 contracts; 89.3%) and most common (US\$11 344 (51.5%) physicians receiving payments for lecturing) payment categories ģ (table 1).

Regarding payment distribution, the top 1%, 5%, 10%and 25% of board-certified gastroenterologists accounted for 39.4% (95% CI: 37.0% to 41.7%), 69.6% (95% CI: 67.9% to 71.2%), 82.1% (95% CI: 81.0% to 83.1%) and 95.0% (95% CI: 94.7% to 95.4%) of total payments, 95.0% (95% CI: 94.7% to 95.4%) of total payments, respectively (online supplemental material 2). While **6** 47.2% (10 395 out of 22 018) of the gastroenterologists did not receive any payment for lecturing, consulting and writing, 7.4% (1630 out of 22 018), 1.6% (343 out of 22 018), 0.61% (135 out of 22 018) and 0.22% (49 out of 22 5 018) received more than US\$10 000, US\$50 000, US\$100 e 000 and US\$200000 over the 4 years, respectively. The and Gini index for the 4year combined total payments per gastroenterologist was 0.889.

The average and median payment values per gastroenterologist were US\$4049 (SD: US\$18 875) and US\$297 (IQR: US\$0-US\$1,715), respectively. The payment contracts per gastroenterologist were 6.1 (SD: 20.6) on average and 1.0 (IQR: 0-4.0) on a median. For the payments per gastroenterologist with payments, the average and median payments were US\$7670 (SD: US\$26 842) and US\$1533 (IQR: US\$582-US\$4781), respectively. One gastroenterologist maximumly received 11.6 (SD: 27.2) payment contracts from 4.4 pharmaceutical similar technol companies between 2016 and 2019.

# Payment trend between 2016 and 2019

The median annual payments per gastroenterologist were 0 across the 4years, as only 31.8%-33.9% of the gastroenterologists received payments each year (table 2). The  $\mathbf{a}$ median annual payments per gastroenterologist ranged **8** from 829 in 2017 to 946 in 2018. Among the 84 companies that made at least one payment during the 4 years of the study period, 71 continuously made at least 1 payment throughout 4 years. After limiting payments to these 71 companies, the annual payments per gastroenterologist remained stable, with an annual rate of change of 1.20% (95% CI: -0.069% to 2.45%, p=0.064). The number of gastroenterologists with payments decreased from 33.2% in 2016 to 31.1% in 2019, with an annual change rate

Table 1

Verichles	Values	
	values	
lotal	00454.050	
Payment values, US\$	89151253	
Contracts, n	134249	
Companies, n	84	
Gastroenterologists with payments, n (%)	11623 (52.8)	
Payment distribution		
Physicians with specific payments, n (%)		
No payment	10395 (47.2)	
US\$1-US\$500	2036 (9.3)	
US\$501–US\$1000	2389 (10.9)	
US\$1,001–US\$5000	4404 (20.0)	
US\$5,001–US\$10000	1164 (5.3)	
US\$10,001–US\$50000	1287 (5.8)	
US\$50,001–US\$100000	208 (0.94)	
US\$100,001–US\$200000	86 (0.39)	
US\$200 001-	49 (0.22)	
Gini index	0.889	
Payment category		
Lecturing		
Payment value, US\$ (%)	77 940 406 (87.4)	
Contracts, n (%)	119910 (89.3)	
Physicians, n (%)	11344 (51.5)	
Consulting		
Payment value, US\$ (%)	7 195 684 (8.1)	
Contracts, n (%)	8533 (6.4)	
Physicians, n (%)	2220 (10.1)	
Writing		
Payment value, US\$ (%)	3067693 (3.4)	
Contracts, n (%)	4642 (0.9)	
Physicians, n (%)	1686 (7.7)	
Other		
Payment value, US\$ (%)	947470 (1.1)	
Contracts, n (%)	1164 (0.9)	
Physicians, n (%)	682 (3.1)	
	Per gastroenterologist	Per gastroenterologist with payments
Average (SD)		
Payment values, US\$	4049 (19 875)	7670 (26 842)
Contracts, n	6.1 (20.6)	11.6 (27.2)
Companies, n	2.3 (3.9)	4.4 (4.4)
Median (IQR)		
Payment values, US\$	297 (0–1715)	1533 (582–4781)
Contracts, n	1.0 (0.0–4.0)	4.0 (2.0–10.0)
Companies, n	1.0 (0.0–3.0)	3.0 (1.0–6.0)
Range		

Summary of personal payments from pharmaceutical companies to board-certified gastroenterologists by the

Continued

Table 1 Continued	
Variables	Values
Payment values, US\$	51–555 553
Contracts, n	1.0-481.0
Companies, n	1.0–36.0

of -1.01% (95% CI: -1.61% to -0.40%, p<0.001) in the number of gastroenterologists with payments.

Subgroup analyses by aggregated payment values showed that both payments per physician and the number of physicians with payments significantly decreased among the gastroenterologists with US\$1-US\$500 and US\$501-US\$1000 personal payments. Meanwhile, gastroenterologists with higher aggregate payments received stable personal payments throughout the 4 years. (table 3)

### Payments to the society board members and the clinical practice guideline authors

Of the 22018 gastroenterologists, 24 were board members of the JSG in 2021 (online supplemental material 3). All the board members (24 out of 24) received personal payments from pharmaceutical companies between 2016 and 2019, with median payments of US\$132777 (IQR: US\$79 771-US\$215 036) and average payments of US\$162576 (SD: US\$127 573). Board members received much higher payments than non-board member gastroenterologists (US\$132777 vs US\$284, p<0.001 in the Mann-Whitney U test) (table 4).

Among the 22018 board-certified gastroenterologists, 231 authored 10 clinical practice guidelines issued by the ISG between 2016 and 2021 (online supplemental material 3). Of 231 gastroenterologists authoring the guidelines, 35 were chairpersons and vice-chairpersons of the guidelines. Overall, 90.5% (209 out of 231) of gastroenterologists authoring guidelines received payments, while 52.4% of non-guideline-author gastroenterologists received payments. The guideline chairpersons received higher payments (US\$106069 in median (IQR: US\$25 556–US\$289914)) than non-chairperson authors (US\$11131 in median (IQR: US\$1801–US\$61293), p=0.009) and general gastroenterologists (US\$284 in median (IQR: US\$0-US\$1633), p<0.001). In addition, non-chairperson authors received higher payments than general gastroenterologists (p<0.001) (table 4).

Board members and gastroenterologists who authored the guidelines were 1.6 times (95% CI: 1.4 to 1.7, p<0.001) and 1.7 times (95% CI: 1.6 to 1.8, p<0.001) more likely, respectively, to receive payments than other gastroenterologists. Multivariable negative binomial regression analyses showed that board members received 29.9 times (95% CI: 19.0 to 47.2, p<0.001) higher payment values than non-board gastroenterologists. Similarly, the gastroenterologists authoring the JSG guidelines received 17.3 times (95% CI: 13.9 to 21.6, p<0.001) larger personal payments from pharmaceutical companies than those not authoring the guidelines (table 4).

# Payment by pharmaceutical companies

Among the 84 companies making payments, payments from the top 10 companies accounted for 53.9% (US\$48 062 603) of the total payments. Takeda Pharmaceutical paid the largest amounts (US\$8 437 501; 9.5%), followed by AbbVie (US\$6 094 536, 6.8%), Otsuka Pharmaceutical (US\$5 926 679; 6.6%), Daiichi Sankyo (US\$5 313 357, 6.0%) and Mitsubishi Tanabe Pharma (US\$4 207 821; 4.7%). The number of gastroenterologists receiving payments was the largest by Daiichi Sankyo (3651 gastroenterologists), followed by Otsuka Pharmaceutical (3467 gastroenterologists) and Takeda Pharmaceutical (3242 gastroenterologists). The payment amounts in each year and payment categories are described by the company in ₫ figure 1 and online supplemental material 4, respectively. uses related

# DISCUSSION

đ This study found that between 2016 and 2019, approximately 90 million dollars were paid to board-certified e gastroenterologists by the ISG for the reimbursement of lecturing, consulting and writing by pharmaceutical companies. Among the 22018 Japanese board-certified ő gastroenterologists, 11623 (52.8%) received a median of a US\$1533 in personal payments over 4 years.

The payments and prevalence of gastroenterologists with payments were lower than those of other specialties in Japan. For example, the median 4year combined ≥ payments were US\$2210 among pulmonologists, US\$2471 among haematologists and US\$3183 among infectious Bu disease physicians. In addition, the proportion of physicians receiving payments ranges from 62.0% among pulmonologists to 70.6% among medical oncologists in Japan. As our payment data were limited to the reimbursement for lecturing, consulting and writing, and the number of specialists was the largest in gastroenterology, the prevalence of gastroenterologists with payments per physician was lower than that of other specialists.<sup>10 12 13 41 4</sup>

Additionally, it is meaningful to compare our findings with those of previous studies conducted in the **3** USA. In summary, more gastroenterologists in the USA reportedly receive personal payments compared with Japanese gastroenterologists. For instance, for the prevalence of gastroenterologists with payments, Tringale et al estimated that 72.2% of gastroenterologists received personal payments from pharmaceutical and medical device companies in 2015.<sup>21</sup> Similarly, Nusrat et al demonstrated that 86.9% of gastroenterologists and hepatologists received personal payments in 2016.<sup>25</sup> The median

All pharmaceutical companies       21008749       2233858       23602999       2305646         Total payments, US\$       21008749       2233358       23602999       2305646         Per gastroenterologist       554 (4756)       1010 (5241)       1072 (5354)       1013 (5.276)         Nectian payments (SD), US\$       954 (4756)       1010 (5241)       1072 (5354)       1013 (5.276)         Nectian payments (SD), US\$       0(-473)       0 (0-473)       0 (0-413)       1013 (5.276)       1013 (5.276)         Nectian payments (ICP), US\$       954 (4756)       1010 (5241)       1072 (5354)       1013 (5.276)         Nectian payments (ICP), US\$       0 (0-473)       0 (0-473)       0 (0-4167)       0 (0-467)         Average payments (ICP), US\$       832 (459-2146)       829 (511-2169)       314 (8977)       0 (0-467)         Maximum payment, US\$       7372 (33.5)       7102 (32.3)       7467 (33.9)       7106 (51-2273)         Maximum payment, US\$       7372 (33.5)       7102 (32.3)       7467 (33.9)       7006 (31.8)         Orini index       0.904       0.312       2415 (32.9)       7102 (51-228)       917 (511-2273)         Physicians with payments, U\$\$       0.304       0		change (95% CI), % P value	Combined total
Total payments, US\$       Z1008749       Z233358       Z3602999       Z305646         Per gastroenterologist       954 (4756)       1010 (5241)       1072 (5354)       1013 (5.276)         Median payments (SD), US\$       954 (4756)       1010 (5241)       1072 (5354)       1013 (5.276)         Median payments (SD), US\$       05-473)       0 (0-473)       0 (0-409)       0 (0-467)         Per gastroenterologist with payments       2850 (7885)       3131 (8862)       3161 (8929)       3184 (8977)         Median payments (IDR), US\$       832 (459-2146)       829 (511-2189)       946 (511-2289)       917 (511-2273)         Maximum payment, US\$       34-153552       51-167 862       51-1657 892       7006 (31.8)         Physicians with payments (IDR), US\$       34-153552       51-167 882       7106 (31.8)       7006 (31.8)         Physicians with payments (IDR), US\$       34-153555       51-167 882       51-1657 892       7166 707       51-15273         Physicians with payments, US\$       7322 (33.5)       7102 (32.3)       7006 (31.8)       7006 (31.8)         Physicians with payments, US\$       732 (33.5)       7102 (32.3)       7457 (33.9)       7106 (31.8)         Physicians with tayear <t< td=""><td></td><td></td><td></td></t<>			
Per gastroenterologist       1072 (5354)       1013 (5.276)         Median payments (SD), US\$       954 (4756)       1010 (5241)       1072 (5354)       1013 (5.276)         Median payments (SD), US\$       954 (4756)       1010 (5241)       1072 (5354)       1013 (5.276)         Per gastroenterologist with payments       0 (0-473)       0 (0-473)       0 (0-467)       0 (0-467)         Per gastroenterologist with payments       2850 (7885)       3131 (8862)       3141 (8829)       3144 (8977)         Average payments (SD), US\$       832 (455-2146)       829 (511-2195)       44 (611-228)       917 (611-2273)         Maximum payment, US\$       34-153552       51-167 886       47-166 707       51-153255         Physicians with payments, US\$       7372 (33.5)       7102 (32.3)       7467 (33.9)       7766 (31.8)         Gini index       7372 (33.5)       7102 (32.3)       7467 (33.9)       7766 (31.8)         Pharmaceutical companies with 4-year       7372 (33.5)       7102 (32.3)       7467 (33.9)       7766 (31.8)         Pharmaceutical companies with 4-year       7372 (33.5)       7102 (32.3)       7467 (33.9)       7166 707       917 (511-2273)         Pharmaceutical comparies with 4-year       7102 (32.3)	49       22 233 858       23 602 999       22 305 640	- 9.	89 151 253
Average payments (SD), US\$       954 (4756)       1010 (5241)       1072 (5354)       1013 (5.276)         Median payments (IQR), US\$       0 (0-409)       0 (0-511)       0 (0-467)       0 (0-467)         Per gastroenterologist with payments       2850 (7885)       3131 (8862)       3161 (8299)       314 (8977)         Average payments (IQR), US\$       2850 (7885)       3131 (8862)       3161 (8829)       314 (8977)         Median payments (IQR), US\$       2850 (7885)       3131 (8862)       3161 (8829)       314 (8977)         Median payments (IQR), US\$       2850 (7885)       3131 (8862)       3161 (8829)       314 (8977)         Median payments (IQR), US\$       34-15352       51-167 886       946 (511-2289)       917 (511-2273)         Maximum payment, US\$       7322 (33.5)       7102 (32.3)       7467 (33.9)       7006 (31.8)         Maximum payment, US\$       7372 (33.5)       7102 (32.3)       7102 (32.3)       7167 (33.9)       7006 (31.8)         Maximum payment, US\$       7372 (33.5)       7102 (32.3)       7467 (33.9)       7066 (31.8)         Maximum payment, US\$       7372 (33.5)       7102 (32.3)       7467 (33.9)       7066 (31.8)         Payment data'       Total payments (0			
Median payments (IQP), US\$       0 (0-473)       0 (0-409)       0 (0-511)       0 (0-467)         Per gastroenterologist with payments       3	56) 1010 (5241) 1072 (5354) 1013 (5.2	(76) 2.4 (1.1 to 3.8) <0.001	4049 (19 875)
Per gastroenterologist with payments       2850 (7885)       3131 (8862)       3161 (8829)       3184 (8977)         Average payments (DR), US\$       2820 (7885)       3131 (8862)       3161 (8829)       3184 (8977)         Median payments (IDR), US\$       832 (459-2146)       829 (511-2195)       946 (511-2289)       917 (511-2273)         Maximum payment, US\$       34-153552       51-167 886       47-166 707       51-153255         Physicians with payment, US\$       7372 (33.5)       7102 (32.3)       7467 (33.9)       7006 (31.8)         Gini index       0.904       0.912       0.905       0.912       0.912         Physicians with payments, n (%)       7372 (33.5)       7102 (32.3)       7467 (33.9)       7006 (31.8)         Physicians with payments, US\$       0.904       0.912       0.905       0.912         Physicians with payments, US\$       0.904       0.912       0.912       0.912         Payment dat*       0.904       0.912       0.905       0.912       0.912         Payment dat*       0.904       0.912       0.905       0.916       0.912         Per gastroenterologist       Average payments (DS), US\$       0.926 (4685)       0.00-511 <td>3) 0 (0-409) 0 (0-511) 0 (0-467)</td> <td></td> <td>297 (0-1715)</td>	3) 0 (0-409) 0 (0-511) 0 (0-467)		297 (0-1715)
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Median payments (IQF), US\$       832 (459–2146)       829 (511–2295)       917 (511–2273)         Maximum payment, US\$       34–1533552       51–167886       47–166707       51–153255         Physicians with payments, n (%)       7372 (33.5)       7102 (32.3)       7467 (33.9)       7006 (31.8)         Physicians with payments, n (%)       7372 (33.5)       7102 (32.3)       7467 (33.9)       7006 (31.8)         Physicians with payments, n (%)       0.904       0.912       0.905       0.912         Physicians with payments, n (%)       7372 (33.5)       7102 (32.3)       7467 (33.9)       7006 (31.8)         Physicians with payments       0.904       0.912       0.905       0.912       0.912         Payment data*       0.904       0.912       0.905       0.912       0.912         Payment data*       0.904       0.912       0.905       0.912       0.912         Payment data*       0.904       0.912       0.912       0.912       0.912         Payment data*       0.918       0.912       0.912       0.912       0.912         Payment data*       0.91       0.912       0.912       0.916       0.912 <tr< td=""><td>885) 3131 (8862) 3161 (8829) 3184 (897</td><td>(77)</td><td></td></tr<>	885) 3131 (8862) 3161 (8829) 3184 (897	(77)	
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Gini index       0.904       0.912       0.905       0.912         Pharmaccutical companies with 4-year payment data*       0.904       0.912       0.905       0.912         Pharmaccutical companies with 4-year payment data*       20579953       2.2215866       2.2879333       21196892         Total payments, US\$       20579953       22215866       22879333       21196892         Per gastroenterologist       935 (4685)       1009 (5238)       1039 (5179)       963 (5012)         Average payments (SD), US\$       935 (4685)       1009 (5238)       1039 (5179)       963 (5012)         Average payments (SD), US\$       0.0-459)       0.00-409)       0.00-511)       0.0-315)         Per gastroenterologist with payments       0.0-459)       0.00-409)       0.00-511)       0.0-315)         Average payments (SD), US\$       2818 (7802)       3128 (8856)       3099 (8580)       3094 (8611)         Average payments (SD), US\$       2818 (7802)       3128 (8856)       3099 (8580)       3094 (8611)         Average payments (SD), US\$       826 (459-2094)       829 (511-2195)       920 (511-2277)       842 (511-3094)         Payment range, US\$       24-153552       51-167 886       71-144 352 <td>3.5) 7102 (32.3) 7467 (33.9) 7006 (31.8</td> <td>.8) -1.0 (-1.6 to -0.4) 0.001</td> <td>11 623 (52.8)</td>	3.5) 7102 (32.3) 7467 (33.9) 7006 (31.8	.8) -1.0 (-1.6 to -0.4) 0.001	11 623 (52.8)
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Total payments, US\$       20579953       22215866       22879333       21196892         Per gastroenterologist       Average payments (SD), US\$       935 (4685)       1009 (5238)       1039 (5179)       963 (5012)         Average payments (SD), US\$       935 (4685)       1009 (5238)       1039 (5179)       963 (5012)         Median payments (IQR), US\$       0 (0-459)       0 (0-409)       0 (0-511)       0 (0-315)         Per gastroenterologist with payments       Average payments (IQR), US\$       2818 (7802)       3128 (8856)       3099 (8580)       3094 (8611)         Average payments (IQR), US\$       826 (459-2094)       829 (511-2195)       3094 (8611)       Payment range, US\$       3094 (8511)       3094 (8611)         Payment range, US\$       34-153552       51-167 886       47-144352       51-137 882       21004)       21004)       210040       2100040       210040       2100040			
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Average payments (SD), US\$       2818 (7802)       3128 (8856)       3099 (8580)       3094 (8611)         Median payments (IQR), US\$       826 (459–2094)       829 (511–2195)       920 (511–2277)       842 (511–3094)         Payment range, US\$       34–153552       51–167 886       47–144 352       51–137 882			
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Payment range, US\$       34–153552       51–167886       47–144352       51–137882         Priviting and the second state of the se	9–2094) 829 (511–2195) 920 (511–2277) 842 (511–	-3094)	(-)
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Gini index 0.905 0.912 0.905 0.913	0.912 0.905 0.913	I	0.890

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Table 3       Payment trend by aggregate p.	ayments per gastroen	terologist			
				Relative yearly change (95	5% CI), %
Physicians with specific payments	Physicians, n (%)	Median payments (IQR), US\$	Average payments (SD), US\$	Physicians with payments, n	Payments per physician
Overall	22018	297 (0–1715)	4049 (19 875)	-1.5 (-2.1 to -0.9)†	1.2 (-0.1 to 2.5)
US\$1-US\$500	2036 (9.3)	307 (284–307)	298 (84)	−11.3 (−14.7 to −7.9)†	-11.2 (-14.7 to -7.5)†
US\$501-US\$1000	2389 (10.9)	619 (511–817)	676 (153)	−5.5 (−7.9 to −3.0)†	−6.0 (−8.8 to −3.2)†
US\$1001-US\$5000	4404 (20.0)	2043 (1410–3089)	2340 (1108)	0.2 (-0.8 to 1.2)	-1.7 (-3.2 to -0.2)*
US\$5001-US\$10000	1164 (5.3)	6769 (5813–8121)	7036 (1414)	-0.07 (-0.8 to 0.7)	0.6 (-1.4 to 2.7)
US\$10 001-US\$50 000	1287 (5.8)	17089 (12 426–25 274)	20279 (9838)	0.04 (-0.3 to 0.4)	1.2 (-0.5 to 2.9)
US\$50 001-US\$100 000	208 (0.94)	67554 (55 815–80 658)	69626 (14 778)	0.2 (-0.2 to 0.5)	3.1 (-1.1 to 7.5)
US\$100 001-US\$200 000	86 (0.39)	133718 (112 643-161 029)	139 828 (28 231)	No estimation‡	0.6 (-3.9 to 5.4)
US\$200 001-	49 (0.22)	300675 (252 501–360 139)	323 010 (91 055)	No estimation‡	3.5 (-0.3 to 7.5)
*p<0.05. †p<0.001. ‡All physicians received the payments throug.	hout the 4 years.				

payment per gastroenterologist in the USA was US\$398-US\$481.<sup>21 24</sup> These differences between our findings and previous studies in the USA were probably due to the coverage of more general categories of payments, such as meals, travel and lodging, in the studies. In 2016, 83.5% of all US gastroenterologists received payments for meals and beverages.<sup>25</sup>

Although most Japanese gastroenterologists received small payments (about US\$900 per year), we found that their financial relationships with pharmaceutical companies have not changed in recent years. In a previous study of French general practitioners, it was discovered that physicians tolerate presentations from sales representatives for continuing education as well as civility towards sales representatives, despite their negative view of pharmaceutical company influence.43 Similarly, many Japanese gastroenterologists accept modest payments from the industry, and the influence of these payments cannot be underestimated. Even a small payment may influence a physician's prescription patterns, leading to favourable prescriptions for pharmaceutical companies making payments, increasing healthcare costs and less effective treatment.<sup>1 44–47</sup> The influence of small payments was not only on physician clinical practice but also on patients' trust in their physicians in Japan.<sup>48</sup> All gastroenterologists must be bona fide with their patients and treat them without disturbing their own interests.

One of the novelties of our study was the assessment đ of the differences in personal payments between general gastroenterologists and influential gastroenterologists such as society board members and authors of clinical practice guidelines. Compared with general gastroenterologists, pharmaceutical authors were 1.6 times and  $\mathbf{\bar{a}}$ 1.7 times more likely to receive payments and received 29.9 times and 17.3 times higher personal payments from pharmaceutical companies than general gastroenterolo-≥ gists, respectively. The skewed distribution of payments to certain gastroenterologists is evident from the Gini coefficient of 0.889 in the present study, which reveals that payments from pharmaceutical companies are highly g skewed towards authoritative gastroenterologists and key opinion leaders. These findings are consistent with those of a previous study, as the guideline authors were 1.41 times more likely to receive payments for consulting and lecturing in the USA in 2007.<sup>49</sup> Similar to the guideline authors, board members of professional medical associations have extensive financial relationships with the industry in France.<sup>29</sup> Pharmaceutical companies and **B** industries have implemented sales strategies targeting key opinion leaders among physicians<sup>50 51</sup> and physicians who receive payments are forced to bridge the gap between pharmaceutical companies and the medical community.<sup>52</sup> Extremely high concentrations of payments to influential physicians such as board members and guideline authors could be a serious concern for downstream healthcare and patient care. In Japan, there is no legal requirement to follow these guidelines; however, it is highly recommended that physicians providing care in

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	Physician with payments	Payment per gastı	roenterologist, US\$	40	Relative payments			
	Number (%)	Average (SD)	Median (IQR)	P value*	Relative risk for receiving payments (95% Cl)	P value	Relative monetary value (95% CI)	P value
Board membership								
Non-board members	11599 (52.7)	3876 (18 734)	284 (0–1701)	<0.001	Ref.	<0.001	Ref.	<0.001
Board membership	24 (100)	162 576 (127 573)	132 777 (79 771–215 036)		1.6 (1.4 to 1.7)		29.9 (19.0 to 47.2)	
Clinical practice guideline								
Non-guideline author gastroenterologists	11 414 (52.4)	3412 (15 918)	284 (0–1633)	<0.001	Ref.	<0.001	Ref.	<0.001
Gastroenterologists authoring guideline without chairpersonship	174 (88.8) p	48523 (80 763)	11 131 (1801–61 293)		1.7 (1.6 to 1.8)†		17.3 (13.9 to 21.6)†	
Gastroenterologists authoring guideline with chairpersonship	35 (100)	151 697 (148 056)	106 069 (25 556–289 914)					
*The difference in payments per gastroe †To stabilise the multiple Poisson and n	enterologist was eva negative binomial re <u>c</u>	luated by the Mann-Whi ression model, the guid	tney U test for two gro eline authors and guid	oups and Kr leline chairp	uskal-Wallis H test for thre ersons integrated into one	e or more gr e category.	.sdnc	



Payment trends by company. Figure 1

the relevant areas do so in accordance with their recommendations. The guidelines released by the ISG discussed in this article are meant to be followed by professionals in society. As a result, many physicians look to standards as literal guides when making prescriptions. In general, statements and recommendations endorsed by authoritative society board members and guideline authors with strong industry ties create a sense of the standards of care and rules to follow<sup>53</sup>; however, these statements and recommendations are often unduly biased<sup>54-57</sup> and have no strong evidence other than the opinions of the physicians supporting the statements.<sup>58–62</sup>

Following repeated examples of guidelines biased by conflicts of interest (COI) with industries, rigorous and transparent COI management strategies were developed for the guideline authors domestically and internationally.63-67 However, no consensus has been reached on the management of COI among leaders of professional medical societies.<sup>28</sup> 68 As Rothman et al proposed in 2009,69 the leaders of professional medical societies should abstain from financial interests with industry and must safeguard the patient's best interest. Transparent and rigorous COI policies are also required for leaders of professional medical societies.

#### Limitations

This study has several limitations. First, despite crosschecking the payment data by more than two independent investigators, we could not rule out the inclusion of errors in the payment data because we manually collected payments from each company's webpage. Second,

to according to the guidelines of the JPMA, as the payment data were voluntarily disclosed by the companies and there were no penalties for deviations from the guidelines in Japan, the payment data disclosed by the companies might be inaccurate. Third, as the payment data were limited to those from pharmaceutical companies, there could be payments to gastroenterologists from other pharmaceutical companies that do not disclose payment data or medical device companies. Fourth, it would be preferable to consider economic indicators, such as the inflation rate, when analysing changes in monetary provisions, but this was not done in this study. We estimate that the influence on the market price of monetary gifts from pharmaceutical corporations was negligible due to the fact that Japan's inflation rate throughout the relevant time was less than 1%. Finally, the JSG only discloses the latest-year name lists of board-certified gastroenterologists; thus, our study included some gastroenterologists without board certification during the payment period.

#### CONCLUSION

More than half of board-certified gastroenterologists in Japan received personal payments for lecturing, consulting and writing. Although the majority of gastroenterologists received small payments, payments per gastroenterologist remained stable between 2016 and 2019. Furthermore, influential gastroenterologists such as board members and clinical practice guideline authors of the JSG are strongly tied to pharmaceutical companies.

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Transparent and rigorous management strategies are required among leaders of professional medical societies and guideline authors.

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Acknowledgements The authors thank Tansa (formerly known as Waseda Chronicle) for collaboration for this project. Also, we appreciate Mr. Takuto Sakaemura, Mr. Kohki Yamada and Ms Megumi Aizawa for their dedicated contribution on collecting and cross-checking the payment data.

**Contributors** AM contributed to study conceptualisation, data collection, formal analysis, methodology, visualisation, software, project administration, resources, writing of the original draft and reviewing of the original draft. SK contributed to study conceptualisation, data collection, methodology, visualisation, writing of the original draft and reviewing of the original draft. MK contributed to study data collection, methodology, and writing of the original draft. HS contributed to study conceptualisation, methodology, software, writing of the original draft, reviewing of the original draft. HS contributed to study conceptualisation, methodology, software, writing of the original draft, reviewing of the original draft. TC contributed to study conceptualisation, methodology, writing of the original draft, reviewing of the original draft, funding acquisition and supervision. AM is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Funding** This study was funded in part by the Medical Governance Research Institute. This non-profit enterprise receives donations from a dispensing pharmacy, namely Ain Pharmacies, and private individuals. This study also received support from the Tansa (formerly known as the Waseda Chronicle), an independent nonprofit news organisation dedicated to investigative journalism. There were no award/grant numbers of the support from the organisations and companies. None of the entities providing financial support for this study contributed to the design, execution, data analyses or interpretation of study findings and the drafting of this manuscript.

**Competing interests** HS received personal fees from Taiho Pharmaceutical Co outside the scope of the submitted work. AO and TT received personal fees from MNES, a company developing diagnostic AI tool, outside the scope of the submitted work. TT also received personal fees from Bionics Co, a medical device company, outside the scope of the submitted work. Regarding non-financial conflicts of interest among the study authors, all are engaged in ongoing research examining financial and non-financial conflicts of interest among healthcare professionals and pharmaceutical companies in Japan. HS is a board-certified gastroenterologist by the Japanese Society of Gastroenterology. The other authors have no example conflicts of interest to disclose.

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.

#### Patient consent for publication Not applicable.

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

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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Supplemental Material 3. Payments to board members and clinical practice guideline authors with the board certification as gastroenterologists



Supplemental Material 4. Payment categories by company

