

BMJ Open Voluntary disclosures of payments from pharmaceutical companies to healthcare professionals in Germany: a descriptive study of disclosures in 2015 and 2016

Marlene Stoll ^{1,2}, Lara Hubenschmid,² Cora Koch ³, Klaus Lieb^{1,2}

To cite: Stoll M, Hubenschmid L, Koch C, *et al.* Voluntary disclosures of payments from pharmaceutical companies to healthcare professionals in Germany: a descriptive study of disclosures in 2015 and 2016. *BMJ Open* 2020;**10**:e037395. doi:10.1136/bmjopen-2020-037395

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2020-037395>).

Received 31 January 2020
Revised 14 May 2020
Accepted 19 July 2020



© Author(s) (or their employer(s)) 2020. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

¹Department of Psychiatry and Psychotherapy, University Medical Center Mainz, Mainz, Germany

²Leibniz Institute for Resilience Research (LIR) gGmbH, Mainz, Germany

³Department of Neurology and Neurophysiology, Medical Center - University of Freiburg, Freiburg, Germany

Correspondence to

Prof. Dr. Klaus Lieb;
Klaus.Lieb@unimedizin-mainz.de

ABSTRACT

Objective To analyse voluntary payment reports of pharmaceutical companies to German healthcare professionals (HCPs) in 2015 and 2016 based on an industry-self-regulating transparency codex.

Design and participants Cohort study of all German HCPs who voluntarily agreed that at least one payment they received in 2015 and 2016 from pharmaceutical companies is disclosed.

Main outcome measures Number of HCPs who disclosed at least one payment in the database; separated by year of disclosure and whether they disclosed once or repeatedly. Amount of disclosed payments and distribution parameters of disclosed annual payment sums per person; separated by year of disclosure and whether they disclosed once or repeatedly.

Results 28 230 HCPs agreed to the disclosure of at least one payment in the database. In 2015, 19 905 HCPs agreed to the disclosure, decreasing to 15 782 HCPs in 2016. Whereas 7457 disclosed payments in both years, 12 448 disclosed only in 2015 and 8325 only in 2016. Payments of €32 426 721 in 2015 and €23 289 343 in 2016 were disclosed, that is, 27% and 23% of the total amounts spent on HCPs, respectively. Distribution of annual payments was skewed: the top 1% of HCPs disclosed annual payment sums between €17 049 and €200 194, while the median disclosed annual payment sum per person was €536 (IQR €1092). Disclosed payments were higher in male physicians and in physicians with higher academic degree.

Conclusions If voluntary, disclosure rates of payments are low and therefore only provide a fragmented picture of interactions between HCPs and pharmaceutical companies. Efforts must be intensified to ensure obligatory disclosure of all payments worldwide.

INTRODUCTION

Pharmaceutical companies pay large sums to physicians to support their continuing medical education, to pay for lectures, meals, travel, speaking and consulting, and to support drug research.^{1 2} In 2017, US\$8.4 billion were paid by US pharmaceutical companies to about 628 000 US physicians and 1100 teaching hospitals.³ Studies show that in 2017, nearly half of all US physicians received payments

Strengths and limitations of this study

- This is the first study analysing the publicly available payments of pharmaceutical industry to healthcare professionals (HCPs) in Germany over 2 years.
- Payment data of a large number of HCPs (n=28 230) are analysed.
- Data are given at the individual level and only with the individual consent for disclosure, thereby allowing to analyse disclosure behaviour, that is, how many HCPs disclosed both years or only once.
- Disclosed annual payments only give total payments with no specification for which the payments were given.
- In cases of non-disclosure it remains unclear whether the HCP had not agreed to disclose or did not receive any payments.

by a pharmaceutical company⁴ and between 2015 and 2017, pharmaceutical companies paid US\$5.8 billion to US physicians with estimated mean annual payment values of about US\$1100–US\$4700 per physician.⁵ Such financial ties create conflict of interests (COIs), that is, the risk that the professional judgement or action of a physician or researcher is unduly influenced.^{6–8} Indeed, a large body of evidence exists that industry sponsorship is related to research outcomes^{2 9–11} and may influence physicians' prescribing patterns.^{12–16}

Some form of regulation regarding pharmaceutical companies' disclosure of such financial ties to the public exists in many countries worldwide but these rules vary considerably.^{17 18} One important difference is whether pharmaceutical companies' disclosure is based on legally binding laws and therefore mandatory or whether disclosure is introduced through self-regulation codices by the pharmaceutical companies themselves. Legally binding disclosure laws have been implemented in the US through the

Physician Payment Sunshine Act,¹⁹ but also in Australia, France, Belgium, Portugal, Denmark and Romania.^{17 18 20} In contrast, some European countries such as Germany, Italy and Spain have no transparency laws but leave transparency entirely to a self-regulatory approach of the pharmaceutical industry, implemented in form of a Disclosure Code by the European Federation of Pharmaceutical Industries and Associations (EFPIA).²¹ Combined with data protection laws this means in Germany that payments are only made transparent if the individual healthcare professional (HCP) agrees. Therefore, disclosure is voluntary, because companies are not allowed to publish individual information without consent. Another major difference between disclosure policies is whether the disclosed information is aggregated centrally or exists only on the different pharmaceutical companies' websites. The US Open Payments website, for example, provides a publicly visible search interface that supports the search of the individual HCP and provides analysable files for free download. In most European states, however, the information is only provided on the websites of the pharmaceutical companies in non-searchable and non-analysable documents.

Voluntary disclosure databases have been described for the UK²² and Austria,²³ by analysing disclosed payment sums by the pharmaceutical companies. However, to the best of our knowledge, the disclosure behaviour of individual HCPs in voluntary databases has not been examined in detail before. In the current study, we analysed disclosed data from 54 pharmaceutical companies representing about 75% of the German pharmaceutical industry market for prescription drugs.^{24 25} The database is unique as it not only allows for analysis of the number of HCPs that agreed to the disclosure of their financial ties and the amount of annual disclosed payments, but also allows to examine individual HCPs' disclosing behaviour, that is, whether HCPs agreed to disclosure only in 1 year or repeatedly in both years. The objective of this study was, therefore, to investigate (1) how many German HCPs agreed to disclose their payments in the database in total and per year, and whether they agreed to disclose repeatedly or only once, (2) how much money was disclosed (A) in total and (B) on average per HCP and (3) how payment amounts differ with respect to disclosure behaviour, year of disclosure, gender and academic degree of the disclosing HCP.

METHODS

Database

Since 2016, German pharmaceutical companies organised in the association of voluntary self-regulation in the pharmaceutical industry (Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V., FSA) have agreed to annually publish documents on their homepages containing information about transfers of value (ToVs) to healthcare organisations and individual HCPs during the previous year, in the context of a transparency codex.

Due to data protection laws in Germany, pharmaceutical companies are not allowed to make the ToV to individual HCPs public without their consent. Thus all individual disclosures are voluntary for the HCP. HCPs are free to disclose none, some or all payments made to them. Where consent cannot be acquired, companies publish aggregated data for this year. Irrespective of this, all ToVs related to research and development are disclosed in aggregated form without identification of individuals.²⁶ The codex further determines the location of the disclosure—the companies' public websites—and provides a non-binding example for the structure of the disclosure document, but otherwise it does not state how disclosure should occur. In the past, this resulted in different document formats from different companies, of which many were non-searchable. The FSA explicitly does not aim to aggregate these data.²⁷ In Germany, first data of the transparency codex were published in summer 2016 for the payments of the year 2015.

The German non-profit investigative journalism newsroom CORRECTIV combined the separate disclosure documents for the years 2015 and 2016 into the database 'Euros for Doctors', aiming to integrate the companies' individual data per HCP. Based on extrapolations using the total amount of payments spent by pharmaceutical companies to HCPs and the disclosed payment sums per HCP, CORRECTIV estimated the number of HCPs who received payments by these companies to be 71 000 in 2015 and 66 000 in 2016.²⁸

The publicly available online version of the CORRECTIV database offers a search tool by which individual HCPs can be searched by name, location or postcode. All individual entries are headed with 'Mr/Ms (name of HCP) agreed to disclose the following payments:' and include a table with all ToV the HCP agreed to disclose. Each entry concludes with the overall payment sum the HCP received in that year. In the case that data for 1 year are missing, it is not apparent whether HCPs did not agree to disclose the payment or whether they did not receive any payments that year. CORRECTIV provided us with the data behind this database in form of an analysable excel sheet which contained the following information for each HCP who is listed in the 'Euros for Doctors' database: name, academic degree, gender, address, number of companies from which payments were received for 2015 and 2016, and disclosed annual payment sums in 2015 and 2016. We, therefore, could not distinguish between different kind of payments or companies. Data of the pharmaceutical companies' total payment amounts were taken from press releases by the FSA.^{24 25}

Procedure

Preparation of the database

CORRECTIV's data collection for the 'Euros for Doctors' database was machine based. Parts of the pharmaceutical companies' documents were in a non-editable format, leading to spelling errors that complicated the correct mapping of payments to HCP. We, therefore, screened

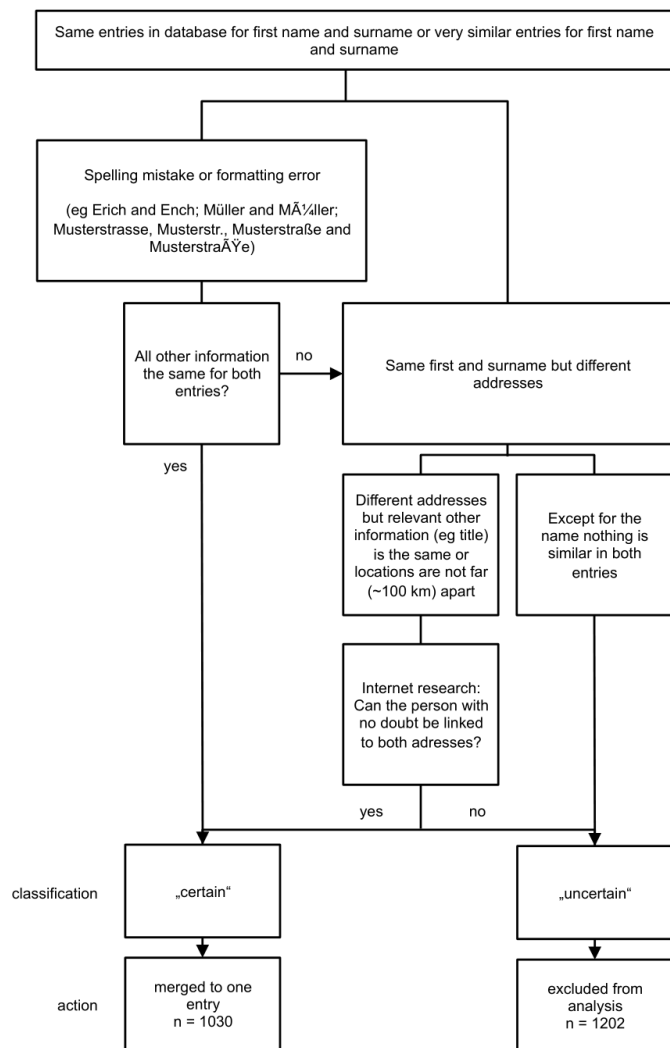


Figure 1 Decision tree for handling of duplicate entries in the database.

the data for duplicates (see figure 1) and matched entries that obviously belonged to the same person but were separated because of, for example, two working addresses or typing errors—2076 double or triple entries were found

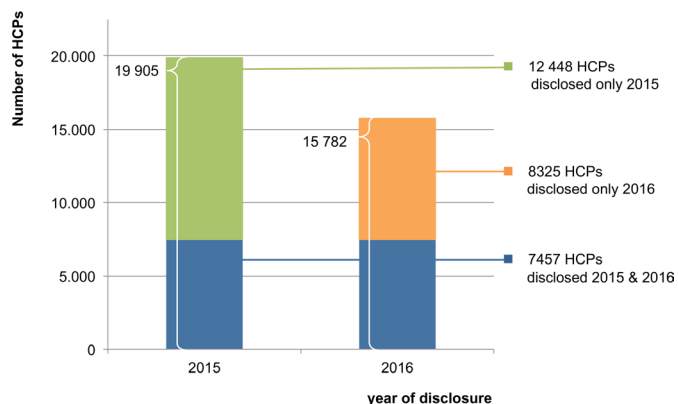


Figure 2 Number of HCPs who disclosed their annual payment sums per year, separated by disclosure behaviour (onetime vs repeated disclosure). HCPs, healthcare professionals.

and could be merged into 1030 entries. A total of 1202 duplicates could neither be traced to one HCP, nor could we identify an obvious error, so we excluded these entries from further analyses.

Endpoints of interest

The main outcomes of the analyses were the number of HCPs who disclosed at least one payment in the database, further separated by year of disclosure and disclosure behaviour; and the amount of disclosed payments as well as distribution parameters of disclosed annual payment sums per person, separated by year of disclosure and disclosure behaviour.

Analysis

First, we analysed the number of HCPs who disclosed their received payments in total, dependent on year (2015 vs 2016) and disclosure behaviour (repeatedly vs once). We then examined the total amount of disclosed payments as well as the annual disclosed payments and number of companies from which HCPs received payments per person. To gain insight in the distribution of payment sums, the median, IQR and the 99th percentile was calculated. These analyses were also examined separately for year, disclosure behaviour, gender and academic degree. For quantification of the differences between various groups of HCPs regarding payment amount, we calculated two-sided non-parametric tests and separated the analyses into examination of independent samples on the one hand and dependent samples on the other. For the comparison of two independent samples, Wilcoxon rank-sum tests, and for the comparison of three independent samples, Kruskal-Wallis tests were conducted. For dependent samples, Wilcoxon signed-rank tests were performed. Effect sizes are given as rank-biserial correlation r_b (Wilcoxon tests) and epsilon squared ϵ^2 (Kruskal-Wallis test) with the corresponding 95% CI.

Analyses were done in JASP V.0.10.2,²⁹ RStudio, R V.3.6.1³⁰ and Microsoft Excel (2011).

Patient and public involvement

Patients or the public were not involved.

RESULTS

Number of HCPs who disclosed payments

In total, 28 230 HCPs disclosed payments in at least 1 year. Figure 2 shows the total number of HCPs separated by year and disclosure behaviour. The total number of HCPs decreased from 2015 to 2016 by 21%. Of all HCPs, 26% agreed to disclose repeatedly in both years, and 74% only in 1 year (44% in 2015, 29% in 2016).

The proportion of HCPs who disclosed payments in relation to the number of HCPs who received payments (as estimated by CORRECTIV) was about 28% in 2015 (19 905/71 000) and 24% in 2016 (15 782/66 000).

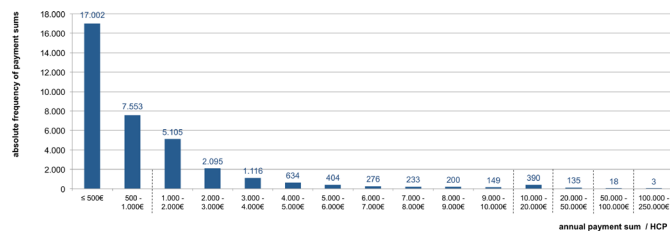


Figure 3 Absolute frequencies of disclosed annual payment sums in respective categories 2015–2016 up to the maximum amount of payment. HCP, healthcare professional.

Amount of disclosed payments

Total payment amounts

The investigated 54 companies paid €119 000 000 to HCPs in 2015 and €105 000 000 to HCPs in 2016, resulting in a total of €224 000 000.^{24 25} Summarised over both years, €55 716 063 (25%) of payments were disclosed in the form of 35 687 annual payment sums. The minimum disclosed annual payment sum per person was €1 and the maximum sum €200 194. The mean annual payment sum per person was €1561 (SD €4221). Half of all HCPs disclosed annual payment sums of €536 or less (IQR €1092). The top percentile included payments equal or larger than €17 049. This indicates a distribution of annual payment sums per person that is strongly skewed to lower payments, see [figure 3](#).

Disclosed payment amounts in 2015 vs 2016

A higher percentage of the total sum of payments was disclosed to HCPs in 2015 (€32 426 721/€119 000 000; 27%) than 2016 (€23 289 343/€105 000 000; 22%). The total amount of disclosed payments per year decreased by 28% from €32 426 721 in 2015 to €23 289 343 in 2016. The mean annual payment sum per person decreased by 9% from 2015 to 2016 (see [table 1](#) for further descriptive data). In 2015, the top 10 highest annual payment sums per person summarised to €1 048 929, meaning that the ten HCPs with the highest payments disclosed 3% of the total disclosed payments; in 2016, the top 10 highest annual payment sums summarised to €845 597, which is 4% of the disclosed payments.

On average, an HCP received payments from two pharmaceutical companies per year (Mdn=1) both in 2015 and 2016. The top percentile for company count per HCP was 10 in both years, which means that 99% of HCPs received payments by less than 10 pharmaceutical companies per year. The HCP with the highest company count per year received payments by 31 pharmaceutical companies in 2015 and by 28 companies in 2016.

Comparison of disclosed payments: year and disclosure behaviour

[Table 1](#) shows descriptive statistics split up for disclosing behaviour and year of disclosure and [table 2](#) shows the quantification of differences between the analysed groups.

Regarding year of disclosure, those who agreed to disclose only once in 2015 disclosed slightly higher

payments than those who disclosed only once in 2016, as indicated by a Wilcoxon rank-sum test with a trivial effect size of $r_b=0.07$ (0.06; 0.09). Those who agreed to disclose both in 2015 and 2016 also showed slightly higher annual payment sums in 2015 than in 2016, indicated by a Wilcoxon signed-ranked test with a small effect size of $r_b=0.14$ (0.12; 0.17).

Regarding disclosure behaviour, those HCPs who disclosed only in 1 year disclosed lower payments than HCPs who agreed to disclose in both years, with a medium effect sizes as indicated by a Wilcoxon rank-sum test, $r_b=-0.31$ (-0.32; -0.29) (see [table 2](#) for similar results for 2016).

Comparison of disclosed payments: gender and academic degree

The descriptive annual and total payment sums and absolute frequencies separated by gender and academic degree can be seen in [table 1](#). Of all 28 230 HCPs, 40% were female and 60% were male. Regarding academic degree, 8% had a German postdoctoral degree ('habilitation' / 'Prof. '), 39% had a doctoral degree but no habilitation, and 53% had no academic degree stated.

The proportion of female HCPs in our sample was higher for those who agreed to disclose only once: 44% female vs 56% male, compared with those who disclosed repeatedly: 30% female vs 70% male. In 2015 (see [table 2](#) for similar results for 2016), male HCPs disclosed higher annual payment sums than female HCP, indicated by a Wilcoxon rank-sum test delivering a small effect size: $r_b=0.28$ (0.26; 0.29).

The proportion of habilitations and doctoral degrees in our sample was higher for those who disclosed only once: 6% habilitation vs 35% doctoral degree vs 59% no academic degree, compared with those who disclosed repeatedly: 14% habilitation, 50% doctoral degree and 36% no academic degree. Academic degree had a medium effect on disclosed payment sums, $\epsilon^2=0.12$ (0.11; 0.13), as indicated by a Kruskal-Wallis test. Pairwise comparisons indicate that habilitated HCPs disclosed higher annual payment sums than doctoral HCPs and those without academic degree; and doctoral HCPs disclosed higher annual payment sums than those without academic degree (see [table 2](#) for further details). Median annual payment sums including IQR, separated by year of disclosure, disclosure behaviour, gender and academic degree are depicted in [figure 4](#).

DISCUSSION

Principal findings

To our knowledge, this is the first analysis of a 2-year database of voluntary disclosures of payments from pharmaceutical companies to HCPs allowing for a detailed description of disclosing behaviour of individual HCPs. Our analyses showed that the amount of disclosed payments, as well as the number of HCPs who agreed to disclose payments, decreased over the period of

Table 1 Disclosed annual payments per person and in total, separated per disclosure behaviour, gender and academic degree for each year

	2015										2016										2015 and 2016				
	amount of disclosed annual paym. per person in €					n (paym.)					amount of disclosed annual paym per person in €					n (paym.)					total amount in €				
	Mean (SD)	Median (IQR)	Min*	Perc	99th Perc	Max						Mean (SD)	Median (IQR)	Min*	Perc	99th Perc	Max								
All	19 905	1629 (4363)	551 (1162)	1	17 429	200 194	15 782	1476 (4033)	516 (1033)	1	16 667	199 775	35 687	55 716 063											
Disclosure behaviour																									
Once	12 448	1021 (2367)	452 (773)	1	10 082	61 380	8325	760 (1490)	387 (660)	1	6352	59 250	20 773	19 035 707											
Rep.	7457	2644 (6310)	899 (2102)	4	26 735	200 194	7457	2275 (5544)	790 (1732)	1	23 198	199 775	14 914	36 680 357											
Gender																									
Female	7516	935 (2298)	380 (669)	3	9651	85 062	6122	830 (2103)	347 (619)	1	8547	69 906	11 375	12 108 475											
Male	12 385	2051 (5188)	741 (1492)	1	21 866	200 194	9655	1886 (4832)	712 (1353)	1	19 859	199 775	16 848	43 601 289											
Academic degree																									
Professor	1764	5675 (10 740)	2404 (5309)	4	46 493	200 194	1463	4904 (9756)	2062 (3928)	3	50 609	199 775	2211	16 885 282											
Dr	8370	1650 (3608)	669 (1301)	3	15 657	86 654	6398	1512 (3371)	629 (1167)	1	15 938	70 923	11 005	23 623 640											
None	9771	881 (1817)	393 (686)	1	9040	57 787	7921	813 (1745)	375 (647)	2	7879	54 483	15 014	15 207 142											

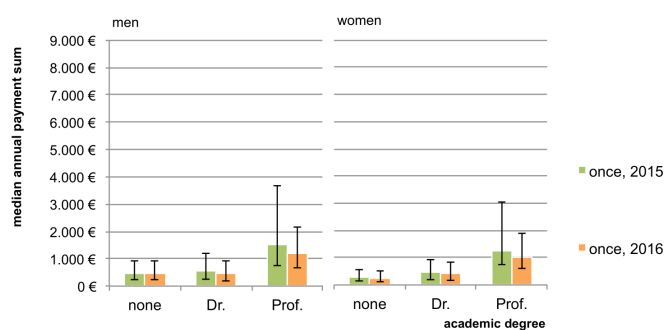
*In contrast to other databases, there is no threshold for disclosure. N=87 HCPs received annual payments sums ≤ €10; the reasons for these low payments are unclear. HCP, healthcare professional; Paym, payments; Perc, Percentile.

Table 2 Effect sizes and 95% CI for the comparison of various groups regarding annual payment amounts per person

Independent variable	Factor levels	Effect size	(95% CI)
Disclosure behaviour: once			
Year	2015 vs 2016	$r_b = -0.07$	(0.06 to 0.09)
Disclosure behaviour: repeatedly			
Year	2015 vs 2016	$r_b = 0.14$	(0.12 to 0.17)
2015			
Disclosure behaviour	Once vs repeatedly	$r_b = -0.31$	(-0.32 to -0.29)
Gender	Male vs female	$r_b = 0.28$	(0.26 to 0.29)
Academic degree	None vs Dr vs Professor	$\epsilon^2 = 0.12$	(0.11 to 0.13)
	None vs Dr	$r_b = -0.24$	(-0.25 to -0.22)
	None vs Professor	$r_b = -0.68$	(-0.69 to -0.66)
	Dr vs Professor	$r_b = -0.51$	(-0.53 to -0.49)
2016			
Disclosure behaviour	Once vs repeatedly	$r_b = -0.32$	(-0.34 to -0.31)
Gender	Male vs female	$r_b = 0.31$	(0.30 to 0.33)
Academic degree	none vs Dr vs Professor	$\epsilon^2 = 0.12$	(0.11 to 0.13)
	None vs Dr	$r_b = -0.21$	(-0.23 to -0.20)
	None vs Professor	$r_b = -0.68$	(-0.70 to -0.66)
	Dr vs Professor	$r_b = -0.50$	(-0.53 to -0.48)

r_b =rank-biserial correlation: positive values indicate that the after scores are smaller than the before scores.

HCPs who disclosed only 2015 vs. HCPs who disclosed only 2016



HCPs who disclosed in both years, 2015 vs. 2016

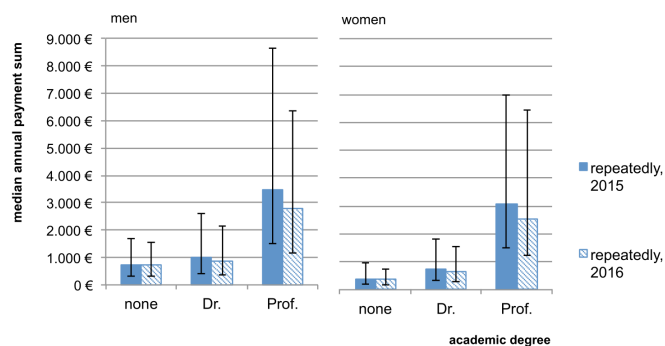


Figure 4 Median annual payment sums with IQR separated by year, disclosing behaviour, gender and academic degree. HCP, healthcare professional.

2 years. Furthermore, of all HCPs disclosing at least one payment in 2015 and 2016, only 26% disclosed payments in both years. The disclosures by German pharmaceutical companies can, therefore, be described as a very fragmented and limited insight into the actual interactions with German HCPs. The distribution of disclosed annual payment amounts was skewed to lower amounts of payments with half of all disclosing HCPs disclosing annual payment sums up to €536, while one percent of HCPs disclosed payment sums of €17 049 to €200 194. This is comparable to the distribution of non-voluntary disclosed payments in the US⁵: a large proportion of the total payments is concentrated among few physicians, whereas many physicians receive comparable smaller amount of payments.

We observed that on average, female HCPs disclosed lower amounts of payments than male HCPs and HCPs with lower academic degrees disclosed lower amounts of payments than HCPs with higher academic degrees. This is comparable to studies from the US that have shown that male physicians,^{4 5 31} physicians who have been practising longer, and those who graduated from a top-ranked US medical school receive higher industry payments.⁵ These factors, however, might interact at various levels: for example, women are less likely to attain senior-level positions, and therefore, are more likely to have lower academic degrees.^{32 33}

Findings in context

It is often argued by pharmaceutical companies that adherence to self-regulation codices like the EFPIA provides a sufficient basis for transparency of payments to HCPs.²⁶ Based on our data, we would argue against this view as only approximately a quarter of all payments were disclosed. Comparison of disclosure rates to other countries providing voluntary transparency of payments is difficult since transparency codices can be implemented in many different ways and because companies did not report the number of all HCPs who received payments. However, analyses of comparable European databases for the year 2015 and 2016 show that the proportion of disclosed payments to HCPs in 2015 was higher in Switzerland (estimated 56%)³⁴ and Great Britain (48%),²² but even lower in Austria (17%).²³ In contrast to our finding that disclosure rates decreased from 2015 to 2016, disclosure rates increased from 2015 to 2016 in Switzerland and Great Britain. Even more problematic to analyse is the proportion of HCPs agreeing to disclose payments because pharmaceutical companies in Germany did not give the exact number of HCPs who received payments. Indeed, we only had estimates of those numbers by CORRECTIV and thereof calculated consent rates of 28% (2015) and 24% (2016).²⁸ In other countries, estimates show a development of consent rates from 2015 to 2016 of 22%–21% in Austria²³ and of 56%–65% in UK.²² The reasons for these discrepancies between countries are unclear but might be found in the different implementations of the EFPIA. Even within one country, a transparency guideline might be implemented differently by different pharmaceutical companies. The German example shows that there is high variance of consent rates between the companies, ranging from 91% for GlaxoSmithKline (GSK) to 16% for Genzyme.³⁵ In reply to an enquiry by CORRECTIV, the pharmaceutical companies with the highest consent rates stated that they actively endeavoured to reach HCPs' consent, for example, by multiple inquiries if an HCP did not respond. GSK stated that they prefer working with physicians who agree to disclose ToVs and may quit collaborating with HCPs who are not supporting transparency. The companies with the lowest disclosure rates did either not provide a statement, or stated that they requested written consent by HCPs.³⁵ Other factors that influence the consent rate might lie in the communication and framing of the transparency guideline towards the public. Some physicians in Germany reported that they did not disclose because they were afraid the public might get a 'false impression' by the disclosed information.³⁶ Unfortunately, we have no data regarding these factors, nor on the further development of disclosure rates, as the CORRECTIV database was only available for 2015 and 2016.

Strengths and weaknesses

A strength of our dataset is that it allowed for an analysis of the individual disclosing behaviour of HCPs over 2 years. Our analyses showed that only 26% disclosed

repeatedly. A major weakness of the given database was that no information was available whether HCPs disclosed all their payments or just some; and whether HCPs without an entry did not receive any payments or did receive payments but did not agree to disclose. This left us with the uncertainty that HCPs without an entry in one or both years could either have decided against disclosure or not have received any payments. An argument for the latter is that the group of HCPs who only disclosed in 2015 disclosed smaller annual payment sums than those who disclosed repeatedly. This group may, therefore, consist of HCPs who sometimes receive smaller payments and sometimes none at all, whereas repeatedly disclosing HCPs sometimes receive higher payments and sometimes lower payments. If this is the case and payments 'naturally fluctuate', however, the consent rate between the years should have been similar, where in reality it decreased from 27% to 22%. Also, in 2015, the ratio of those who disclosed only once was higher than 2016—63% vs 53% of all disclosing HCPs. This might be a clue that in 2016, more HCPs decided against disclosure. However, from the current body of evidence, we can only speculate.

A further weakness was that the database was not the original database as for example, in analyses of Open Payments/Disclosure UK but collected by a third party. This may have created transcription and transmission errors. We worked hard to omit obvious transcription errors by conscientiously examining the duplicates in the database, merging obvious duplicates and deleting cases in which it was unsure whether a transcription error was apparent from the analysis. A standardised procedure that not only builds and maintains a centralised database, but compares disclosed and actually transferred payments and provides the opportunity for HCPs to feedback errors in their entries would contribute to full transparency.

Policy implications

Our data are of relevance for policymakers. Voluntary disclosures of payments lead to low numbers of physicians agreeing to disclose and are dependent on how the guidelines are interpreted and implemented by those responsible, resulting in a fragmented picture of the interactions between HCPs and pharmaceutical companies. Full transparency of such payments, therefore, can only be provided if disclosures are required by legislation. In our view, full transparency is necessary for several reasons. Only full transparency provides an unbiased view on the true degree of financial ties between HCPs and pharmaceutical companies. This is the basis for all further measures of COI regulation.^{20 37 38} In addition, patients can use this information to make informed decisions about which physicians to place their trust in, and, under certain circumstances, how to interpret their physicians' recommendations.^{20 37–40} All data should be made transparent through user-friendly, searchable and downloadable databases to allow for continuing analysis of interactions between HCPs and pharmaceutical companies.

CONCLUSION

This example of a self-regulating transparency codex of German pharmaceutical companies shows that only every third to fourth HCP decides to make their payments by pharmaceutical companies voluntarily transparent, and consent rates decrease over the years. The analysis shows that only a quarter of those HCPs who disclosed 2015 or 2016 disclosed payments in both years. To gain true transparency, disclosed information must be complete. Only on that condition the disclosed information adds value to current discussions about COIs and only then further regulation mechanisms can be discussed and implemented.

Twitter Marlene Stoll @starlene_moll

Acknowledgements The authors thank CORRECTIV for providing the database and Jasmin Peifer and Marc Himmelmann for their help with the database.

Contributors MS, CK and KL were responsible for the study conception and design. MS and KL were responsible for title and abstract and full-text review. MS and LH were responsible for data extraction and validation. MS, KL and CK analysed and interpreted results. MS and KL drafted the manuscript. All authors provided a critical review and approved the final manuscript. KL is the guarantor.

Funding Funded by Volkswagen Foundation (grant no. A118085 (ref.91498) to KL).

Competing interests All authors have completed the ICMJE uniform disclosure form at www.icmje.org/doi_disclosure.pdf. CK and KL disclosed that they are members of the German no-free-lunch-organisation 'MEZIS eV'. CK, MS and LH declared that they had received salary from the Volkswagen Foundation. KL declared that he received a research grant by Volkswagen Foundation.

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 required.

Ethics approval Since we analysed a publicly accessible database, we did not ask for an ethics approval.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request by emailing KL.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iDs

Marlene Stoll <http://orcid.org/0000-0001-8847-5497>

Cora Koch <http://orcid.org/0000-0003-0827-7023>

REFERENCES

- Agrawal S, Brown D. The physician payments sunshine act--two years of the open payments program. *N Engl J Med* 2016;374:906–9.
- Bekelman JE, Li Y, Gross CP. Scope and impact of financial conflicts of interest in biomedical research: a systematic review. *JAMA* 2003;289:454–65.
- Sullivan T. Open payments data 2017: significant drop in number of payments, 2020. Available: <https://www.policymed.com/2018/07/open-payments-data-2017-shows-significant-drop-in-number-of-payments.html>
- Tringale KR, Marshall D, Mackey TK, et al. Types and distribution of payments from industry to physicians in 2015. *JAMA* 2017;317:1774–84.
- Inoue K, Blumenthal DM, Elashoff D, et al. Association between physician characteristics and payments from industry in 2015–2017: observational study. *BMJ Open* 2019;9:e031010.
- Institute of Medicine Committee on Conflict of Interest in Medical Research E, Practice. The National Academies Collection: Reports funded by National Institutes of Health. In: Lo B, Field B, eds. *Conflict of interest in medical research, education, and practice*. Washington (DC): National Academies Press (US), National Academy of Sciences, 2009.
- Thompson DF. Understanding financial conflicts of interest. *N Engl J Med* 1993;329:573–6.
- Koch CSet al. Conflicts of interest in medicine and their management. *CEJ* 2016;2:3–26.
- Lundh A, Lexchin J, Mintzes B, et al. Industry sponsorship and research outcome. *Cochrane Database Syst Rev* 2017;2:Mr000033.
- Schott G, Pacht H, Limbach U, et al. The financing of drug trials by pharmaceutical companies and its consequences: Part 2: a qualitative, systematic review of the literature on possible influences on authorship, access to trial data, and trial registration and publication. *Dtsch Arztebl Int* 2010;107:295–301.
- Schott G, Pacht H, Limbach U, et al. The financing of drug trials by pharmaceutical companies and its consequences. Part 1: a qualitative, systematic review of the literature on possible influences on the findings, protocols, and quality of drug trials. *Dtsch Arztebl Int* 2010;107:279–85.
- Brax H, Fadlallah R, Al-Khaled L, et al. Association between physicians' interaction with pharmaceutical companies and their clinical practices: a systematic review and meta-analysis. *PLoS One* 2017;12:e0175493.
- Brunt CS. Physician characteristics, industry transfers, and pharmaceutical prescribing: empirical evidence from Medicare and the physician payment sunshine act. *Health Serv Res* 2019;54:636–49.
- DeJong C, Aguilar T, Tseng C-W, et al. Pharmaceutical industry-sponsored meals and physician prescribing patterns for Medicare beneficiaries. *JAMA Intern Med* 2016;176:1114–22.
- Lieb K, Scheurich A. Contact between doctors and the pharmaceutical industry, their perceptions, and the effects on prescribing habits. *PLoS One* 2014;9:e110130.
- Sharma M, Vadhariya A, Johnson ML, et al. Association between industry payments and prescribing costly medications: an observational study using open payments and medicare part D data. *BMC Health Serv Res* 2018;18:236.
- Europe M-MH. Shedding light on transparent cooperation in healthcare. The way forward for sunshine and transparency laws across Europe, 2020. Available: <https://mhe-sme.org/wp-content/uploads/2019/01/MHE-SHEDDING-LIGHT-REPORT-Final.pdf>
- Fabbri A, Santos Ala, Mezinska S, et al. Sunshine policies and murky shadows in Europe: disclosure of pharmaceutical industry payments to health professionals in nine European countries. *Int J Health Policy Manag* 2018;7:504–9.
- Ornstein C. Public disclosure of payments to physicians from industry. *JAMA* 2017;317:1749–50.
- Grundy Q, Habibi R, Shnier A, et al. Decoding disclosure: comparing conflict of interest policy among the United States, France, and Australia. *Health Policy* 2018;122:509–18.
- EFPIA. *Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organizations*. EFPIA, 2014.
- Mulinari S, Ozieranski P. Disclosure of payments by pharmaceutical companies to healthcare professionals in the UK: analysis of the association of the British pharmaceutical industry's disclosure UK database, 2015 and 2016 cohorts. *BMJ Open* 2018;8:e023094.
- Mantsch S, Petersen P, Wild C. *Pharma: offenlegung geldwerter leistungen in osterreich 2015 systematische analyse*. Wien: Ludwig Boltzmann Institut für Health Technology Assessment, 2016.
- FSA. *Forschende pharma-unternehmen setzen transparenzkodex um*, 2020. Available: <https://www.fsa-pharma.de/de/mitteilungen/presse/archiv/forschende-pharma-unternehmen-setzen-transparenzkodex-um/>
- FSA. *Transparenzkodex: das zweite Jahr*, 2020. Available: <https://www.fsa-pharma.de/de/mitteilungen/presse/archiv/transparenzkodex-das-zweite-jahr/>
- FSA-Kodex. *FSA-Kodex zur transparenz bei der Zusammenarbeit mit den angehörigen der fachkreise und medizinischen einrichtungen*, 2020. Available: https://www.fsa-pharma.de/de/kodizes/sk_fsa_transparenzkodex_13.03.2019.pdf
- Solberg P. *FSA-Transparenzkodex*, 2020. Available: <https://www.fsa-pharma.de/de/kodizes/transparenzkodex/inhaltsübersicht>
- Grill MW S. *Pharmakonzerne haben 562 millionen euro an Ärzte gezahlt*, 2020. Available: <https://correctiv.org/aktuelles/euros-fuer-aerzte/2017/06/21/pharmakonzerne-haben-562-millionen-euro-an-aerzte-gezahlt>
- JASP. *Announcing JASP 0.10.2*, 2019.

- 30 Team RC. *R: a language and environment for statistical computing*, 2013.
- 31 Weng JK, Valle LF, Nam GE, *et al*. Evaluation of sex distribution of industry payments among radiation oncologists. *JAMA Netw Open* 2019;2:e187377.
- 32 Carr PL, Gunn C, Raj A, *et al*. Recruitment, promotion, and retention of women in academic medicine: how institutions are addressing gender disparities. *Womens Health Issues* 2017;27:374–81.
- 33 Carr PL, Raj A, Kaplan SE, *et al*. Gender differences in academic medicine: retention, RANK, and leadership comparisons from the National faculty survey. *Acad Med* 2018;93:1694–9.
- 34 Gruhnwald SL. *Der Doktor und sein Sponsor*. Correctiv, 2017.
- 35 LHG K. M. erstaunliche unterschiede, 2020. Available: <https://correctiv.org/aktuelles/euros-fuer-aerzte/2016/07/15/erstaunliche-unterschiede>
- 36 Boytchev H. Warum Ärzte schweigen, 2020. Available: <https://correctiv.org/aktuelles/euros-fuer-aerzte/2016/07/17/warum-aerzte-schweigen>
- 37 Bero L. Addressing bias and conflict of interest among biomedical researchers. *JAMA* 2017;317:1723–4.
- 38 Kanter GP, Loewenstein G. Evaluating open payments. *JAMA* 2019. doi:10.1001/jama.2019.8171. [Epub ahead of print: 01 Jul 2019].
- 39 Cain DM, Loewenstein G, Moore DA. When sunlight fails to disinfect: understanding the perverse effects of disclosing conflicts of interest. *J Consum Res* 2011;37:836–57.
- 40 Koch C, Stoll M, Klemperer D, *et al*. Transparency of conflicts of interest: a mixed blessing? the patients' perspective. *Am J Bioeth* 2017;17:27–9.