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Complete List of Authors:	Stoll, Marlene; Universitätsmedizin der Johannes Gutenberg-Universität Mainz, Department of Psychiatry and Psychotherapy; Leibniz Institute for Resilience Research Hubenschmid, Lara; Leibniz Institute for Resilience Research gGmbH Koch, Cora; Medical Center-University of Freiburg, Department of Neurology and Neurophysiology Lieb, Klaus; Universitätsmedizin der Johannes Gutenberg-Universität Mainz, Department of Psychiatry and Psychotherapy Egloff, Boris; Johannes Gutenberg University Mainz, Department of Psychology
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Physicians' attitudes towards disclosure of payments from pharmaceutical companies in a nation-wide voluntary transparency database: a cross-sectional survey

Marlene Stoll*, Lara Hubenschmid, Cora Koch, Klaus Lieb, Boris Egloff

Marlene Stoll (marlene.stoll@unimedizin-mainz.de)
Department of Psychiatry and Psychotherapy, University Medical Center Mainz, Untere Zahlbacher Straße 8, 55131 Mainz, Germany
Leibniz Institute for Resilience Research (LIR) gGmbH, Mainz, Germany
http://orcid.org/0000-0001-8847-5497

Lara Hubenschmid (lara.hubenschmid@lir-mainz.de)
Leibniz Institute for Resilience Research (LIR) gGmbH, Mainz, Germany

Cora Koch (cora.koch@uniklinik-freiburg.de)
Department of Neurology and Neurophysiology, Medical Center - University of Freiburg, Freiburg, Germany
http://orcid.org/0000-0003-0827-7023

Klaus Lieb (klaus.lieb@lir-mainz.de)
Department of Psychiatry and Psychotherapy, University Medical Center Mainz, Mainz, Germany
Leibniz Institute for Resilience Research (LIR) gGmbH, Mainz, Germany

Boris Egloff (egloff@uni-mainz.de)
https://orcid.org/0000-0002-5736-9912
Department of Psychology, Johannes Gutenberg University Mainz

* Corresponding author

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ABSTRACT

Objectives: To investigate German physicians' attitudes towards and experiences with voluntary disclosure of payments by pharmaceutical companies in a public database and their impact on future decisions for or against disclosure.

Design: National cross-sectional survey conducted in 2018 among physicians who voluntarily disclosed at least one payment in the German transparency regulation.

Setting: Retrospective paper-pencil questionnaire about attitudes towards and experiences with voluntary payment disclosures in the first (2015) and second year (2016) of the German transparency regulation.

Participants: German physicians who disclosed either in the first year only, the second year only, or in both years of the transparency regulation.

Primary outcomes: (1) the probability to disclose in 2016, predicted by physicians' experience of reactions from others in 2015, descriptive norms, and attitudes towards transparency; (2) frequency and (3) content of reactions from others 2015 compared to 2016.

Results: Data of 234 respondents were analysed (n = 42, 45, and 147 physicians who disclosed in 2015, 2016 or both years, respectively). The probability to disclose in 2016 was not predicted by perceived reactions, norms, or attitudes towards transparency (p>.01). Most participants reported not to have received any reactions by patients (190/234, 81%), colleagues (128/234, 55%) or the private environment (153/234, 65%). Neither frequency nor content of reactions differed between the first and second year (scale 1-5; frequency: $Mdn_{2015,2016}$ = 1.33 vs. 1.36, r_b = -.17, p>.01; content: $Mdn_{2015,2016}$ = 2.69 vs. 2.96, r_b = .19, p>.01). However, media reporting, fear of reputational damage and a feeling of being defamed were mentioned as reasons for non-disclosure.

Conclusions: While confirmatory analyses did not provide significant results, descriptive analyses showed that participants who voluntarily disclose payments mainly do not experience any reactions towards their disclosures but report fears about losing their reputation due to disclosures.

Registration: https://osf.io/ztvur

ARTICLE SUMMARY

Strengths and limitations of this study

- This study is the first survey of attitudes and experiences of physicians who voluntarily disclosed payments by pharmaceutical companies in a nation-wide transparency database.
- The sample takes into account whether physicians disclosed only in one year or in two consecutive years.
- The study was preregistered and provides qualitative and quantitative data on reasons for non-disclosure in this database.
- The questionnaire used in this study was only constructed for this purpose, so a direct comparison with other data is not possible.

INTRODUCTION

The medical care-giving sector has long been interconnected with the pharmaceutical industry. One patient-oriented, the other competition-driven, this constellation has brought along observations of systematic biases in research and daily care.[1–3] Situations in which a secondary interest such as financial gain creates a risk that a primary interest such as patient welfare is unduly influenced are defined as conflicts of interest (COI).[4,5] Several approaches have been established as an answer to the challenge of COI in medicine, amongst which transparency regulations have been very popular in the latest years.[6–8]

This study explores the effects of the European transparency regulation of payments by pharmaceutical companies to healthcare professionals (HCPs) in Germany. Transparency regulations have been introduced to "shed light" on formerly unknown information,[9] in this case: information about payments from pharmaceutical companies to HCPs. In the United States, such payments are fully transparent since the introduction of the Physician Payments Sunshine Act (PPSA). Payments are publicly disclosed on the Open Payments website.[10] Metaphorically speaking, the transatlantic sun shines brightly on the financial interactions between industry and HCPs. In Europe, sunlight is partly concealed, since transparency is mandatory only in some European countries whereas in countries such as Germany, pharmaceutical companies only fragmentarily disclose payments.[6,8,11] In Germany, transparency of payments to HCPs is regulated primarily by self-regulation of the pharmaceutical industry. Because of data protection laws, the HCP's consent is needed for the respective financial interaction to be disclosed on each company's website.[11,12]

The disclosure of financial COI can have unintended effects (e.g., loss of patient trust [13,14]). While research has been done on the experiences of U.S. physicians with the PPSA,[15] there is a lack of research on experiences with industry-driven transparency regulations such as the European approach.

Physicians' experiences with transparency guidelines

In focus groups conducted in the United States in 2015,[15] physicians reported they did not know much about the PPSA and had only limited experience with the Open Payments website. They expressed a positive attitude towards the general concept of transparency, but also reported negative experiences with the regulation such as administrative burden. They felt treated unfairly and were worried the disclosures might mislead patients.[15] A similar attitude was reported towards the German voluntary

transparency regulation in a newspaper article.[16] In this report about physicians who explicitly decided against disclosure in the German transparency database, the interviewees stated to approve transparency in general, but also said the current regulation was unfair, that the disclosed information was misleading, and that patients' trust would suffer.[16] However, a systematic survey on that topic has not been conducted yet.

Effects of recipients' attention to transparency databases on physicians

One aim of COI disclosure is that it could motivate conflicted persons to change their behaviour for the better.[17] Physicians who must disclose payments might feel ashamed or like they are standing in the spotlight.[15] This may lead the disclosing physicians to a behavioural adjustment: They might subsequently avoid COIs so that they do not have to disclose them and do not feel ashamed about them anymore. This effect, however, might cease if disclosers realize that the public is not aware of the disclosed information.[17] According to two surveys of U.S. citizens in 2014 and 2015, public salience of the Open Payments website is low: Only 9-12 % knew about the disclosed information.[18,19] While the interviewed U.S. physicians believed that patients were uninterested in the data,[15] the unsystematically interviewed German physicians feared that patients would be misled by the disclosed data and draw false conclusions, which is why they decided against disclosure in the German database.[16]

Conflicted physicians who believe that patients are aware of disclosed information may behave differently as compared to physicians who believe that no one pays attention. It might therefore be important whether physicians notice people reacting to the COI disclosure, since this could function as an indication that recipients are aware of the disclosed COI. Whether reactions are negative or positive may further indicate how people interpret the disclosed information. Such reactions could affect physicians' handling of COI in the future and their willingness to disclose industry payments in a public database. This study, therefore, investigates the reactions to voluntarily disclosed COI that German physicians experienced and whether these reactions impact future disclosure behaviour.

Norms

In case of voluntary transparency regulations, the number of cooperating HCPs who disclose COI could be important for the commitment of all HCPs, since it may indicate that COI disclosure is seen as "normal". The descriptive norm (i.e., the perceived prevalence of behaviour) might be decisive for HCPs' decision whether to disclose COI. Since social norms are indications for behaviour that is accepted by a group,[20,21] the first time that area-wide information about the frequency of behaviour becomes available may be critical

for the establishment of new norms. Implementing a nation-wide transparency guideline implies a first time when new information is disclosed to the public. From this point on, information is available about how many HCPs disclose payments and how much money they disclose. Such information could form a new reference frame for what is seen as "normal" behaviour.

This first time when information is disclosed is also a critical moment because the disclosed information is new to the public, meaning that it may not yet be perceived as "normal" but as scandalous. In the first year of a voluntary transparency regulation, the media and the public may pay considerable attention to the disclosures, directing the spotlight on those who decided to disclose. Recipients may show more extreme reactions towards a disclosing physician in the first year of a transparency database than in the following years. By rewarding or punishing the behaviour, recipients may thus reinforce the social norm to disclose. Relevant recipients for information about physicians' payments by pharmaceutical companies are their patients, colleagues, and persons in their private environment.

This study, therefore, also investigates how physicians' descriptive norm to disclose (i.e., the estimated prevalence of transparency cooperativeness) predicts future disclosure behaviour; and whether reactions by recipients differed between the first and the second year of the transparency regulation.

Germany's transparency regulation

In Germany, pharmaceutical companies organized in the "association of voluntary self-regulation in the pharmaceutical industry" passed a self-regulation transparency codex requiring German HCPs to give consent to each pharmaceutical company for the public disclosure of the payment sums they have received from that company.[12,22] The companies then disclose single transfers of values on their websites. First data were disclosed 2016 for payments of the year 2015. The investigative newsroom CORRECTIV subsequently gathered all data from pharmaceutical companies that follow this transparency codex and established the "Euros for Doctors" database, aiming to provide easy access to the disclosed data. They accompanied the kick-off of the Euros for Doctors database with investigative articles [23], collaborating with the popular German online news magazine SPIEGEL ONLINE. Since this media attention might have had unintended effects on disclosers, this study also exploratively investigates the role of the media.

Study aims and research questions

The study aims were to (A) predict physicians' consent to disclose through their experiences with COI disclosure in the previous year and (B) investigate whether these experiences differ between the first and second year of the transparency regulation. Research question 1 is: Does a physician's subjective appraisal of reactions to disclosure in one year and the descriptive norm to disclose predict the decision to disclose in the following year? Does a positive attitude towards transparency moderate this relationship? We hypothesized that the probability for deciding against disclosure in the subsequent year was higher the more unpleasant reactions were perceived and the lower the percentage of people agreeing to disclose is estimated, and that a positive attitude towards transparency moderates this relationship. Research questions 2 and 3 are: Do physicians experience a higher number of reactions and more negative reactions in the first than in the second year of the regulation? We hypothesized that reactions in the first year were more frequent and more negative than in the following year.

METHODS

Sample

Our sample was drawn from the population of 28,230 HCPs who disclosed at least one financial interaction with a pharmaceutical company in 2015 or 2016 in the German transparency regulation.[12] We built our sample of 5 groups, consisting of HCPs who disclosed only 2015 (group 1), only 2016 (group 2), 2015 and 2016 with approximately equal payment sums (group 3), with higher payment sums 2015 than 2016 (group 4) and with lower payment sums 2015 than 2016 (group 5)1. We focused on HCPs who firstly, disclosed an annual payment sum ≥ 1,000 € and secondly, worked as physicians at the time point of the survey. We excluded 19,267 HCPs with annual payment sums < 1,000 €. From the remaining 8,963 HCPs, possible participants were selected (see below). The second criterion was evaluated after selection: for each chosen HCP we verified by internet research whether they currently worked as a physician. If they did not or no information was available, another HCP was randomly selected, and it was checked whether they worked as physicians. This was repeated until the determined sample size was reached.

[1] Groups 3-5 were further investigated in the underlying dissertation [24]. For the purpose of this study, these groups are not further compared.

Procedure and sample size

For the planned regression model, an analysable sample of 150 participants (30 per group) was estimated based on Green's rule of thumb.[25] Expecting a response rate of 30-50%, we formulated a detailed sample plan: Starting in August 2018, we sent out questionnaires in waves of 50 questionnaires per group. Questionnaires were sent by mail, accompanied by a cover letter and a reply envelope. A reminder letter was sent after two weeks. Two weeks after that, we phoned those with a publicly available phone number. If the planned sample size was not reached a month after the last contact attempt, the next wave was started: The next 50 physicians were randomly selected and contacted as described above. We stopped this procedure for each group after the 30th questionnaire was received, which was after we had sent the third wave of questionnaires in February 2019. All examinable questionnaires that we received afterwards were also included in the data analysis. Study procedures were preregistered at www.osf.io/ztvur.

Questionnaire

The two-page questionnaire contains questions about demographics, disclosure, and attitude towards transparency in German language. Response formats include five-level Likert items, default categories, and open formats. All items and response options can be found in Supplement A.

Main outcomes

The items to investigate research questions 1–3 are listed in Table 1. Physicians were asked about the frequency, content, and pleasantness of reactions that they experienced. Those questions could be answered separately for the reactions of patients, colleagues, and the private environment. For the analyses of the main research questions, an average value was calculated across the three groups of people. Participants of group 2 were asked about reactions to their disclosure 2016; all other participants were asked about reactions to their disclosure 2015.

Table 1.

Translated List of Relevant Questionnaire Items With Response Format

Variable	Item *Response format*
	Research question 1
Pleasantness of reactions	"If there were reactions, how did you perceive them?" *1-5: very unpleasant, rather unpleasant, neutral, rather pleasant, very pleasant*
Descriptive norm	"What percentage of German physicians do you estimate consented to disclose in the database?" ___ *% (open format in percent)*
Attitude	"To what extent do you agree with the following statement: In principle, I approve of transparency." *1-5: strongly disagree, disagree, neutral, agree, strongly agree*
	Research question 2
Frequency of reactions	"How many reactions did you get from patients / colleagues / your private environment?" *1-5: none, very few, rather few, rather many, many*
	Research question 3
Content of reactions	"If there were reactions, how was their content?" *1-5: very negative, somewhat negative, neutral, somewhat positive, very positive*

Note. The original questionnaire was in German; the translated complete questionnaire can be found in Supplement A.

Analysis

To investigate hypothesis 1, a multiple logistic regression with the outcome variable disclosure 2016 (0 = no disclosure, 1 = disclosure) and the main predictors X1: pleasantness of reactions, and X2: descriptive norm was conducted. To investigate the moderating role of X3: attitude, two interactions terms were added as predictors: X3*X1 and X3*X2. To test hypothesis 2 and 3, the frequency and content of reactions 2015 were compared with the frequency and content of reactions 2016. Directed tests for independent samples were conducted (more frequent/more negative reactions in 2015 than 2016). To test for normal distribution, the Shapiro-Wilk test was used. Data in all groups were not normally distributed on the respective dependent variable, therefore Wilcoxon tests were conducted. Effect sizes with 95% CI are given as rank-biserial correlations (r_b). A conservative alpha level of .01 was used for all tests.

Exploratively, we performed a content analysis of answers to the question “Was there anything that bothered you about the reactions?”. All answers were reviewed by two researchers independently and categories were suggested. From the suggested categories, ten final categories were decided upon based on mutual consensus. Then, each answer was categorized independently (overall interrater agreement: 93%). Diverging ratings were discussed until consensus was reached. Statistical analyses were performed in JASP version 0.10.2,[26] RStudio, R version 3.6.1,[27] and Microsoft Excel (2011).

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

Sample

We contacted *n* = 750 physicians and received 236 filled-in questionnaires (Figure 1). The response rate was 35% (236/678; 72 questionnaires were undeliverable). Two questionnaires needed to be excluded. The remaining 234 questionnaires were allocated to the groups and analysed. Mean and median age of participants was 53 years (*SD* = 8.29; *IQR* = 10; Range: 31-75; 48/234 (21%) female; 185/234 (79%) male). Further sample characteristics are listed in Supplement B.

- Insert Figure 1 about here -

Participants' use of the transparency database

Of the 234 participants, 87 (37%) stated they had not looked at the database, and 131 (56%) reported to have at least somewhat followed media coverage about the database. Most participants said they did not know whether their payments had been correctly reported: Of 189 participants who agreed to disclose payments in 2015, 91 (48%) did not know; 70 (37%) said their payments had been correctly reported, and 24 (13%) said they had been incorrectly reported. Of 192 participants who agreed to disclose payments in 2016, 105 (55%) did not know, 60 (31%) said their payments had been correctly reported and 23 (13%) said they had been incorrectly reported.

Reactions participants received

Most participants stated they had not received any reactions from patients (190/234, 81%), colleagues (128/234, 55%) or the private environment (153/234, 65%). Response rates for items of content and pleasantness of reactions were between 26% (60/234, pleasantness of patients' reactions) and 48% (113/234, content of colleagues' reactions). See Figure 2 for detailed results.

- insert Figure 2 about here -

Descriptive norm

For investigating how high participants estimated the percentage of German physicians who disclosed in the database in 2015 and 2016, data were available from 216 and 218 participants and ranged between 0% and 100%. For 2015, participants estimated on average that 33% of German physicians had agreed to disclose (*SD* = 21, *Mdn* = 30, *IQR* = 30) and for 2016, participants estimated on average that 31% of German physicians agreed to disclose (*SD* = 20, *Mdn* = 25, *IQR* = 25).

Investigating non-disclosure

To answer research question 1, we investigated data of those participants who disclosed in 2015 (groups 1, 3-5; *n* = 189) to predict whether they disclosed again in 2016 (groups 3-5; *n* = 147) or did not disclose again in 2016 (group 1; *n* = 42). Neither regression

model 1 with the three predictor variables X1: pleasantness of reactions, X2: descriptive norm and X3: attitude significantly improved the model fit compared to the null model ($\chi 2$ = 1.0, p = .792) nor regression model 2, in which the interaction terms X3*X2 and X3*X1 were added ($\chi 2$ = 12.66, p = .027). The low pseudo-R^2-values indicate that this prediction model is of poor quality. A more detailed description of regression model 1 and 2 can be seen in Supplement C.

We additionally explored the reasons for participants' non-disclosure in general. In our sample, two groups did not disclose payments in one year: Participants of group 1 had an entry in 2015 but not in 2016 (n = 42, „no-more-group"), and participants of group 2 had no entry in 2015 but in 2016 (n = 45, „not-yet-group"). We asked these participants for the reason for the missing entry (Table 2). The most frequently chosen reason in the no-more-group was that they had consciously decided against disclosure (50%, vs. 18% in the not-yet-group). The most frequently chosen answer in the not-yet-group was that they were not asked for their consent to disclose (36%, vs. 7% in the no-more-group). We further asked how several statements applied to the participants in case they consciously decided against disclosure. Most participants reported that considerations of public opinion or media reporting led to the decision against disclosure (25/32, 78%) (Figure 3).

Table 2
Reasons for Non-disclosure

	No-more-group	**Not-yet-group**
You don't have an entry in the year 2015 (2016). Why?	***abs. frequency (%)***	***abs. frequency (%)***
I have not received any payments.	14/42 (33%)	10/45 (22%)
I was not asked for my consent to disclose.	3/42 (7%)	16/45 (36%)
I forgot to answer the inquiry for disclosure consent.	1/42 (2%)	2/45 (4%)
I consciously decided against disclosure.	21/42 (50%)	8/45 (18%)
No reply	3/42 (7%)	9/45 (20%)

Note. Participants were asked to choose one of the four options.

- insert Figure 3 about here -

Year of disclosure

To investigate research questions 2 and 3, we compared the frequency and content of reactions to participants who disclosed for the first time in 2015 (groups 1, 3-5) with data of participants who disclosed for the first time in 2016 (group 2). Data for frequency of reactions were available for 2015 from 187/198 (99%) and for 2016 from 44/45 (98%) participants; data for content of reactions were available for 2015 from 110/198 (60%) and for 2016 from 19/45 (42%) participants. All variables were significantly non-normal (all W = 0.71-0.90, all p <.01). Testing hypothesis 2, we found no statistically significant difference between frequency of reactions 2015 and 2016 (2015: M = 1.54, SD = 0.66, Mdn = 1.33, IQR = 1; and 2016: M = 1.36, SD = 0.53, Mdn = 1.00, IQR = 0.67), as evidenced by a Wilcoxon rank-sum test (W = 3410, r_b = -.17, 95% CI [-∞, -0.01], p = .031). Testing hypothesis 3, we found no statistically significant difference between negativity of reactions 2015 and 2016 (2015: M = 2.69, SD = 0.71, Mdn = 3.00, IQR = 1; and 2016: M = 2.96, SD = 0.67, Mdn = 3.00, IQR = 0.33), as indicated by a Wilcoxon rank-sum test (W = 1243, r_b =.19; 95% CI [-0.05, ∞], p = .085).

Further exploratory investigations

Participants were asked to indicate their agreement with statements about attitude towards disclosure in general and in research. The statements that participants agreed with most strongly were that disclosure of payments should be more nuanced, that the undifferentiated display of the disclosures brings science into disrepute and that disclosure leads to a wrong impression in the public (Table 3).

Table 3

Attitudes towards Transparency.

	n	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Payments by pharmaceutical companies are a risk for the independence of clinical practice and research.	233	26/233 (11%)	41/233 (18%)	35/233 (15%)	90/233 (39%)	41/233 (18%)
In principle, I approve of transparency.	233	4/233 (2%)	3/233 (1%)	16/233 (7%)	39/233 (17%)	171/233 (73%)
Collaboration with pharmaceutical companies and receiving payments by those companies is part of the medical profession.	233	19/230 (8%)	35/230 (15%)	66/230 (28%)	71/230 (31%)	39/230 (17%)
Disclosure of payments should be more nuanced.	233	8/233 (3%)	2/233 (3%)	43/233 (18%)	51/233 (22%)	124/230 (53%)
Disclosure of payments increases patients' trust in me.	230	72/233 (31%)	45/233 (19%)	75/233 (32%)	32/233 (14%)	9/233 (4%)
Disclosure leads to a wrong impression in the public.	233	9/233 (4%)	24/233 (10%)	31/233 (13%)	78/233 (33%)	91/233 (39%)
In case you are working in research:						
Transparency guidelines impede my scientific work.	154	45/154 (29%)	40/154 (26%)	29/154 (19%)	32/154 (21%)	8/154 (5%)
I have been confronted with disclosures within the context of a published study at least once.	154	56/154 (36%)	17/154 (11%)	22/154 (14%)	24/154 (16%)	35/154 (23%)
My research results were criticized because of my disclosures at least once.	152	119/152 (78%)	11/152 (7%)	13/152 (9%)	5/152 (3%)	4/152 (3%)
The undifferentiated displaying of the disclosures brings science into disrepute.	155	10/155 (6%)	5/155 (3%)	16/155 (10%)	37/155 (24%)	87/155 (56%)

Sixty-eight participants answered the question “Was there anything that bothered you about the reactions?”. The content categories with respective frequencies are:

- negative media reporting (20/68, 29%)
- defamation / criminalization (17/68, 25%)
- dark figure of undisclosed information (12/68, 18%)
- disclosed information is not put into context with services rendered in return (12/68, 18%)
- misleading data representation (7/68, 10%)
- contacted by lawyer who aimed a class action against CORRECTIV (7/68, 10%)
- feeling of being dragged into the public eye (5/68, 7%)
- feeling of being treated unfairly (5/68, 7%)
- involvement of employer (4/68, 6%)
- others expressed lack of understanding (2/68, 3%).

DISCUSSION

Principal findings

The aim of this study was to gain insight into physicians’ attitudes towards and experiences with the voluntary German transparency regulation. Research question 1 aimed to investigate how these experiences affect future disclosure behaviour, but no significant prediction model was found. Research questions 2 and 3 aimed to investigate whether reactions to disclosures between the first and the second year of the database differed. No significant difference in the frequency or content reactions was found on the alpha level of .01, which might be related to the fact that most participants in our sample had not received any reactions towards their disclosure. The fewest reactions came from patients. Only every fifth physician stated they had received at least “very few” reactions by patients.

We observed that the reasons for non-disclosure in our sample differed depending on the time point of non-disclosure: Participants who had disclosed in the first but not in the second year more often said they had consciously decided against disclosure than those who had not disclosed in the first year but in the second year. The latter more often said that they had not been asked for consent by the respective pharmaceutical company. Most physicians who had consciously decided against disclosure said it was because of public opinion and media reporting. We also found that nearly half of the participating physicians had not looked at the database and did not know whether their disclosed payment sum was correct. However, more than half of them at least somewhat followed the media coverage

about the database and some reported high objections to public exposure. This can be interpreted according to the spotlight effect which describes that people overestimate the attention they receive by others.[17] Several participants stated concerns about the public opinion and a feeling about being denunciated, which is in line with the observation that physicians are concerned that COI disclosure may damage their reputation.[15] This tendency relates to the psychological heuristic that people do not like to be viewed as biased. Studies show that if people are able to avoid COI, they may be motivated to avoid such conflicts so that they can disclose the absence of conflicts.[28] In case of voluntary disclosure, however, people can simply avoid being viewed as biased by deciding against disclosure.

Strengths and weaknesses

The strength of this study is that it provides quantitative and qualitative data on physicians' experiences with COI disclosure in a national database. To our knowledge, no such evidence exists for any European transparency regulation in medicine. The investigated sample was stratified to their disclosing behaviour. Due to the otherwise random selection of participants, our sample comprises a great bandwidth of age, disciplines, and workplaces. The study, however, also has several limitations. A common problem in survey methods, answers may be skewed by social desirability.[29] The answers to a controversially discussed subject may be even more skewed: Physicians may be more motivated to respond to the survey if they have strong opinions on transparency, or if they experienced extreme reactions towards their disclosure. We tried to counter this by our efforts to increase the response rate. Additionally, the questionnaire we used was only constructed for this study, so our data cannot be directly compared to other data.

Meaning of the study

While most physicians in our sample reported a positive attitude towards transparency in general, they appeared concerned about reputational damage. Those who did not disclose payments had various reasons. Mandatory transparency could approach some of these issues: Firstly, if disclosure is mandatory, it will no longer feel "unfair" that some disclose information and some hide this information. Secondly, if conducted in a standardized form, everyone's information is available, and therefore the disclosed information is easier to compare and better to interpret, which will lessen the risk of unfair reputational damage and might enable a fair discussion between pharmaceutical companies, physicians, researchers, and the public.

Currently, the consent rate to disclose payments by pharmaceutical companies in Germany is low, compared to other countries.[11,12] In our study we observed that even if physicians consented to disclosure, our participants mainly appear not to have used the database nor checked their entries. Therefore, we propose that disclosers need to be educated about the background of transparency regulations and the concept of COI to raise commitment.

Unanswered questions and future research

In this sample, reasons for non-disclosure were heterogeneous. More research is needed about the motives for and against voluntary disclosure to improve current transparency policies. Our data show that there are more issues that need to be considered about the experiences with transparency guidelines, such as the fear of reputational damage. Broad evaluations of transparency guidelines including all involved persons are needed to get a full picture of the current situation.

CONCLUSION

The study at hand was the first survey of physicians who disclosed voluntarily in a nation-wide transparency database. We found no significant predictors for future disclosure behaviour and no statistically significant difference between reactions to disclosures in the first year compared to the second year of the database. One reason is that physicians in our sample reported to have experienced few reactions to the disclosures. The exploratory results of this study show preliminary evidence that although attitude towards transparency appears positive and only few reactions were experienced, German HCPs are concerned that disclosing payments in a public database will result in reputational damage. We propose that mandatory disclosure could be a solution to this problem by creating a standardized environment for an open discussion.

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Footnotes

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

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Patient consent for publication: not required.

Provenance and peer review: -

Data sharing statement: Data are available on reasonable request by emailing MS.

Note: This paper contains passages from the dissertation by Marlene Stoll [24].

Ethics statement: The ethics committee of the State Chamber of Physicians of Rhineland-Palatinate decided that further consultation is not necessary since no personal but anonymous data were processed (appl. no. 2018-13295-Epidemiologie).

REFERENCES

1. Lundh A, Lexchin J, Mintzes B, et al. Industry sponsorship and research outcome: systematic review with meta-analysis. *Intensive Care Med.* 2018 Oct 1;44(10):1603–12 https://doi.org/10.1007/s00134-018-5293-7.
2. Mitchell AP, Trivedi NU, Gennarelli RL, et al. Are Financial Payments From the Pharmaceutical Industry Associated With Physician Prescribing? *Ann Intern Med.* 2021 Mar 16;174(3):353–61 https://doi.org/10.7326/M20-5665.
3. Nejstgaard CH, Bero L, Hróbjartsson A, et al. Association between conflicts of interest and favourable recommendations in clinical guidelines, advisory committee reports, opinion pieces, and narrative reviews: systematic review. *BMJ.* 2020 Dec 9;371:m4234 https://doi.org/10.1136/bmj.m4234.
4. Thompson D. Understanding financial conflicts of interest. *N Engl J Med.* 1993.
5. Institute of Medicine Committee on Conflict of Interest in Medical Research. 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; 2009.
6. Fabbri A, Santos A, 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 Mar 14;7(6):504–9 https://doi.org/10.15171/ijhpm.2018.20.
7. 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 May 1;122(5):509–18 https://doi.org/10.1016/j.healthpol.2018.03.015.
8. 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
9. Grassley C. Grassley, Kohl say public should know when pharmaceutical makers give money to doctors. Available from: https://www.grassley.senate.gov/news/news-releases/grassley-kohl-say-public- should-know-when-pharmaceutical-makers-give-money (accessed 13 July 2021).
10. Open Payments [Website]. Available from: https://www.cms.gov/openpayments (accessed 13 July 2021).
11. Mulinari S, Martinon L, Jachiet P-A, et al. Pharmaceutical industry self-regulation and non-transparency: country and company level analysis of payments to healthcare professionals in seven European countries. *Health Policy.* 2021 Jul 1;125(7):915–22

https://doi.org/10.1016/j.healthpol.2021.04.015.

12. 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 Sep 1;10(9):e037395 http://dx.doi.org/10.1136/bmjopen-2020-037395.
13. Loewenstein G, Sah S, Cain DM. The Unintended Consequences of Conflict of Interest Disclosure. *JAMA*. 2012 Feb 15;307(7):669–70 https://doi.org/10.1001/jama.2012.154.
14. Sah S, Loewenstein G, Cain DM. Insinuation Anxiety: Concern That Advice Rejection Will Signal Distrust After Conflict of Interest Disclosures. *Pers Soc Psychol Bull.* 2019;45(7);1099-1112 https://doi.org/10.1177/0146167218805991.
15. Chimonas S, DeVito NJ, Rothman DJ. Bringing Transparency to Medicine: Exploring Physicians' Views and Experiences of the Sunshine Act. *Am J Bioeth*. 2017 Jun 3;17(6):4–18 https://doi.org/10.1080/15265161.2017.1313334.
16. Boytchev WB. Warum Ärzte schweigen. 2016 Jul 17; Available from: https://correctiv.org/aktuelles/euros-fuer-aerzte/2016/07/17/warum-aerzte-schweigen (accessed 13 July 2021).
17. Loewenstein G, Sunstein CR, Golman R. Disclosure: Psychology Changes Everything. *Annu Rev Econ.* 2014;6:391–419 https://doi.org/10.1146/annurev-economics-080213-041341.
18. Pham-Kanter G, Mello MM, Lehmann LS, et al. Public Awareness of and Contact With Physicians Who Receive Industry Payments: A National Survey. *J Gen Intern Med.* 2017 Jul 1;32(7):767–74 http://dx.doi.org/10.1007/s11606-017-4012-3.
19. Young PD, Xie D, Schmidt H. Towards Patient-Centered Conflicts of Interest Policy. *Int J Health Policy Manag.* 2017 Oct 29;7(2):112–9 https://dx.doi.org/10.15171%2Fijhpm.2017.128.
20. Chung A, Rimal RN. Social norms: a review. Rev Commun Res. 2016;4:1–28 https://doi.org/10.12840/issn.2255-4165.2016.04.01.008.
21. Lapinski MK, Rimal RN. An Explication of Social Norms. *Commun Theory.* 2005 May 1;15(2):127–47 https://doi.org/10.1111/j.1468-2885.2005.tb00329.x.
22. Freiwillig Selbstkontrolle für die Arzneimittelindustrie e.V. FSA-Transparenzkodex. 2019. Available from: https://www.fsa-pharma.de/de/kodizes/sk_fsa_transparenzkodex_13.03.2019.pdf (accessed 13 July 2021).
23. CORRECTIV. Euros für Ärzte. 2021. Available from: https://correctiv.org/aktuelles/euros-fuer-aerzte (accessed 13 July 2021).
24. Stoll M. Unintended Consequences of Conflict of Interest Disclosure: a Psychological Perspective [Internet]. Johannes Gutenberg-Universität Mainz; 2021 [cited 2021 Jul 28].

Available from: https://openscience.ub.uni-mainz.de/handle/20.500.12030/5731

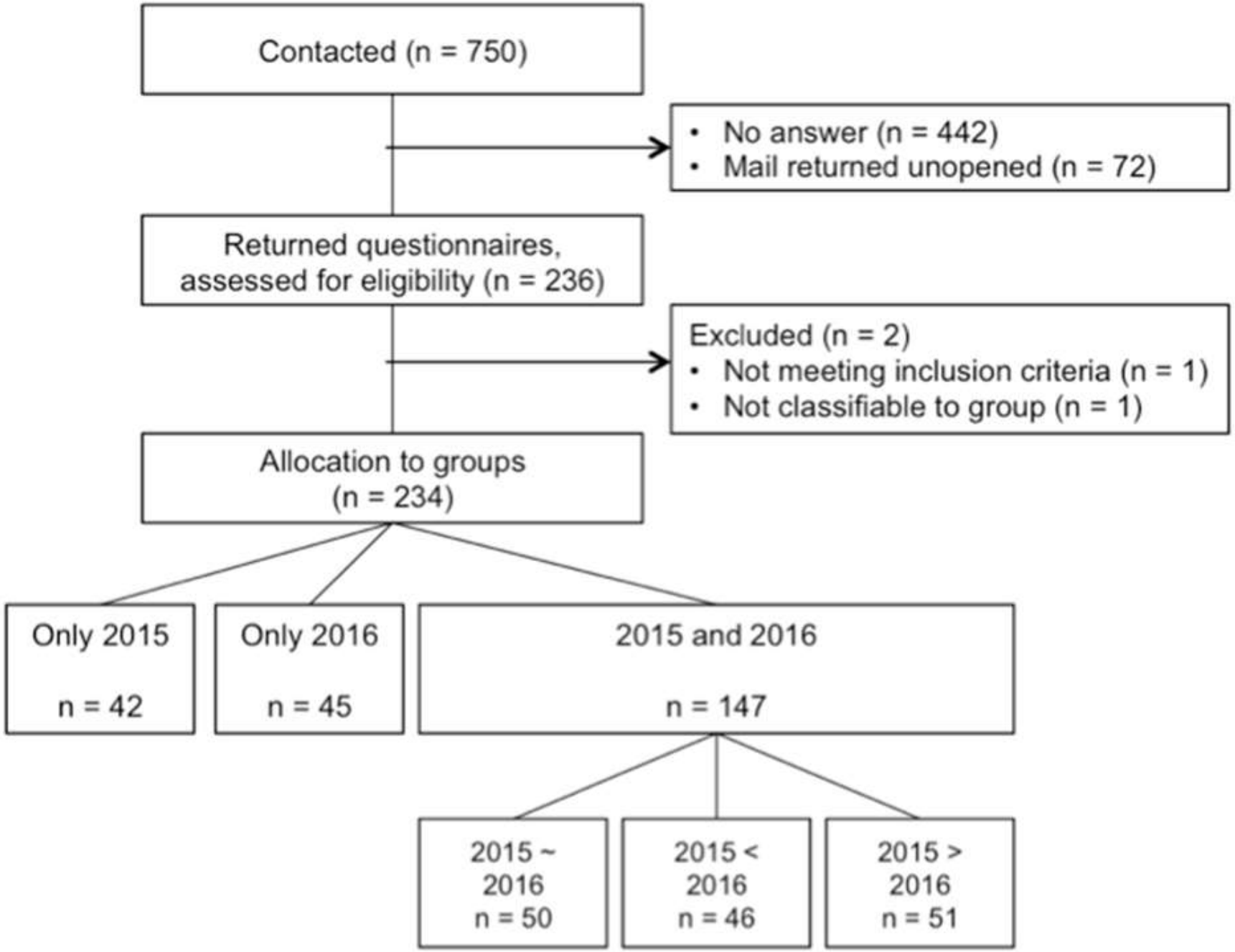
25. Green SB. How Many Subjects Does It Take To Do A Regression Analysis. *Multivar Behav Res.* 1991 Jul 1;26(3):499–510 https://doi.org/10.1207/s15327906mbr2603_7.
26. JASP Team. JASP (Version 0.10.2). 2019.
27. R Core Team. R: A Language and Environment for Statistical Computing. 2019. Available from: https://www.R-project.org
28. Sah S, Loewenstein G. Nothing to Declare: Mandatory and Voluntary Disclosure Leads Advisors to Avoid Conflicts of Interest. Psychol Sci. 2014;25(2):575-584 https://doi.org/10.1177%2F0956797613511824.
29. Barclay S, Todd C, Finlay I, et al. Not another questionnaire! Maximizing the response rate, predicting non-response and assessing non-response bias in postal questionnaire studies of GPs. *Fam Pract*. 2002 Feb 1;19(1):105–11 https://doi.org/10.1093/fampra/19.1.105.

Figures

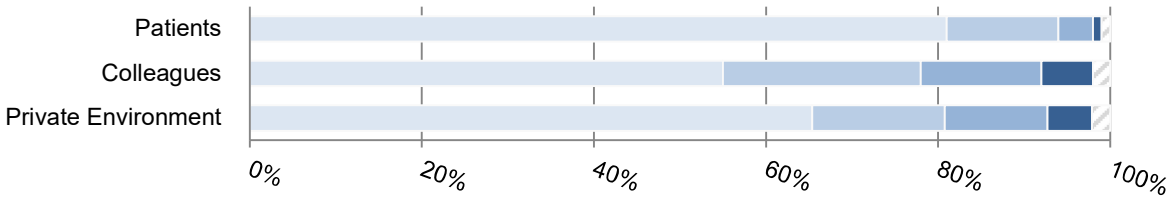
Figure 1. Participant Flow Chart.

Figure 2. Relative Frequencies of Item Answers for Frequency, Content, and Pleasantness of Reactions from Recipients, N = 234.

Figure 3. Factors Considered for Decision Against Disclosure.

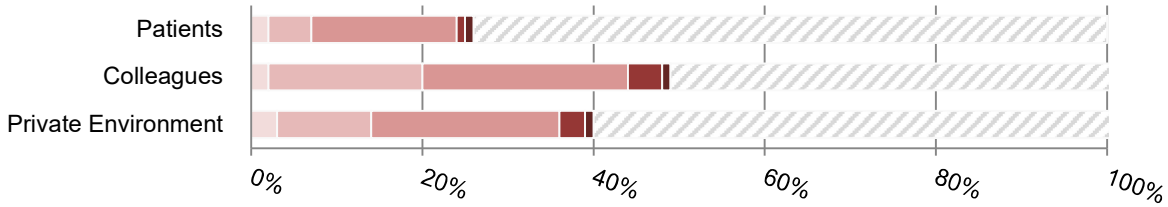

Contacted (n = 750)
• No answer (n = 442)
• Mail returned unopened (n = 72)
Returned questionnaires, assessed for eligibility (n = 236)
Excluded (n = 2)
• Not meeting inclusion criteria (n = 1)
• Not classifiable to group (n = 1)
Allocation to groups (n = 234)
Only 2015 n = 42
Only 2016 n = 45
2015 and 2016 n = 147
2015 ~ 2016 n = 50
2015 < 2016 n = 46
2015 > 2016 n = 51

Frequency of Reactions



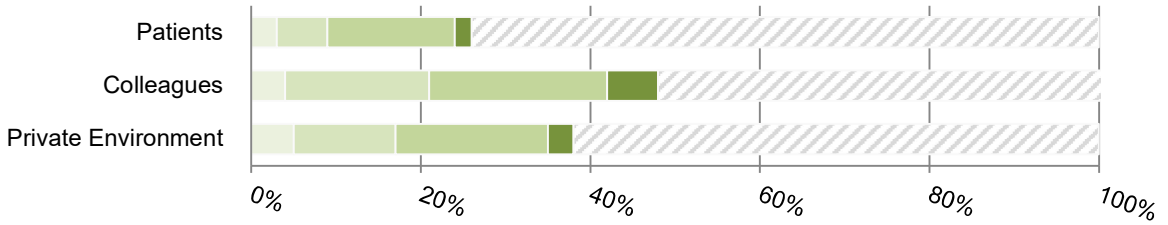
	Private Environment	Colleagues	Patients
none	65%	55%	81%
very few	15%	23%	13%
rather few	12%	14%	4%
rather many	5%	6%	1%
many	0%	0%	0%
NA	2%	2%	1%

Content of Reactions

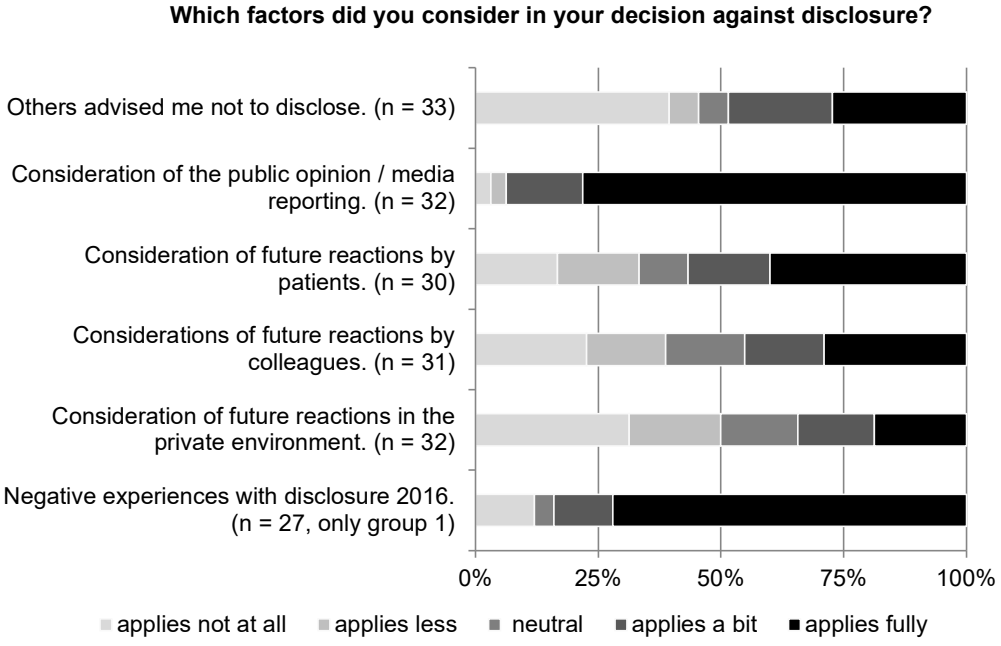


	Private Environment	Colleagues	Patients
very negative	3%	2%	2%
negative	11%	18%	5%
neutral	22%	24%	17%
positive	3%	4%	1%
very positive	1%	1%	1%
NA	61%	52%	74%

Pleasantness of Reactions



	Private Environment	Colleagues	Patients
very unpleasant	5%	4%	3%
rather unpleasant	12%	17%	6%
neutral	18%	21%	15%
rather pleasant	3%	6%	2%
very pleasant	0%	0%	0%
NA	62%	53%	74%



Supplement A
Translated Questionnaire (not formatted)

1) Discipline:
[open format]

2) Gender:
- ❑ male
- ❑ female

3) Age:
[open format]

4) Do you work in a hospital?
- ❑ yes, university hospital
- ❑ yes, non-university hospital
- ❑ no

5) If yes: Which position do you have?
- ❑ head
- ❑ senior
- ❑ resident

6) If no: How do you work?
- ❑ licensed
- ❑ employed
- ❑ other

7) How much of your working hours (in %) do you spend on patient care?
[open format]

8) How much of your working hours (in %) do you spend on research?
[open format]

9) Please tick every box that resembles a research area that you have been actively working in in the last five years (multiple responses are possible).
- ❑ non-interventional post-marketing studies
- ❑ clinical studies on behalf of pharmaceutical companies
- ❑ clinical studies investigated by yourself
- ❑ own, academical research
- ❑ other: _____
- ❑ I do not work in research.

10) What percentage of German physicians do you estimate consented to disclose in the database?

In 2016 for disclosure 2015: [open format]

In 2017 for disclosure 2016: [open format]

11) Do you know the actual percentage approximately, for example from the media?

2016:

- ❑ yes
- ❑ no

2017:

- ❑ yes
- ❑ no

12) Have your information about payments been correctly reported in the database? "Euros for Doctors"?

[groups 1, 3-5] In 2017 for 2016:

- ❑ yes
- ❑ no
- ❑ I don't know

[groups 2-5] In 2016 for 2015:

- ❑ yes
- ❑ no
- ❑ I don't know

13) In the summer of 2016, first data were disclosed in the database. How much do the following statements apply to you?

- I looked into the database.
- I followed media coverage about the database.
- I searched for persons in the database.

scale:

- ❑ applies not at all
- ❑ applies less
- ❑ neutral
- ❑ applies a bit
- ❑ applies fully

14) How high is the amount of money you disclosed, compared to the other disclosed payments?

- ❑ definitely below average
- ❑ somewhat below average
- ❑ average
- ❑ somewhat above average
- ❑ definitely above average

15. 1) [group 1, 3-5] You disclosed data in 2015. We are interested in how your environment reacted to this entry.
15.2) [group 2] You disclosed data in 2015. We are interested in how your environment reacted to this entry.

How many reactions did you get from …

- **patients?**
- **colleagues?**
- **your private environment?**

scale:

- ❑ none
- ❑ very few
- ❑ rather few
- ❑ rather many
- ❑ many

16) If there were reactions, how was their content? Reactions from …

- **patients**
- **colleagues**
- **your private environment**

scale:

- ❑ very negative
- ❑ somewhat negative
- ❑ neutral
- ❑ somewhat positive
- ❑ very positive

17) If there were reactions, how did you perceive them? Reactions from …

- **patients**
- **colleagues**
- **your private environment**

scale:

- ❑ very unpleasant
- ❑ rather unpleasant
- ❑ neutral
- ❑ rather pleasant
- ❑ very pleasant

18) Was there anything that bothered you about the reactions?
[open format]

19.1) [group 1] You do not have an entry in the database in the year 2016. Why?
19.2) [group 2] You do not have an entry in the database in the year 2015. Why?

- ❑ I have not received any payments.
- ❑ I was not asked for my consent to disclose.
- ❑ I forgot to answer the inquiry for disclosure consent.
- ❑ I consciously decided against disclosure.

20.1) [group 1] In case you decided consciously against disclosure: Which factors did you consider in your decision against disclosure?

- Others advised me not to disclose.
- Consideration of the public opinion / media reporting.
- Consideration of future reactions by patients.
- Consideration of future reactions by colleagues.
- Consideration of future reactions in the private surrounding.
- Negative experiences with disclosure 2015.

scale:

- ❑ applies not at all
- ❑ applies less
- ❑ neutral
- ❑ applies a bit
- ❑ applies fully

20.2) [group 2] In case you decided consciously against disclosure: Which factors did you consider in your decision against disclosure?

- Others advised me not to disclose.
- Consideration of the public opinion / media reporting.
- Consideration of future reactions by patients.
- Consideration of future reactions by colleagues.
- Consideration of future reactions in the private surrounding.

scale:

- ❑ applies not at all
- ❑ applies less
- ❑ neutral
- ❑ applies a bit
- ❑ applies fully

20.3) [groups 3-5] In 2016, you decided to disclose a second time. Please state how much the following statements apply to you.

- [groups 3-5] Coming to decision whether or not to disclose was easier for the second year than for the first year.
- [groups 4,5] My payments shifted because the opportunities by the pharmaceutical companies changed.
- [group 4] My payments shifted because I consciously accepted more money.
- [group 5] My payments shifted because I consciously accepted less money.

scale:

- ❑ applies not at all
- ❑ applies less
- ❑ neutral
- ❑ applies a bit
- ❑ applies fully

21) To what extent do you agree with the following statements:

- Payments by pharmaceutical companies are a risk for the independence of clinical practice and research.
- Disclosure of payments increases patients' trust in me.
- Receiving payments is fine if regulation measures (disclosure, exclusion from committees) are adopted.
- In principle, I approve of transparency.
- Disclosure leads to a wrong impression in the public.
- Collaboration with pharmaceutical companies and receiving payments by those companies is part of the medical profession.
- Some payments should be avoided, while others are indispensable.
- Without good alternatives in research and training, nothing about financial interactions in the medical sector will change.
- Disclosure of payments should be more nuanced.

In case you are working in research:

- Transparency guidelines impede my scientific work.
- I have been confronted with disclosures within the context of a published study at least once.
- My research results were criticized because of my disclosures at least once.
- If I do not cooperate with the industry, the research that is relevant for me lacks financial resources.
- The undifferentiated displaying of the disclosures brings science into disrepute.

scale:

- ❑ strongly disagree
- ❑ disagree
- ❑ neutral
- ❑ agree
- ❑ strongly agree

22) In your opinion: Disclosure of financial payments is more important in which area?

- ❑ definitely in patient care
- ❑ rather in patient care
- ❑ equally important
- ❑ rather in research
- ❑ definitely in research

Supplement B

Sample Characteristics

Characteristic		*n*	%
Gender	Female	48	21
	Male	185	79
	NA	1	0
Field	General and internal medicine	129	55
	Psychiatry, neurology and psychosomatics	33	14
	Surgery	31	13
	Other	38	16
Workplace	University hospital	67	29
	Non-university hospital	51	22
	Of which position: Head	*49*	*42*
	Senior	*53*	*19*
	Resident	*11*	*9*
	NA	*5*	*4*
	Practice	113	48
	Of which: Licensed	*104*	*92*
	Employed	*9*	*8*
	NA	3	1

Note. N= 234

Supplement C

Investigating non-disclosure, regression analysis.

To answer the first research question, we investigated data of those participants who disclosed in 2015 (n = 189) to predict whether they disclosed again in 2016 (n = 147, 78%) or did not disclose again in 2016 (n = 42, 22%). Response rate per item differed: For the items attitude, descriptive norm 2015, and pleasantness of reactions 2015, data were available from 188, 174, and 107 participants, respectively. For pleasantness of reactions 2015, we thus only had data of 22 people who did not disclose in 2016. All variables were significantly non-normal: all W = 0.52 - 0.92, all p < .01.

In regression model 1, the predictors were the three variables X1: pleasantness of reactions, X2: descriptive norm and X3: attitude. This model did not significantly improve the model fit compared to the null model, $\chi 2$ = 1.0, p = .792. Regression model 2 included the three variables as well as the interaction terms X3*X2 as well as X3*X1. This second model also did not significantly improve the model fit compared to the null model, $\chi 2$ = 12.66, p = .027. Effect sizes, pseudo-R^2-values and variance inflation factors (VIF) of regression model 1 and 2 can be seen in Table C1. The pseudo-R^2-values, being very low, indicate that this prediction model is of poor quality. We further explored the data by investigating whether participants who disclosed in 2016 had systematically different values on the main outcomes from the participants who did not disclose in 2016. Results from the performed Wilcoxon tests provided no indication for systematic differences between the groups (all p < .01).

Table C1

Logistic Regression Coefficients and Effect Sizes of Regression Model 1 and 2

	B (SE)	*p*	*OR*
Regression model 1: Only main effects			
Intercept	1.54 (0.28)	.000	4.66
Pleasantness of reactions	0.24 (0.27)	.373	1.27
Descriptive norm	0.13 (0.37)	.717	1.14
Attitude	-0.10 (0.32)	.753	0.90
Regression model 2: Main effects and interaction terms			
Intercept	2.31 (0.60)	.000	10.11
Pleasantness of reactions	0.61 (0.42)	.142	1.84
Descriptive norm	-0.06 (0.46)	.891	0.94
Attitude	-1.57 (1.08)	.145	0.21
Attitude*pleasantness of reactions	-1.27 (0.64)	.048	0.28
Attitude*descriptive norm	0.98 (0.67)	.140	2.67

Note. Model fit regression model 1: R^2 = .01 (Hosmer-Lemeshow), .01 (Cox-Snell), .02 (Nagelkerke); model 1 compared to null model: $\chi^2(3) = 1.04$, $p = .792$, all *VIF* < 10*;* Model fit regression model 2: R^2 = .01 (Hosmer-Lemeshow), .01 (Cox-Snell), .02 (Nagelkerke); model 2 compared to null model: $\chi^2(5) = 12.66$, $p = .027$; model 2 compared to model 1: $\chi^2(2) = 11.63$, $p = .003$, all *VIF* < 10.

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
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	4-6
Objectives	3	State specific objectives, including any pre-specified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	7-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7-9
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	7-8
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9
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	8-9, Supplement A
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	8

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
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	7, 10
		(b) Give reasons for non-participation at each stage	10
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10, Supplement B
		(b) Indicate number of participants with missing data for each variable of interest	10-14
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	10-11, Figure 2
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	11-13
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11-15
Discussion			
Key results	18	Summarise key results with reference to study objectives	15-16
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	16
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16-17
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	21

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.
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.

BMJ Open

Physicians' attitudes towards disclosure of payments from pharmaceutical companies in a nation-wide voluntary transparency database: a cross-sectional survey

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Physicians' attitudes towards disclosure of payments from pharmaceutical companies in a nation-wide voluntary transparency database: a cross-sectional survey

Marlene Stoll*, Lara Hubenschmid, Cora Koch, Klaus Lieb, Boris Egloff

Marlene Stoll (marlene.stoll@unimedizin-mainz.de)
Department of Psychiatry and Psychotherapy, University Medical Center Mainz, Untere Zahlbacher Straße 8, 55131 Mainz, Germany
http://orcid.org/0000-0001-8847-5497

Lara Hubenschmid (lara.hubenschmid@lir-mainz.de)
Leibniz Institute for Resilience Research (LIR), Mainz, Germany

Cora Koch (cora.koch@uniklinik-freiburg.de)
Department of Neurology and Neurophysiology, Medical Center - University of Freiburg, Freiburg, Germany
http://orcid.org/0000-0003-0827-7023

Klaus Lieb (klaus.lieb@lir-mainz.de)
Department of Psychiatry and Psychotherapy, University Medical Center Mainz, Mainz, Germany

Boris Egloff (egloff@uni-mainz.de)
https://orcid.org/0000-0002-5736-9912
Department of Psychology, Johannes Gutenberg University Mainz

* Corresponding author

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ABSTRACT

Objectives: To investigate German physicians' attitudes towards and experiences with voluntary disclosure of payments by pharmaceutical companies in a public database and their impact on future decisions for or against disclosure.

Design: National cross-sectional survey conducted in 2018 among physicians who voluntarily disclosed at least one payment in the German transparency regulation.

Setting: Retrospective paper-pencil questionnaire about attitudes towards and experiences with voluntary payment disclosures in the first (2015) and second year (2016) of the German transparency regulation.

Participants: German physicians who disclosed either in the first year only, the second year only, or in both years of the transparency regulation.

Primary outcomes: (1) the probability to disclose in 2016, predicted by physicians' experience of reactions from others in 2015, descriptive norms, and attitudes towards transparency; (2) frequency and (3) content of reactions from others 2015 compared to 2016.

Results: Data of 234 respondents were analysed (n = 42, 45, and 147 physicians who disclosed in 2015, 2016 or both years, respectively). The probability to disclose in 2016 was not predicted by perceived reactions, norms, or attitudes towards transparency (p>.01). Most participants reported not to have received any reactions by patients (190/234, 81%), colleagues (128/234, 55%) or the private environment (153/234, 65%). Neither frequency nor content of reactions differed between the first and second year (scale 1-5; frequency: $Mdn_{2015,2016}$ = 1.33 vs. 1.36, r_b = -.17, p>.01; content: $Mdn_{2015,2016}$ = 2.69 vs. 2.96, r_b = .19, p>.01). However, media reporting, fear of reputational damage and a feeling of being defamed were mentioned as reasons for non-disclosure.

Conclusions: While confirmatory analyses did not provide significant results, descriptive analyses showed that participants who voluntarily disclose payments mainly do not experience any reactions towards their disclosures but report fears about losing their reputation due to disclosures.

Registration: https://osf.io/ztvur

ARTICLE SUMMARY

Strengths and limitations of this study

- This study is the first survey of attitudes and experiences of physicians who voluntarily disclosed payments by pharmaceutical companies in a nation-wide transparency database.
- The sample takes into account whether physicians disclosed only in one year or in two consecutive years.
- The study was preregistered and provides qualitative and quantitative data on reasons for non-disclosure in this database.
- The questionnaire used in this study was only constructed for this purpose, so a direct comparison with other data is not possible.

INTRODUCTION

The services sector of the health industry has a long tradition of close ties to the pharmaceutical industry.[1,2] Such ties have been shown to potentially lead to systematic biases in research and daily patient care.[3-5] Situations in which a secondary interest (e.g., financial gain) creates a risk that a primary interest (e.g., patient welfare) is unduly influenced are defined as conflicts of interest (COI).[1,6] Several approaches have been established to meet the challenge of COI in medicine, amongst which transparency regulations are very popular.[7-10] Transparency regulations have been introduced to shed light on formerly unknown information,[7,8] in this case: information about payments from pharmaceutical companies to health care professionals (HCPs). They differ in their coverage and implementation. In the United States, payments are fully transparent since the introduction of the Physician Payments Sunshine Act (PPSA) and publicly disclosed on the Open Payments website.[11] In Europe, transparency of payments to HCPs is mandatory only in some countries whereas in others such as Germany, it is regulated on a voluntary level.[7,9,12,13] However, disclosing COI may have unintended effects (e.g., loss of patient trust [14,15]), which may interact with the mode of the transparency regulation. This study explores the effects of Germany's voluntary transparency regulation of payments by pharmaceutical companies to HCPs, and investigates factors that lead HCPs to decide against disclosing payments in this database voluntarily.

Effects of transparency guidelines

An intended effect of transparency guidelines is that publicly disclosing COI could motivate conflicted persons to change their behaviour in the sense that they decrease industry contacts in the future.[16] Thus, transparency regulations affect those who disclose information. In focus groups about experiences with the PPSA conducted in 2015,[17] physicians reported to be frustrated with the administrative process, to feel treated unfairly and to worry the disclosures might mislead patients.[17] For voluntary regulations, there is only anecdotal evidence: In a newspaper article[18] about physicians who decided against disclosure in the German transparency database, the interviewees stated to approve of transparency in general, but also said the current regulation was unfair, the disclosed information was misleading, and patients' trust would suffer.[18]

Public awareness thus appears to be a relevant element of transparency regulations.[16] Research has shown that patients would like their physicians to disclose financial COI, since they were concerned about biased clinical judgement.[19,20] However, at least in the United States, public awareness of the Open Payments website was low, as

shown by citizen surveys in 2014 and 2015: Only 9-12 % knew about the disclosed information.[21,22] Accordingly, U.S. physicians believed patients were uninterested in the data.[17] In Germany, physicians reported to fear negative effects on patients and therefore decided against disclosure.[18] The interaction between disclosing HCPs and the public and its effects on disclosing behaviour in a voluntary transparency database has not been systematically investigated yet.

Another important factor when discussing the effects of voluntary transparency regulations is the descriptive norm (i.e., behaviour that most of the peers show is considered "normal" behaviour[23,24]) and thus, the moment when area-wide information about the frequency of behaviour becomes available. From then on, information is available about how many HCPs voluntarily disclose payments, which forms a new reference frame for whether it is considered "normal" to disclose payments. An HCP's decision to voluntarily disclose payments may depend on the subjectively estimated number of disclosing HCPs. Additionally, HCPs themselves will consider the fact that HCPs receive payments by pharmaceutical companies relatively "normal", while most of the public will only learn about it with the first disclosure round and judge the behaviour as "abnormal" - an impression which will decline over time. Therefore, reactions by the public may be more pronounced in the first year of a transparency database than in the following.

Germany's transparency regulation

In Germany, transparency of payments to HCPs is self-regulated by the pharmaceutical industry: 54 pharmaceutical companies organized in the "association of voluntary self-regulation in the pharmaceutical industry" passed a transparency codex which requires HCPs' consent for the respective financial interaction to be disclosed on each company's website.[12,13,25] First data were disclosed 2016 for payments from 2015. The investigative newsroom CORRECTIV gathered this data from each company's website and established the "Euros for Doctors" database - a searchable platform that provided, per HCP, an overview of all payments they had received. The database started in 2016, but it was discontinued after only two years, making the investigation of long-term changes of disclosing rates difficult.[26] The kick-off was accompanied with investigative articles,[27] collaborating with the popular German online news magazine SPIEGEL ONLINE. They criticised the undifferentiated way of disclosing (e.g., the designated use of the money was not disclosed), and the large number of HCPs who did not disclose information.[18,28] An analysis of the 2015 and 2016 data of this database by our group [13] showed that about 28% and 24% of all HCPs who had received payments agreed to disclose payments in 2015 and 2016, respectively. Of all disclosing HCPs, 26% disclosed payments in both years, 44%

disclosed only in 2015, and 29% only in 2016. The total number of disclosing HCPs decreased by 21%.

Study aims and research questions

This study investigated HCPs' attitudes towards and experiences with the voluntary transparency database, and reasons for non-disclosure. Main research question 1 was: Do the reactions physicians experienced to their disclosed information or their perception of how normal it is to disclose predict the decision to disclose in the following year? Does a positive attitude moderate this effect? We hypothesized that the probability for deciding against disclosure in the subsequent year was higher the more unpleasant reactions were experienced and the lower the descriptive norm to disclose was estimated, and that a positive attitude towards transparency moderates this relationship. Research questions 2 and 3 were: Do physicians experience a higher number of reactions and more negative reactions in the first than in the second year of the regulation? We hypothesized that reactions were more frequent and more negative in the first compared to the following year.

METHODS

Sample

Our sample was drawn from the population of 28,230 HCPs who disclosed at least one financial interaction with a pharmaceutical company in 2015 or 2016 in the German transparency regulation.[13] We built our survey sample of 3 groups: HCPs who disclosed only 2015 (group 1), only 2016 (group 2), and HCPs who disclosed both 2015 and 2016 (group 3)[1]. To enhance the probability that we survey HCPs who receive payments annually, we excluded HCPs who disclosed an annual payment sum < 1,000 €. This was based on the observation that the median disclosed annual payments of HCPs who disclosed in both years was 899€ in 2015, compared to the median disclosed sum of HCPs who disclosed only once, which was 452€.[13] Based on that, we excluded 19,267 HCPs with annual payment sums < 1,000 €. From the remaining 8,963 HCPs, possible participants were selected (see below). Further, we only included HCPs who worked as physicians at the time point of the survey. This criterion was evaluated after selection: for each chosen HCP, we verified by internet research whether they currently worked as a physician. If they did not or

[1] For further analyses in the underlying dissertation,[29] the third group was split up and analysed in three subgroups. Therefore, group 3 is bigger than groups 1 and 2.

no information was available, another HCP was randomly selected, and it was checked whether they worked as physicians. This was repeated until the determined sample size was reached.

Procedure and sample size

For the planned regression model, an analysable sample of 150 participants was estimated based on Green's rule of thumb.[30] Expecting a response rate of 30-50%, we formulated a detailed sample plan: Starting in August 2018, we sent out questionnaires in waves of 50 questionnaires per group. Questionnaires were sent by mail, accompanied by a cover letter and a reply envelope. A reminder letter was sent after two weeks. Two weeks after that, we phoned those with a publicly available phone number. If the planned sample size was not reached a month after the last contact attempt, the next wave was started: The next 50 physicians were randomly selected and contacted as described above. We stopped this procedure for each group after the 30th questionnaire was received, which was after we had sent the third wave of questionnaires in February 2019. All examinable questionnaires that we received afterwards were also included in the data analysis. Study procedures were preregistered at www.osf.io/ztvur.

Questionnaire

The two-page questionnaire contains questions about demographics, disclosure, and attitude towards transparency in German language. Response formats include five-level Likert items, default categories, and open formats. Responses were given by ticking boxes or writing text onto the questionnaire. It was clarified in the cover letter that sending back completed questionnaires implies that data will be analysed anonymously. All items and response options can be found in Supplement A.

Main outcomes

The items to investigate research questions 1–3 are listed in Table 1. Physicians were asked about the frequency, content, and pleasantness of reactions that they experienced. Those questions could be answered separately for the reactions of patients, colleagues, and the private environment. For the analyses of the main research questions, an average value was calculated across the three groups of people. Participants of group 2 were asked about reactions to their disclosure 2016; all other participants were asked about reactions to their disclosure 2015.

Table 1.

Translated List of Relevant Questionnaire Items With Response Format

Variable	Item *Response format*
	Research question 1
Pleasantness of reactions	"If there were reactions, how did you perceive them?" *1-5: very unpleasant, rather unpleasant, neutral, rather pleasant, very pleasant*
Descriptive norm	"What percentage of German physicians do you estimate consented to disclose in the database?" ___ *% (open format in percent)*
Attitude	"To what extent do you agree with the following statement: In principle, I approve of transparency." *1-5: strongly disagree, disagree, neutral, agree, strongly agree*
	Research question 2
Frequency of reactions	"How many reactions did you get from patients / colleagues / your private environment?" *1-5: none, very few, rather few, rather many, many*
	Research question 3
Content of reactions	"If there were reactions, how was their content?" *1-5: very negative, somewhat negative, neutral, somewhat positive, very positive*

Note. The original questionnaire was in German; the translated complete questionnaire can be found in Supplement A.

Analysis

To investigate hypothesis 1, a multiple logistic regression with the outcome variable disclosure 2016 (0 = no disclosure, 1 = disclosure) and the main predictors X1: pleasantness of reactions, and X2: descriptive norm was conducted. To investigate the moderating role of X3: attitude, two interactions terms were added as predictors: X3*X1 and X3*X2. To test hypothesis 2 and 3, the frequency and content of reactions 2015 were compared with the frequency and content of reactions 2016. Directed tests for independent samples were conducted (more frequent/more negative reactions in 2015 than 2016). To test for normal distribution, the Shapiro-Wilk test was used. Data in all groups were not normally distributed on the respective dependent variable, therefore Wilcoxon tests were conducted. Effect sizes with 95% CI are given as rank-biserial correlations (r_b). A conservative alpha level of .01 was used for all tests.

Exploratively, we performed a content analysis[31] of answers to the question “Was there anything that bothered you about the reactions?”. All answers were reviewed by two researchers independently and categories were suggested. From the suggested categories, ten final categories were decided upon based on mutual consensus. Then, each answer was categorized independently (overall interrater agreement: 93%). Diverging ratings were discussed until consensus was reached. Statistical analyses were performed in JASP version 0.10.2,[32] RStudio, R version 3.6.1,[33] and Microsoft Excel (2011).

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

Sample

We contacted *n* = 750 physicians and received 236 filled-in questionnaires (Figure 1). The response rate was 35% (236/678; 72 questionnaires were undeliverable). Two questionnaires needed to be excluded: one was missing a page and could not be allocated to a group; another contained a note that the participant was not a medical doctor but a biologist. The remaining 234 questionnaires were allocated to the groups and analysed. Mean and median age of participants was 53 years (*SD* = 8.29; *IQR* = 10; Range: 31-75;

48/234 (21%) female, 185/234 (79%) male, 1/234 (0%) missing). Further sample characteristics are listed in Supplement B.

- Insert Figure 1 about here -

Physicians' experiences with the transparency database

Of the 234 participants, 87 (37%) stated they had not looked at the database, and 131 (56%) reported to have at least somewhat followed media coverage about the database. Most participants said they did not know whether their payments had been correctly reported: Of 189 participants who agreed to disclose payments in 2015, 91 (48%) did not know; 70 (37%) said their payments had been correctly reported, and 24 (13%) said they had been incorrectly reported. Of 192 participants who agreed to disclose payments in 2016, 105 (55%) did not know, 60 (31%) said their payments had been correctly reported and 23 (13%) said they had been incorrectly reported. Most participants stated they had not received any reactions from patients (190/234, 81%), colleagues (128/234, 55%) or the private environment (153/234, 65%). Response rates for items of content and pleasantness of reactions were between 26% (60/234, pleasantness of patients' reactions) and 48% (113/234, content of colleagues' reactions). See Figure 2 for detailed results.

- insert Figure 2 about here -

Descriptive norm

For investigating how high participants estimated the percentage of German physicians who disclosed in the database in 2015 and 2016, data were available from 216 and 218 participants and ranged between 0% and 100%. For 2015, participants estimated on average that 33% of German physicians had agreed to disclose (*SD* = 21, *Mdn* = 30, *IQR* = 30) and for 2016, participants estimated on average that 31% of German physicians agreed to disclose (*SD* = 20, *Mdn* = 25, *IQR* = 25).

Investigating non-disclosure

To answer research question 1, we investigated data of those participants who disclosed in 2015 (groups 1, 3; *n* = 189) to predict whether they disclosed again in 2016 (group 3; *n* = 147) or did not disclose again in 2016 (group 1; *n* = 42). Neither regression model 1 with the three predictor variables X1: pleasantness of reactions, X2: descriptive

norm and X3: attitude significantly improved the model fit compared to the null model ($\chi 2$ = 1.0, p = .792) nor regression model 2, in which the interaction terms X3*X2 and X3*X1 were added ($\chi 2$ = 12.66, p = .027). A more detailed description of regression model 1 and 2 can be seen in Supplement C.

We additionally explored the reasons for participants' non-disclosure in general. In our sample, two groups did not disclose payments in one year: Participants of group 1 had an entry in 2015 but not in 2016 (n = 42), and participants of group 2 had no entry in 2015 but in 2016 (n = 45). We asked these participants for the reason for the missing entry (Table 2). The most frequently chosen reason in group 1 was that they had consciously decided against disclosure (50%, vs. 18% in group 2). The most frequently chosen answer in group 2 was that they were not asked for their consent to disclose (36%, vs. 7% in group 1). We further asked how several statements applied to the participants in case they consciously decided against disclosure. Most participants reported that considerations of public opinion or media reporting led to the decision against disclosure (25/32, 78%) (Figure 3).

Table 2
Reasons for Non-disclosure

	group 1	**group 2**
You don't have an entry in the year 2015 (2016). Why?	***abs. frequency (%)***	***abs. frequency (%)***
I have not received any payments.	14/42 (33%)	10/45 (22%)
I was not asked for my consent to disclose.	3/42 (7%)	16/45 (36%)
I forgot to answer the inquiry for disclosure consent.	1/42 (2%)	2/45 (4%)
I consciously decided against disclosure.	21/42 (50%)	8/45 (18%)
No reply	3/42 (7%)	9/45 (20%)

Note. Participants were asked to choose one of the four options. Group 1 = disclosure in 2015, but not in 2016; group 2 = no disclosure in 2015, but in 2016.

- insert Figure 3 about here -

Year of disclosure

To investigate research questions 2 and 3, we compared the frequency and content of reactions to participants who disclosed for the first time in 2015 (groups 1, 3) with data of participants who disclosed for the first time in 2016 (group 2). Data for frequency of reactions were available for 2015 from 187/198 (99%) and for 2016 from 44/45 (98%) participants; data for content of reactions were available for 2015 from 110/198 (60%) and for 2016 from 19/45 (42%) participants. All variables were significantly non-normal (all W = 0.71-0.90, all p <.01). Testing hypothesis 2, we found no statistically significant difference between frequency of reactions 2015 and 2016 (2015: M = 1.54, SD = 0.66, Mdn = 1.33, IQR = 1; and 2016: M = 1.36, SD = 0.53, Mdn = 1.00, IQR = 0.67), as evidenced by a Wilcoxon rank-sum test (W = 3410, r_b = -.17, 95% CI [-∞, -0.01], p = .031). Testing hypothesis 3, we found no statistically significant difference between negativity of reactions 2015 and 2016 (2015: M = 2.69, SD = 0.71, Mdn = 3.00, IQR = 1; and 2016: M = 2.96, SD = 0.67, Mdn = 3.00, IQR = 0.33), as indicated by a Wilcoxon rank-sum test (W = 1243, r_b =.19; 95% CI [-0.05, ∞], p = .085).

Further exploratory investigations

Participants were asked to indicate their agreement with statements about attitude towards disclosure in general and in research. The statements that participants agreed with most strongly were that disclosure of payments should be more nuanced, that the undifferentiated display of the disclosures brings science into disrepute and that disclosure leads to a wrong impression in the public (Table 3).

Table 3

Attitudes towards Transparency.

	n	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Payments by pharmaceutical companies are a risk for the independence of clinical practice and research.	233	26/233 (11%)	41/233 (18%)	35/233 (15%)	90/233 (39%)	41/233 (18%)
In principle, I approve of transparency.	233	4/233 (2%)	3/233 (1%)	16/233 (7%)	39/233 (17%)	171/233 (73%)
Collaboration with pharmaceutical companies and receiving payments by those companies is part of the medical profession.	233	19/230 (8%)	35/230 (15%)	66/230 (28%)	71/230 (31%)	39/230 (17%)
Disclosure of payments should be more nuanced.	233	8/233 (3%)	2/233 (3%)	43/233 (18%)	51/233 (22%)	124/230 (53%)
Disclosure of payments increases patients' trust in me.	230	72/233 (31%)	45/233 (19%)	75/233 (32%)	32/233 (14%)	9/233 (4%)
Disclosure leads to a wrong impression in the public.	233	9/233 (4%)	24/233 (10%)	31/233 (13%)	78/233 (33%)	91/233 (39%)
In case you are working in research:						
Transparency guidelines impede my scientific work.	154	45/154 (29%)	40/154 (26%)	29/154 (19%)	32/154 (21%)	8/154 (5%)
I have been confronted with disclosures within the context of a published study at least once.	154	56/154 (36%)	17/154 (11%)	22/154 (14%)	24/154 (16%)	35/154 (23%)
My research results were criticized because of my disclosures at least once.	152	119/152 (78%)	11/152 (7%)	13/152 (9%)	5/152 (3%)	4/152 (3%)
The undifferentiated displaying of the disclosures brings science into disrepute.	155	10/155 (6%)	5/155 (3%)	16/155 (10%)	37/155 (24%)	87/155 (56%)

Sixty-eight participants answered the question “Was there anything that bothered you about the reactions?”. The content categories with respective frequencies are:

- negative media reporting (20/68, 29%)
- defamation / criminalization (17/68, 25%)
- unknown cases of undisclosed information (12/68, 18%)
- disclosed information is not put into context with services rendered in return (12/68, 18%)
- misleading data representation (7/68, 10%)
- contacted by lawyer who aimed a class action against CORRECTIV (7/68, 10%)
- feeling of being dragged into the public eye (5/68, 7%)
- feeling of being treated unfairly (5/68, 7%)
- involvement of employer (4/68, 6%)
- others expressed lack of understanding (2/68, 3%).

DISCUSSION

Principal findings

The aim of this study was to gain insight into physicians’ attitudes towards and experiences with the voluntary German transparency regulation. Research question 1 aimed to investigate how these experiences affect future disclosure behaviour, but no significant prediction model was found. Research questions 2 and 3 aimed to investigate whether reactions to disclosures between the first and the second year of the database differed. No significant difference in the frequency or content reactions was found on the alpha level of .01, which might be related to the fact that most participants in our sample had not received any reactions towards their disclosure. The fewest reactions came from patients. Only every fifth physician stated they had received at least “very few” reactions by patients.

We observed that the reasons for non-disclosure in our sample differed depending on the time point of non-disclosure: Participants who had disclosed in the first but not in the second year more often said they had consciously decided against disclosure than those who had not disclosed in the first year but in the second year. The latter more often said that they had not been asked for consent by the respective pharmaceutical company. Most physicians who had consciously decided against disclosure said it was because of public opinion and media reporting. We also found that nearly half of the participating physicians had not looked at the database and did not know whether their disclosed payment sum was correct. However, more than half of them at least somewhat followed the media coverage

about the database and some reported high objections to public exposure. This can be interpreted according to the spotlight effect which describes that people overestimate the attention they receive by others.[16] Several participants stated concerns about the public opinion and a feeling about being denunciated, which is in line with the observation that physicians are concerned that COI disclosure may damage their reputation.[17] This tendency relates to the psychological heuristic that people do not like to be viewed as biased. Studies show that if people are able to avoid COI, they may be motivated to avoid such conflicts so that they can disclose the absence of conflicts.[34] In case of voluntary disclosure, however, people can simply avoid being viewed as biased by deciding against disclosure.

Strengths and weaknesses

The strength of this study is that it provides quantitative and qualitative data on physicians' experiences with COI disclosure in a national database. To our knowledge, no such evidence exists for any European transparency regulation in medicine. The investigated sample was stratified to their disclosing behaviour. Due to the otherwise random selection of participants, our sample comprises a great bandwidth of age, disciplines, and workplaces. The study, however, also has several limitations. A common problem in survey methods, answers may be skewed by social desirability.[35] The answers to a controversially discussed subject may be even more skewed: Physicians may be more motivated to respond to the survey if they have strong opinions on transparency, or if they experienced extreme reactions towards their disclosure. We tried to counter this by our efforts to increase the response rate. Additionally, the questionnaire we used was only constructed for this study, so our data cannot be directly compared to other data.

Meaning of the study

Physicians in our sample reported to be concerned about reputational damage and public exposure. Those who did not disclose payments had various reasons. Mandatory transparency could approach these issues: Firstly, if disclosure is mandatory, it will no longer feel "unfair" that some disclose information and some hide this information. Secondly, if conducted in a standardized form, everyone's information is available, and therefore the disclosed information is easier to compare and better to interpret, which will lessen the risk of unfair reputational damage and might enable a fair discussion between pharmaceutical companies, physicians, researchers, and the public.

Currently, the consent rate to disclose payments by pharmaceutical companies in Germany is low, compared to other countries.[12,13] In our study we observed that even if

physicians consented to disclosure, our participants mainly appear not to have used the database nor checked their entries. Therefore, we propose that disclosers need to be educated about the background of transparency regulations and the concept of COI to raise commitment.

For the management of financial COI in medicine, transparency is by now seen as a necessary, but not sufficient, measure.[7,10,36] Managing the influence of COI involves further higher action, e.g. people with relevant COI being excluded from guideline development groups.[1,36] Voluntary transparency regulations do not serve this aim. They may fuel discussion and raise awareness for the interaction of pharmaceutical companies with HCPs, however this may backfire if information is not contextualized, and the regulation is not driven forward.

Unanswered questions and future research

In this sample, reasons for non-disclosure were heterogeneous. More research is needed about the motives for and against voluntary disclosure to improve current transparency policies. Our data show that there are more issues that need to be considered about the experiences with transparency guidelines, such as the fear of reputational damage. Broad evaluations of transparency guidelines including all involved persons are needed to get a full picture of the current situation.

CONCLUSION

The study at hand was the first survey of physicians who disclosed voluntarily in a nation-wide transparency database. We found no significant predictors for future disclosure behaviour and no statistically significant difference in the reactions to disclosures between the first year and the second year of the database. The exploratory results of this study show preliminary evidence that although German HCPs experienced only few reactions by patients, colleagues or in private, they are concerned that disclosing payments in a public database will result in reputational damage. Considering public opinion and media exposure was the most frequent reason for non-disclosure in this subsample. We propose that mandatory disclosure could be a solution to this problem by creating a standardized environment for an open discussion.

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Patient consent for publication: not required.

Provenance and peer review: -

Data sharing statement: Data are available on reasonable request by emailing MS.

Note: This paper contains extended passages from the dissertation by Marlene Stoll [24].

Ethics statement: The ethics committee of the Landesärztekammer Rhineland-Palatinate decided that a further consultation is not necessary since no personal but only anonymous data were processed (2018-13295-Epidemiologie).

REFERENCES

1. Institute of Medicine Committee on Conflict of Interest in Medical Research. 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; 2009.
2. Chimonas S, Mammor M, Zimbalist S, Barrow B, Bach PB, Korenstein D. BMJ. 2021 Nov 3; 375:e066576
3. Lundh A, Lexchin J, Mintzes B, et al. Industry sponsorship and research outcome: systematic review with meta-analysis. Intensive Care Med. 2018 Oct 1;44(10):1603–12 https://doi.org/10.1007/s00134-018-5293-7.
4. Mitchell AP, Trivedi NU, Gennarelli RL, et al. Are Financial Payments From the Pharmaceutical Industry Associated With Physician Prescribing? Ann Intern Med. 2021 Mar 16;174(3):353–61 https://doi.org/10.7326/M20-5665.
5. Nejstgaard CH, Bero L, Hróbjartsson A, et al. Association between conflicts of interest and favourable recommendations in clinical guidelines, advisory committee reports, opinion pieces, and narrative reviews: systematic review. BMJ. 2020 Dec 9;371:m4234 https://doi.org/10.1136/bmj.m4234.
6. Thompson D. Understanding financial conflicts of interest. N Engl J Med. 1993.
7. Fabbri A, Santos A, 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 Mar 14;7(6):504–9 https://doi.org/10.15171/ijhpm.2018.20.
8. 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 May 1;122(5):509–18 https://doi.org/10.1016/j.healthpol.2018.03.015.
9. 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
10. Bradley SH, DeVito NJ, Lloyd K, Richards GC, Rombey T, Wayant C, Gill PJ. Reducing bias and improving transparency in medical research: a critical overview of the problems, progress and suggested next steps. J R Soc Med. 2020 Nov 1;113(11):433-443. https://doi.org/10.1177/0141076820956799
11. Open Payments [Website]. Available from: https://www.cms.gov/openpayments (accessed 19 Nov 2021).
12. Mulinari S, Martinon L, Jachiet P-A, et al. Pharmaceutical industry self-regulation and non-transparency: country and company level analysis of payments to healthcare professionals in seven European countries. Health Policy. 2021 Jul 1;125(7):915–22 https://doi.org/10.1016/j.healthpol.2021.04.015.
13. 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 Sep 1;10(9):e037395 http://dx.doi.org/10.1136/bmjopen-2020-037395.

14. Loewenstein G, Sah S, Cain DM. The Unintended Consequences of Conflict of Interest Disclosure. JAMA. 2012 Feb 15;307(7):669–70 https://doi.org/10.1001/jama.2012.154.
15. Sah S, Loewenstein G, Cain DM. Insinuation Anxiety: Concern That Advice Rejection Will Signal Distrust After Conflict of Interest Disclosures. Pers Soc Psychol Bull. 2019;45(7);1099-1112 https://doi.org/10.1177/0146167218805991.
16. Loewenstein G, Sunstein CR, Golman R. Disclosure: Psychology Changes Everything. Annu Rev Econ. 2014;6:391–419 https://doi.org/10.1146/annurev-economics-080213-041341.
17. Chimonas S, DeVito NJ, Rothman DJ. Bringing Transparency to Medicine: Exploring Physicians' Views and Experiences of the Sunshine Act. Am J Bioeth. 2017 Jun 3;17(6):4–18 https://doi.org/10.1080/15265161.2017.1313334.
18. Boytchev WB. Warum Ärzte schweigen. 2016 Jul 17; Available from: https://correctiv.org/aktuelles/euros-fuer-aerzte/2016/07/17/warum-aerzte-schweigen (accessed 19 Nov 2021).
19. Licurse A, Barber E, Joffe S, Gross C. The impact of disclosing financial ties in research and clinical care: a systematic review. Arch Intern Med. 2010;170(8):675-82. https://doi.org/10.1001/archinternmed.2010.39
20. Riedl EM, König J, Koch C, Lieb K. Einstellungen und Erwartungen von Patienten in Bezug auf Interessenkonflikte ihrer behandelnden Ärzte. Z Evid Fortbild Qual Gesundheitswes. 2016 Jan 1;110-111;45-53 https://doi.org/10.1016/j.zefq.2015.12.002
21. Pham-Kanter G, Mello MM, Lehmann LS, et al. Public Awareness of and Contact With Physicians Who Receive Industry Payments: A National Survey. J Gen Intern Med. 2017 Jul 1;32(7):767–74 http://dx.doi.org/10.1007/s11606-017-4012-3.
22. Young PD, Xie D, Schmidt H. Towards Patient-Centered Conflicts of Interest Policy. Int J Health Policy Manag. 2017 Oct 29;7(2):112–9 https://dx.doi.org/10.15171%2Fijhpm.2017.128.
23. Chung A, Rimal RN. Social norms: a review. Rev Commun Res. 2016;4:1–28 https://doi.org/10.12840/issn.2255-4165.2016.04.01.008.
24. Lapinski MK, Rimal RN. An Explication of Social Norms. Commun Theory. 2005 May 1;15(2):127–47 https://doi.org/10.1111/j.1468-2885.2005.tb00329.x.
25. Freiwillig Selbstkontrolle für die Arzneimittelindustrie e.V. FSA-Transparenzkodex. 2019. Available from: https://www.fsa-pharma.de/de/kodizes/sk_fsa_transparenzkodex_13.03.2019.pdf (accessed 19 Nov 2021).
26. Richter, F. "Euros für Ärzte"-Datenbank beendet. 2021 Jan 14; Available from: https://correctiv.org/aktuelles/2021/01/14/euros-fuer-aerzte-datenbank-beendet/ (accessed 19 November 2021).

27. CORRECTIV. Euros für Ärzte. 2021. Available from: https://correctiv.org/aktuelles/euros-fuer-aerzte (accessed 19 November 2021).

28. Elmer C, Stotz P. Warum Ärzte schweigen. 2016 Jul 14; Available from: https://www.spiegel.de/gesundheit/diagnose/euros-fuer-aerzte-datenbank-wie-viel-hat-mein-arzt-bekommen-a-1102819.html (accessed 19 November 2021).

29. Stoll M. Unintended Consequences of Conflict of Interest Disclosure: a Psychological Perspective [Internet]. Johannes Gutenberg-Universität Mainz; 2021 [cited 2021 Jul 28]. Available from: https://openscience.ub.uni-mainz.de/handle/20.500.12030/5731

30. Green SB. How Many Subjects Does It Take To Do A Regression Analysis. Multivar Behav Res. 1991 Jul 1;26(3):499–510 https://doi.org/10.1207/s15327906mbr2603_7.

31. Mayring P. Qualitative content analysis: theoretical foundation, basic procedures and software solutions [Internet]. Social Science Open Access Repository; 2014 [cited 2021 Nov 19]. Available from: https://nbn-resolving.org/urn:nbn:de:0168-ssoar-395173

32. JASP Team. JASP (Version 0.10.2). 2019.

33. R Core Team. R: A Language and Environment for Statistical Computing. 2019. Available from: https://www.R-project.org

34. Sah S, Loewenstein G. Nothing to Declare: Mandatory and Voluntary Disclosure Leads Advisors to Avoid Conflicts of Interest. Psychol Sci. 2014;25(2):575-584 https://doi.org/10.1177%2F0956797613511824.

35. Barclay S, Todd C, Finlay I, et al. Not another questionnaire! Maximizing the response rate, predicting non-response and assessing non-response bias in postal questionnaire studies of GPs. Fam Pract. 2002 Feb 1;19(1):105–11 https://doi.org/10.1093/fampra/19.1.105.

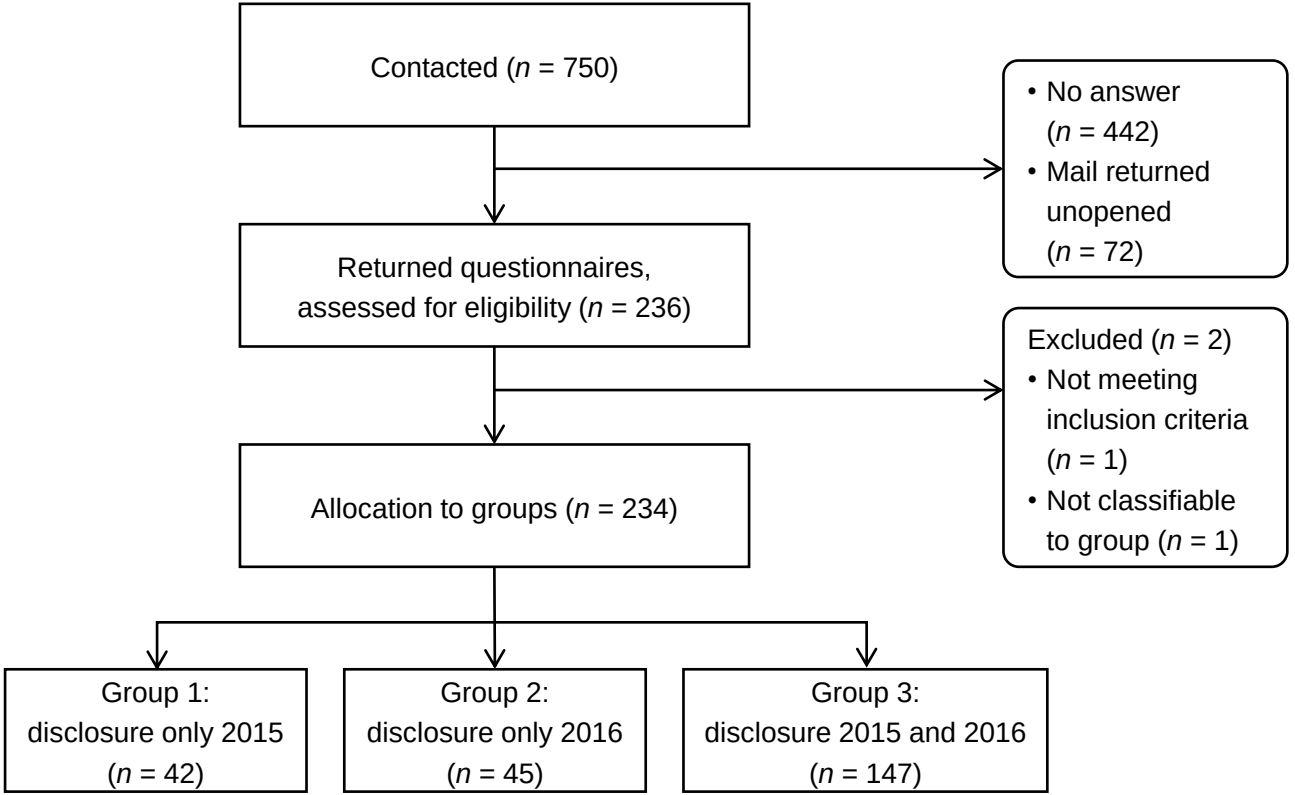
36. Lexchin J, Fugh-Berman A. A Ray of Sunshine: Transparency in Physician-Industry Relationships is not Enough. J Gen Intern Med. 2021 Oct 1;36(10):3194-3198 https://doi.org/10.1007/s11606-021-06657-0

Figures

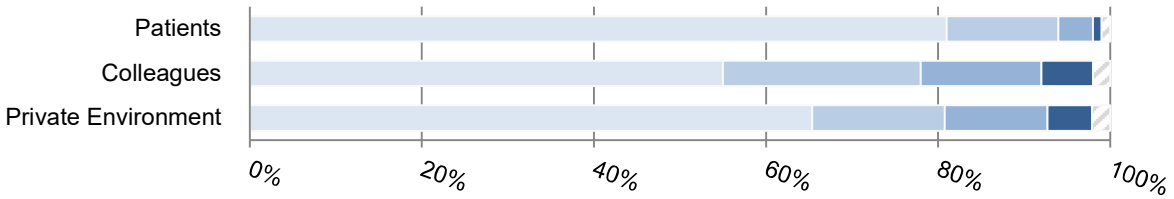
Figure 1. Participant Flow Chart.

Figure 2. Relative Frequencies of Item Answers for Frequency, Content, and Pleasantness of Reactions from Recipients, N = 234.

Figure 3. Factors Considered for Decision Against Disclosure.

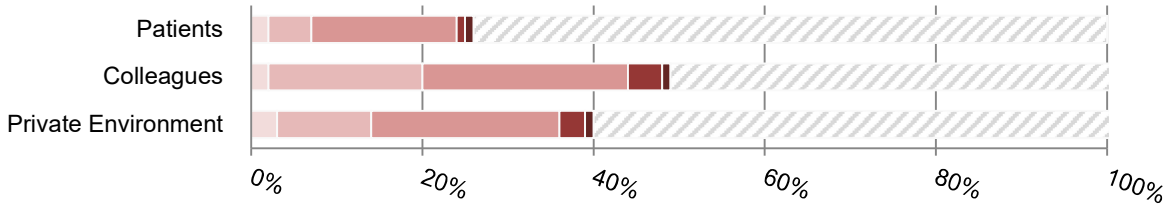

Contacted (n = 750)
• No answer (n = 442)
• Mail returned unopened (n = 72)
Returned questionnaires, assessed for eligibility (n = 236)
Excluded (n = 2)
• Not meeting inclusion criteria (n = 1)
• Not classifiable to group (n = 1)
Allocation to groups (n = 234)
Group 1: disclosure only 2015 (n = 42)
Group 2: disclosure only 2016 (n = 45)
Group 3: disclosure 2015 and 2016 (n = 147)

Frequency of Reactions



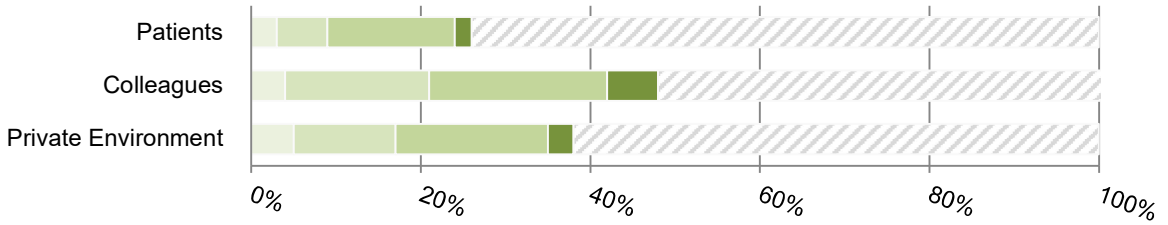
	Private Environment	Colleagues	Patients
none	65%	55%	81%
very few	15%	23%	13%
rather few	12%	14%	4%
rather many	5%	6%	1%
many	0%	0%	0%
NA	2%	2%	1%

Content of Reactions

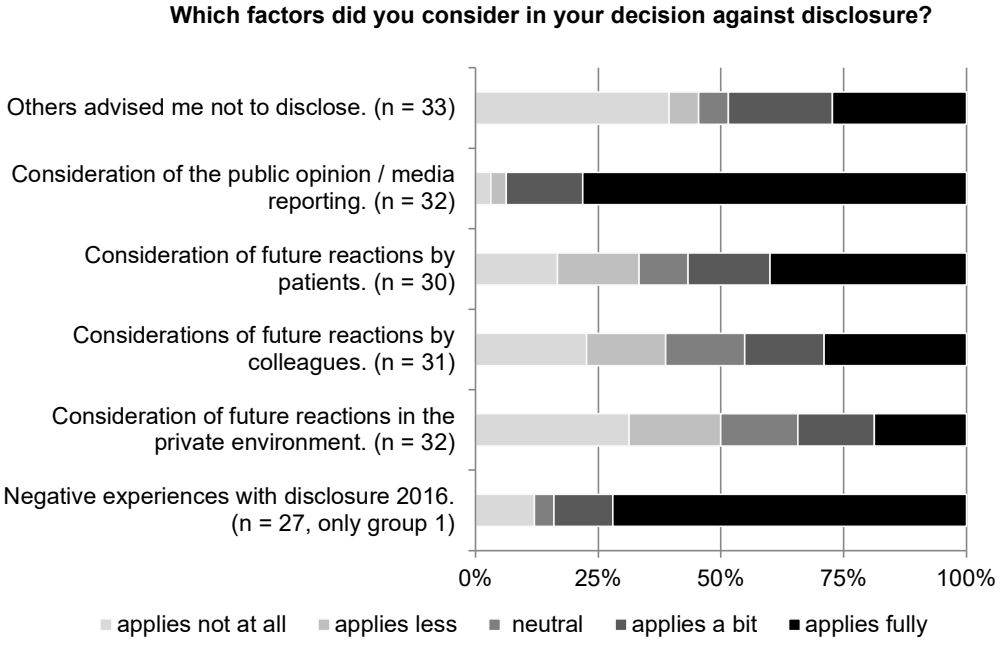


	Private Environment	Colleagues	Patients
very negative	3%	2%	2%
negative	11%	18%	5%
neutral	22%	24%	17%
positive	3%	4%	1%
very positive	1%	1%	1%
NA	61%	52%	74%

Pleasantness of Reactions



	Private Environment	Colleagues	Patients
very unpleasant	5%	4%	3%
rather unpleasant	12%	17%	6%
neutral	18%	21%	15%
rather pleasant	3%	6%	2%
very pleasant	0%	0%	0%
NA	62%	53%	74%



Supplement A
Translated Questionnaire (not formatted)

1) Discipline:
[open format]

2) Gender:
- ❑ male
- ❑ female

3) Age:
[open format]

4) Do you work in a hospital?
- ❑ yes, university hospital
- ❑ yes, non-university hospital
- ❑ no

5) If yes: Which position do you have?
- ❑ head
- ❑ senior
- ❑ resident

6) If no: How do you work?
- ❑ licensed
- ❑ employed
- ❑ other

7) How much of your working hours (in %) do you spend on patient care?
[open format]

8) How much of your working hours (in %) do you spend on research?
[open format]

9) Please tick every box that resembles a research area that you have been actively working in in the last five years (multiple responses are possible).
- ❑ non-interventional post-marketing studies
- ❑ clinical studies on behalf of pharmaceutical companies
- ❑ clinical studies investigated by yourself
- ❑ own, academical research
- ❑ other: _____
- ❑ I do not work in research.

10) What percentage of German physicians do you estimate consented to disclose in the database?

In 2016 for disclosure 2015: [open format]

In 2017 for disclosure 2016: [open format]

11) Do you know the actual percentage approximately, for example from the media?

2016:

- ❑ yes
- ❑ no

2017:

- ❑ yes
- ❑ no

12) Have your information about payments been correctly reported in the database? "Euros for Doctors"?

[groups 1, 3-5] In 2017 for 2016:

- ❑ yes
- ❑ no
- ❑ I don't know

[groups 2-5] In 2016 for 2015:

- ❑ yes
- ❑ no
- ❑ I don't know

13) In the summer of 2016, first data were disclosed in the database. How much do the following statements apply to you?

- I looked into the database.
- I followed media coverage about the database.
- I searched for persons in the database.

scale:

- ❑ applies not at all
- ❑ applies less
- ❑ neutral
- ❑ applies a bit
- ❑ applies fully

14) How high is the amount of money you disclosed, compared to the other disclosed payments?

- ❑ definitely below average
- ❑ somewhat below average
- ❑ average
- ❑ somewhat above average
- ❑ definitely above average

15. 1) [group 1, 3-5] You disclosed data in 2015. We are interested in how your environment reacted to this entry.
15.2) [group 2] You disclosed data in 2015. We are interested in how your environment reacted to this entry.

How many reactions did you get from …

- **patients?**
- **colleagues?**
- **your private environment?**

scale:

- ❑ none
- ❑ very few
- ❑ rather few
- ❑ rather many
- ❑ many

16) If there were reactions, how was their content? Reactions from …

- **patients**
- **colleagues**
- **your private environment**

scale:

- ❑ very negative
- ❑ somewhat negative
- ❑ neutral
- ❑ somewhat positive
- ❑ very positive

17) If there were reactions, how did you perceive them? Reactions from …

- **patients**
- **colleagues**
- **your private environment**

scale:

- ❑ very unpleasant
- ❑ rather unpleasant
- ❑ neutral
- ❑ rather pleasant
- ❑ very pleasant

18) Was there anything that bothered you about the reactions?
[open format]

19.1) [group 1] You do not have an entry in the database in the year 2016. Why?
19.2) [group 2] You do not have an entry in the database in the year 2015. Why?

- ❑ I have not received any payments.
- ❑ I was not asked for my consent to disclose.
- ❑ I forgot to answer the inquiry for disclosure consent.
- ❑ I consciously decided against disclosure.

20.1) [group 1] In case you decided consciously against disclosure: Which factors did you consider in your decision against disclosure?

- Others advised me not to disclose.
- Consideration of the public opinion / media reporting.
- Consideration of future reactions by patients.
- Consideration of future reactions by colleagues.
- Consideration of future reactions in the private surrounding.
- Negative experiences with disclosure 2015.

scale:

- ❑ applies not at all
- ❑ applies less
- ❑ neutral
- ❑ applies a bit
- ❑ applies fully

20.2) [group 2] In case you decided consciously against disclosure: Which factors did you consider in your decision against disclosure?

- Others advised me not to disclose.
- Consideration of the public opinion / media reporting.
- Consideration of future reactions by patients.
- Consideration of future reactions by colleagues.
- Consideration of future reactions in the private surrounding.

scale:

- ❑ applies not at all
- ❑ applies less
- ❑ neutral
- ❑ applies a bit
- ❑ applies fully

20.3) [groups 3-5] In 2016, you decided to disclose a second time. Please state how much the following statements apply to you.

- [groups 3-5] Coming to decision whether or not to disclose was easier for the second year than for the first year.
- [groups 4,5] My payments shifted because the opportunities by the pharmaceutical companies changed.
- [group 4] My payments shifted because I consciously accepted more money.
- [group 5] My payments shifted because I consciously accepted less money.

scale:

- ❑ applies not at all
- ❑ applies less
- ❑ neutral
- ❑ applies a bit
- ❑ applies fully

21) To what extent do you agree with the following statements:

- Payments by pharmaceutical companies are a risk for the independence of clinical practice and research.
- Disclosure of payments increases patients' trust in me.
- Receiving payments is fine if regulation measures (disclosure, exclusion from committees) are adopted.
- In principle, I approve of transparency.
- Disclosure leads to a wrong impression in the public.
- Collaboration with pharmaceutical companies and receiving payments by those companies is part of the medical profession.
- Some payments should be avoided, while others are indispensable.
- Without good alternatives in research and training, nothing about financial interactions in the medical sector will change.
- Disclosure of payments should be more nuanced.

In case you are working in research:

- Transparency guidelines impede my scientific work.
- I have been confronted with disclosures within the context of a published study at least once.
- My research results were criticized because of my disclosures at least once.
- If I do not cooperate with the industry, the research that is relevant for me lacks financial resources.
- The undifferentiated displaying of the disclosures brings science into disrepute.

scale:

- ❑ strongly disagree
- ❑ disagree
- ❑ neutral
- ❑ agree
- ❑ strongly agree

22) In your opinion: Disclosure of financial payments is more important in which area?

- ❑ definitely in patient care
- ❑ rather in patient care
- ❑ equally important
- ❑ rather in research
- ❑ definitely in research

Supplement B

Sample Characteristics

Characteristic		*n*	%
Gender	Female	48	21
	Male	185	79
	NA	1	0
Field	General and internal medicine	129	55
	Psychiatry, neurology and psychosomatics	33	14
	Surgery	31	13
	Other	38	16
Workplace	University hospital	67	29
	Non-university hospital	51	22
	Of which position: Head	*49*	*42*
	Senior	*53*	*19*
	Resident	*11*	*9*
	NA	*5*	*4*
	Practice	113	48
	Of which: Licensed	*104*	*92*
	Employed	*9*	*8*
	NA	3	1

Note. N= 234

Supplement C

Investigating non-disclosure, regression analysis.

To answer the first research question, we investigated data of those participants who disclosed in 2015 (n = 189) to predict whether they disclosed again in 2016 (n = 147, 78%) or did not disclose again in 2016 (n = 42, 22%). Response rate per item differed: For the items attitude, descriptive norm 2015, and pleasantness of reactions 2015, data were available from 188, 174, and 107 participants, respectively. For pleasantness of reactions 2015, we thus only had data of 22 people who did not disclose in 2016. All variables were significantly non-normal: all W = 0.52 - 0.92, all p < .01.

In regression model 1, the predictors were the three variables X1: pleasantness of reactions, X2: descriptive norm and X3: attitude. This model did not significantly improve the model fit compared to the null model, $\chi 2$ = 1.0, p = .792. Regression model 2 included the three variables as well as the interaction terms X3*X2 as well as X3*X1. This second model also did not significantly improve the model fit compared to the null model, $\chi 2$ = 12.66, p = .027. Effect sizes, pseudo-R^2-values and variance inflation factors (VIF) of regression model 1 and 2 can be seen in Table C1. The pseudo-R^2-values, being very low, indicate that this prediction model is of poor quality. We further explored the data by investigating whether participants who disclosed in 2016 had systematically different values on the main outcomes from the participants who did not disclose in 2016. Results from the performed Wilcoxon tests provided no indication for systematic differences between the groups (all p < .01).

Table C1

Logistic Regression Coefficients and Effect Sizes of Regression Model 1 and 2

	B (SE)	*p*	*OR*
Regression model 1: Only main effects			
Intercept	1.54 (0.28)	.000	4.66
Pleasantness of reactions	0.24 (0.27)	.373	1.27
Descriptive norm	0.13 (0.37)	.717	1.14
Attitude	-0.10 (0.32)	.753	0.90
Regression model 2: Main effects and interaction terms			
Intercept	2.31 (0.60)	.000	10.11
Pleasantness of reactions	0.61 (0.42)	.142	1.84
Descriptive norm	-0.06 (0.46)	.891	0.94
Attitude	-1.57 (1.08)	.145	0.21
Attitude*pleasantness of reactions	-1.27 (0.64)	.048	0.28
Attitude*descriptive norm	0.98 (0.67)	.140	2.67

Note. Model fit regression model 1: R^2 = .01 (Hosmer-Lemeshow), .01 (Cox-Snell), .02 (Nagelkerke); model 1 compared to null model: $\chi^2(3) = 1.04$, $p = .792$, all *VIF* < 10*;* Model fit regression model 2: R^2 = .01 (Hosmer-Lemeshow), .01 (Cox-Snell), .02 (Nagelkerke); model 2 compared to null model: $\chi^2(5) = 12.66$, $p = .027$; model 2 compared to model 1: $\chi^2(2) = 11.63$, $p = .003$, all *VIF* < 10.

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
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	4-6
Objectives	3	State specific objectives, including any pre-specified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	7-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7-9
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	7-8
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9
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	8-9, Supplement A
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	8

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
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	7, 10
		(b) Give reasons for non-participation at each stage	10
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10, Supplement B
		(b) Indicate number of participants with missing data for each variable of interest	10-14
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	10-11, Figure 2
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	11-13
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11-15
Discussion			
Key results	18	Summarise key results with reference to study objectives	15-16
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	16
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16-17
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	21

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.
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.

BMJ Open

Physicians' attitudes towards disclosure of payments from pharmaceutical companies in a nation-wide voluntary transparency database: a cross-sectional survey

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Physicians' attitudes towards disclosure of payments from pharmaceutical companies in a nation-wide voluntary transparency database: a cross-sectional survey

Marlene Stoll*, Lara Hubenschmid, Cora Koch, Klaus Lieb, Boris Egloff

Marlene Stoll (marlene.stoll@unimedizin-mainz.de)
Department of Psychiatry and Psychotherapy, University Medical Center Mainz, Untere Zahlbacher Straße 8, 55131 Mainz, Germany
http://orcid.org/0000-0001-8847-5497

Lara Hubenschmid (lara.hubenschmid@lir-mainz.de)
Leibniz Institute for Resilience Research (LIR), Mainz, Germany

Cora Koch (cora.koch@uniklinik-freiburg.de)
Department of Neurology and Neurophysiology, Medical Center - University of Freiburg, Freiburg, Germany
http://orcid.org/0000-0003-0827-7023

Klaus Lieb (klaus.lieb@lir-mainz.de)
Department of Psychiatry and Psychotherapy, University Medical Center Mainz, Mainz, Germany

Boris Egloff (egloff@uni-mainz.de)
https://orcid.org/0000-0002-5736-9912
Department of Psychology, Johannes Gutenberg University Mainz

* Corresponding author

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ABSTRACT

Objectives: To investigate German physicians' attitudes towards and experiences with voluntary disclosure of payments by pharmaceutical companies in a public database and their impact on future decisions for or against disclosure.

Design: National cross-sectional survey conducted in 2018 among physicians who voluntarily disclosed at least one payment in the German transparency regulation.

Setting: Retrospective paper-pencil questionnaire about attitudes towards and experiences with voluntary payment disclosures in the first (2015) and second year (2016) of the German transparency regulation.

Participants: German physicians who disclosed either in the first year only, the second year only, or in both years of the transparency regulation.

Primary outcomes: (1) the probability to disclose in 2016, predicted by physicians' experience of reactions from others in 2015, descriptive norms, and attitudes towards transparency; (2) frequency and (3) content of reactions from others 2015 compared to 2016.

Results: Data of 234 respondents were analysed (n = 42, 45, and 147 physicians who disclosed in 2015, 2016 or both years, respectively). The probability to disclose in 2016 was not predicted by perceived reactions, norms, or attitudes towards transparency (p>.01). Most participants reported not to have received any reactions by patients (190/234, 81%), colleagues (128/234, 55%) or the private environment (153/234, 65%). Neither frequency nor content of reactions differed between the first and second year (scale 1-5; frequency: $Mdn_{2015,2016}$ = 1.33 vs. 1.36, r_b = -.17, p>.01; content: $Mdn_{2015,2016}$ = 2.69 vs. 2.96, r_b = .19, p>.01). However, media reporting, fear of reputational damage and a feeling of being defamed were mentioned as reasons for non-disclosure.

Conclusions: While confirmatory analyses did not provide significant results, descriptive analyses showed that participants who voluntarily disclose payments mainly do not experience any reactions towards their disclosures but report fears about losing their reputation due to disclosures.

Registration: https://osf.io/ztvur

ARTICLE SUMMARY

Strengths and limitations of this study

- This study is the first survey of attitudes and experiences of physicians who voluntarily disclosed payments by pharmaceutical companies in a nation-wide transparency database.
- The sample takes into account whether physicians disclosed only in one year or in two consecutive years.
- The study was preregistered and provides qualitative and quantitative data on reasons for non-disclosure in this database.
- The questionnaire used in this study was only constructed for this purpose, so a direct comparison with other data is not possible.

INTRODUCTION

The services sector of the health industry has a long tradition of close ties to the pharmaceutical industry.[1,2] Such ties have been shown to potentially lead to systematic biases in research and daily patient care.[3-5] Situations in which a secondary interest (e.g., financial gain) creates a risk that a primary interest (e.g., patient welfare) is unduly influenced are defined as conflicts of interest (COI).[1,6] Several approaches have been established to meet the challenge of COI in medicine, amongst which transparency regulations are very popular.[7-10] Transparency regulations have been introduced to shed light on formerly unknown information,[7,8] in this case: information about payments from pharmaceutical companies to health care professionals (HCPs). They differ in their coverage and implementation. In the United States, payments are fully transparent since the introduction of the Physician Payments Sunshine Act (PPSA) and publicly disclosed on the Open Payments website.[11] In Europe, transparency of payments to HCPs is mandatory only in some countries whereas in others such as Germany, it is regulated on a voluntary level.[7,9,12,13] However, disclosing COI may have unintended effects (e.g., loss of patient trust [14,15]), which may interact with the mode of the transparency regulation. This study explores the effects of Germany's voluntary transparency regulation of payments by pharmaceutical companies to HCPs, and investigates factors that lead HCPs to decide against disclosing payments in this database voluntarily.

Effects of transparency guidelines

An intended effect of transparency guidelines is that publicly disclosing COI could motivate conflicted persons to change their behaviour in the sense that they decrease industry contacts in the future.[16] Thus, transparency regulations affect those who disclose information. In focus groups about experiences with the PPSA conducted in 2015,[17] physicians reported to be frustrated with the administrative process, to feel treated unfairly and to worry the disclosures might mislead patients.[17] For voluntary regulations, there is only anecdotal evidence: In a newspaper article[18] about physicians who decided against disclosure in the German transparency database, the interviewees stated to approve of transparency in general, but also said the current regulation was unfair, the disclosed information was misleading, and patients' trust would suffer.[18]

Public awareness thus appears to be a relevant element of transparency regulations.[16] Research has shown that patients would like their physicians to disclose financial COI, since they were concerned about biased clinical judgement.[19,20] However, at least in the United States, public awareness of the Open Payments website was low, as

shown by citizen surveys in 2014 and 2015: Only 9-12 % knew about the disclosed information.[21,22] Accordingly, U.S. physicians believed patients were uninterested in the data.[17] In Germany, physicians reported to fear negative effects on patients and therefore decided against disclosure.[18] The interaction between disclosing HCPs and the public and its effects on disclosing behaviour in a voluntary transparency database has not been systematically investigated yet.

Another important factor when discussing the effects of voluntary transparency regulations is the descriptive norm (i.e., behaviour that most of the peers show is considered "normal" behaviour[23,24]) and thus, the moment when area-wide information about the frequency of behaviour becomes available. From then on, information is available about how many HCPs voluntarily disclose payments, which forms a new reference frame for whether it is considered "normal" to disclose payments. An HCP's decision to voluntarily disclose payments may depend on the subjectively estimated number of disclosing HCPs. Additionally, HCPs themselves will consider the fact that HCPs receive payments by pharmaceutical companies relatively "normal", while most of the public will only learn about it with the first disclosure round and judge the behaviour as "abnormal" - an impression which will decline over time. Therefore, reactions by the public may be more pronounced in the first year of a transparency database than in the following.

Germany's transparency regulation

In Germany, transparency of payments to HCPs is self-regulated by the pharmaceutical industry: 54 pharmaceutical companies organized in the "association of voluntary self-regulation in the pharmaceutical industry" passed a transparency codex which requires HCPs' consent for the respective financial interaction to be disclosed on each company's website.[12,13,25] First data were disclosed 2016 for payments from 2015. The investigative newsroom CORRECTIV gathered this data from each company's website and established the "Euros for Doctors" database - a searchable platform that provided, per HCP, an overview of all payments they had received. The database started in 2016, but it was discontinued after only two years, making the investigation of long-term changes of disclosing rates difficult.[26] The kick-off was accompanied with investigative articles,[27] collaborating with the popular German online news magazine SPIEGEL ONLINE. They criticised the undifferentiated way of disclosing (e.g., the designated use of the money was not disclosed), and the large number of HCPs who did not disclose information.[18,28] An analysis of the 2015 and 2016 data of this database by our group [13] showed that about 28% and 24% of all HCPs who had received payments agreed to disclose payments in 2015 and 2016, respectively. Of all disclosing HCPs, 26% disclosed payments in both years, 44%

disclosed only in 2015, and 29% only in 2016. The total number of disclosing HCPs decreased by 21%.

Study aims and research questions

This study investigated HCPs' attitudes towards and experiences with the voluntary transparency database, and reasons for non-disclosure. Main research question 1 was: Do the reactions physicians experienced to their disclosed information or their perception of how normal it is to disclose predict the decision to disclose in the following year? Does a positive attitude moderate this effect? We hypothesized that the probability for deciding against disclosure in the subsequent year was higher the more unpleasant reactions were experienced and the lower the descriptive norm to disclose was estimated, and that a positive attitude towards transparency moderates this relationship. Research questions 2 and 3 were: Do physicians experience a higher number of reactions and more negative reactions in the first than in the second year of the regulation? We hypothesized that reactions were more frequent and more negative in the first compared to the following year.

METHODS

Sample

Our sample was drawn from the population of 28,230 HCPs who disclosed at least one financial interaction with a pharmaceutical company in 2015 or 2016 in the German transparency regulation.[13] We built our survey sample of 3 groups: HCPs who disclosed only 2015 (group 1), only 2016 (group 2), and HCPs who disclosed both 2015 and 2016 (group 3). For further analyses in the underlying dissertation,[29] the third group was split up and analysed in three subgroups. Therefore, group 3 is bigger than groups 1 and 2. To enhance the probability that we survey HCPs who receive payments annually, we excluded HCPs who disclosed an annual payment sum < 1,000 €. This was based on the observation that the median disclosed annual payments of HCPs who disclosed in both years was 899€ in 2015, compared to the median disclosed sum of HCPs who disclosed only once, which was 452€.[13] Based on that, we excluded 19,267 HCPs with annual payment sums < 1,000 €. From the remaining 8,963 HCPs, possible participants were selected (see below). Further, we only included HCPs who worked as physicians at the time point of the survey. This criterion was evaluated after selection: for each chosen HCP, we verified by internet research whether they currently worked as a physician. If they did not or no information was

available, another HCP was randomly selected, and it was checked whether they worked as physicians. This was repeated until the determined sample size was reached.

Procedure and sample size

For the planned regression model, an analysable sample of 150 participants was estimated based on Green's rule of thumb.[30] Expecting a response rate of 30-50%, we formulated a detailed sample plan: Starting in August 2018, we sent out questionnaires in waves of 50 questionnaires per group. Questionnaires were sent by mail, accompanied by a cover letter and a reply envelope. A reminder letter was sent after two weeks. Two weeks after that, we phoned those with a publicly available phone number. If the planned sample size was not reached a month after the last contact attempt, the next wave was started: The next 50 physicians were randomly selected and contacted as described above. We stopped this procedure for each group after the 30th questionnaire was received, which was after we had sent the third wave of questionnaires in February 2019. All examinable questionnaires that we received afterwards were also included in the data analysis. Study procedures were preregistered at www.osf.io/ztvur.

Questionnaire

The two-page questionnaire contains questions about demographics, disclosure, and attitude towards transparency in German language. Response formats include five-level Likert items, default categories, and open formats. Responses were given by ticking boxes or writing text onto the questionnaire. It was clarified in the cover letter that sending back completed questionnaires implies that data will be analysed anonymously. All items and response options can be found in Supplement A.

Main outcomes

The items to investigate research questions 1–3 are listed in Table 1. Physicians were asked about the frequency, content, and pleasantness of reactions that they experienced. Those questions could be answered separately for the reactions of patients, colleagues, and the private environment. For the analyses of the main research questions, an average value was calculated across the three groups of people. Participants of group 2 were asked about reactions to their disclosure 2016; all other participants were asked about reactions to their disclosure 2015.

Table 1.

Translated List of Relevant Questionnaire Items With Response Format

Variable	Item *Response format*
	Research question 1
Pleasantness of reactions	"If there were reactions, how did you perceive them?" *1-5: very unpleasant, rather unpleasant, neutral, rather pleasant, very pleasant*
Descriptive norm	"What percentage of German physicians do you estimate consented to disclose in the database?" ___ *% (open format in percent)*
Attitude	"To what extent do you agree with the following statement: In principle, I approve of transparency." *1-5: strongly disagree, disagree, neutral, agree, strongly agree*
	Research question 2
Frequency of reactions	"How many reactions did you get from patients / colleagues / your private environment?" *1-5: none, very few, rather few, rather many, many*
	Research question 3
Content of reactions	"If there were reactions, how was their content?" *1-5: very negative, somewhat negative, neutral, somewhat positive, very positive*

Note. The original questionnaire was in German; the translated complete questionnaire can be found in Supplement A.

Analysis

To investigate hypothesis 1, a multiple logistic regression with the outcome variable disclosure 2016 (0 = no disclosure, 1 = disclosure) and the main predictors X1: pleasantness of reactions, and X2: descriptive norm was conducted. To investigate the moderating role of X3: attitude, two interactions terms were added as predictors: X3*X1 and X3*X2. To test hypothesis 2 and 3, the frequency and content of reactions 2015 were compared with the frequency and content of reactions 2016. Directed tests for independent samples were conducted (more frequent/more negative reactions in 2015 than 2016). To test for normal distribution, the Shapiro-Wilk test was used. Data in all groups were not normally distributed on the respective dependent variable, therefore Wilcoxon tests were conducted. Effect sizes with 95% CI are given as rank-biserial correlations (r_b). A conservative alpha level of .01 was used for all tests.

Exploratively, we performed a content analysis[31] of answers to the question “Was there anything that bothered you about the reactions?”. All answers were reviewed by two researchers independently and categories were suggested. From the suggested categories, ten final categories were decided upon based on mutual consensus. Then, each answer was categorized independently (overall interrater agreement: 93%). Diverging ratings were discussed until consensus was reached. Statistical analyses were performed in JASP version 0.10.2,[32] RStudio, R version 3.6.1,[33] and Microsoft Excel (2011).

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

Sample

We contacted *n* = 750 physicians and received 236 filled-in questionnaires (Figure 1). The response rate was 35% (236/678; 72 questionnaires were undeliverable). Two questionnaires needed to be excluded: one was missing a page and could not be allocated to a group; another contained a note that the participant was not a medical doctor but a biologist. The remaining 234 questionnaires were allocated to the groups and analysed. Mean and median age of participants was 53 years (*SD* = 8.29; *IQR* = 10; Range: 31-75;

48/234 (21%) female, 185/234 (79%) male, 1/234 (0%) missing). Further sample characteristics are listed in Supplement B.

- Insert Figure 1 about here -

Physicians' experiences with the transparency database

Of the 234 participants, 87 (37%) stated they had not looked at the database, and 131 (56%) reported to have at least somewhat followed media coverage about the database. Most participants said they did not know whether their payments had been correctly reported: Of 189 participants who agreed to disclose payments in 2015, 91 (48%) did not know; 70 (37%) said their payments had been correctly reported, and 24 (13%) said they had been incorrectly reported. Of 192 participants who agreed to disclose payments in 2016, 105 (55%) did not know, 60 (31%) said their payments had been correctly reported and 23 (13%) said they had been incorrectly reported. Most participants stated they had not received any reactions from patients (190/234, 81%), colleagues (128/234, 55%) or the private environment (153/234, 65%). Response rates for items of content and pleasantness of reactions were between 26% (60/234, pleasantness of patients' reactions) and 48% (113/234, content of colleagues' reactions). See Figure 2 for detailed results.

- insert Figure 2 about here -

Descriptive norm

For investigating how high participants estimated the percentage of German physicians who disclosed in the database in 2015 and 2016, data were available from 216 and 218 participants and ranged between 0% and 100%. For 2015, participants estimated on average that 33% of German physicians had agreed to disclose (*SD* = 21, *Mdn* = 30, *IQR* = 30) and for 2016, participants estimated on average that 31% of German physicians agreed to disclose (*SD* = 20, *Mdn* = 25, *IQR* = 25).

Investigating non-disclosure

To answer research question 1, we investigated data of those participants who disclosed in 2015 (groups 1, 3; *n* = 189) to predict whether they disclosed again in 2016 (group 3; *n* = 147) or did not disclose again in 2016 (group 1; *n* = 42). Neither regression model 1 with the three predictor variables X1: pleasantness of reactions, X2: descriptive

norm and X3: attitude significantly improved the model fit compared to the null model ($\chi 2$ = 1.0, p = .792) nor regression model 2, in which the interaction terms X3*X2 and X3*X1 were added ($\chi 2$ = 12.66, p = .027). A more detailed description of regression model 1 and 2 can be seen in Supplement C.

We additionally explored the reasons for participants' non-disclosure in general. In our sample, two groups did not disclose payments in one year: Participants of group 1 had an entry in 2015 but not in 2016 (n = 42), and participants of group 2 had no entry in 2015 but in 2016 (n = 45). We asked these participants for the reason for the missing entry (Table 2). The most frequently chosen reason in group 1 was that they had consciously decided against disclosure (50%, vs. 18% in group 2). The most frequently chosen answer in group 2 was that they were not asked for their consent to disclose (36%, vs. 7% in group 1). We further asked how several statements applied to the participants in case they consciously decided against disclosure. Most participants reported that considerations of public opinion or media reporting led to the decision against disclosure (25/32, 78%) (Figure 3).

Table 2
Reasons for Non-disclosure

	group 1	**group 2**
You don't have an entry in the year 2015 (2016). Why?	***abs. frequency (%)***	***abs. frequency (%)***
I have not received any payments.	14/42 (33%)	10/45 (22%)
I was not asked for my consent to disclose.	3/42 (7%)	16/45 (36%)
I forgot to answer the inquiry for disclosure consent.	1/42 (2%)	2/45 (4%)
I consciously decided against disclosure.	21/42 (50%)	8/45 (18%)
No reply	3/42 (7%)	9/45 (20%)

Note. Participants were asked to choose one of the four options. Group 1 = disclosure in 2015, but not in 2016; group 2 = no disclosure in 2015, but in 2016.

- insert Figure 3 about here -

Year of disclosure

To investigate research questions 2 and 3, we compared the frequency and content of reactions to participants who disclosed for the first time in 2015 (groups 1, 3) with data of participants who disclosed for the first time in 2016 (group 2). Data for frequency of reactions were available for 2015 from 187/198 (99%) and for 2016 from 44/45 (98%) participants; data for content of reactions were available for 2015 from 110/198 (60%) and for 2016 from 19/45 (42%) participants. All variables were significantly non-normal (all W = 0.71-0.90, all p <.01). Testing hypothesis 2, we found no statistically significant difference between frequency of reactions 2015 and 2016 (2015: M = 1.54, SD = 0.66, Mdn = 1.33, IQR = 1; and 2016: M = 1.36, SD = 0.53, Mdn = 1.00, IQR = 0.67), as evidenced by a Wilcoxon rank-sum test (W = 3410, r_b = -.17, 95% CI [-∞, -0.01], p = .031). Testing hypothesis 3, we found no statistically significant difference between negativity of reactions 2015 and 2016 (2015: M = 2.69, SD = 0.71, Mdn = 3.00, IQR = 1; and 2016: M = 2.96, SD = 0.67, Mdn = 3.00, IQR = 0.33), as indicated by a Wilcoxon rank-sum test (W = 1243, r_b =.19; 95% CI [-0.05, ∞], p = .085).

Further exploratory investigations

Participants were asked to indicate their agreement with statements about attitude towards disclosure in general and in research. The statements that participants agreed with most strongly were that disclosure of payments should be more nuanced, that the undifferentiated display of the disclosures brings science into disrepute and that disclosure leads to a wrong impression in the public (Table 3).

Table 3

Attitudes towards Transparency.

	n	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Payments by pharmaceutical companies are a risk for the independence of clinical practice and research.	233	26/233 (11%)	41/233 (18%)	35/233 (15%)	90/233 (39%)	41/233 (18%)
In principle, I approve of transparency.	233	4/233 (2%)	3/233 (1%)	16/233 (7%)	39/233 (17%)	171/233 (73%)
Collaboration with pharmaceutical companies and receiving payments by those companies is part of the medical profession.	233	19/230 (8%)	35/230 (15%)	66/230 (28%)	71/230 (31%)	39/230 (17%)
Disclosure of payments should be more nuanced.	233	8/233 (3%)	2/233 (3%)	43/233 (18%)	51/233 (22%)	124/230 (53%)
Disclosure of payments increases patients' trust in me.	230	72/233 (31%)	45/233 (19%)	75/233 (32%)	32/233 (14%)	9/233 (4%)
Disclosure leads to a wrong impression in the public.	233	9/233 (4%)	24/233 (10%)	31/233 (13%)	78/233 (33%)	91/233 (39%)
In case you are working in research:						
Transparency guidelines impede my scientific work.	154	45/154 (29%)	40/154 (26%)	29/154 (19%)	32/154 (21%)	8/154 (5%)
I have been confronted with disclosures within the context of a published study at least once.	154	56/154 (36%)	17/154 (11%)	22/154 (14%)	24/154 (16%)	35/154 (23%)
My research results were criticized because of my disclosures at least once.	152	119/152 (78%)	11/152 (7%)	13/152 (9%)	5/152 (3%)	4/152 (3%)
The undifferentiated displaying of the disclosures brings science into disrepute.	155	10/155 (6%)	5/155 (3%)	16/155 (10%)	37/155 (24%)	87/155 (56%)

Sixty-eight participants answered the question “Was there anything that bothered you about the reactions?”. The content categories with respective frequencies are:

- negative media reporting (20/68, 29%)
- defamation / criminalization (17/68, 25%)
- unknown cases of undisclosed information (12/68, 18%)
- disclosed information is not put into context with services rendered in return (12/68, 18%)
- misleading data representation (7/68, 10%)
- contacted by lawyer who aimed a class action against CORRECTIV (7/68, 10%)
- feeling of being dragged into the public eye (5/68, 7%)
- feeling of being treated unfairly (5/68, 7%)
- involvement of employer (4/68, 6%)
- others expressed lack of understanding (2/68, 3%).

DISCUSSION

Principal findings

The aim of this study was to gain insight into physicians’ attitudes towards and experiences with the voluntary German transparency regulation. Research question 1 aimed to investigate how these experiences affect future disclosure behaviour, but no significant prediction model was found. Research questions 2 and 3 aimed to investigate whether reactions to disclosures between the first and the second year of the database differed. No significant difference in the frequency or content reactions was found on the alpha level of .01, which might be related to the fact that most participants in our sample had not received any reactions towards their disclosure. The fewest reactions came from patients. Only every fifth physician stated they had received at least “very few” reactions by patients.

We observed that the reasons for non-disclosure in our sample differed depending on the time point of non-disclosure: Participants who had disclosed in the first but not in the second year more often said they had consciously decided against disclosure than those who had not disclosed in the first year but in the second year. The latter more often said that they had not been asked for consent by the respective pharmaceutical company. Most physicians who had consciously decided against disclosure said it was because of public opinion and media reporting. We also found that nearly half of the participating physicians had not looked at the database and did not know whether their disclosed payment sum was correct. However, more than half of them at least somewhat followed the media coverage

about the database and some reported high objections to public exposure. This can be interpreted according to the spotlight effect which describes that people overestimate the attention they receive by others.[16] Several participants stated concerns about the public opinion and a feeling about being denunciated, which is in line with the observation that physicians are concerned that COI disclosure may damage their reputation.[17] This tendency relates to the psychological heuristic that people do not like to be viewed as biased. Studies show that if people are able to avoid COI, they may be motivated to avoid such conflicts so that they can disclose the absence of conflicts.[34] In case of voluntary disclosure, however, people can simply avoid being viewed as biased by deciding against disclosure.

Strengths and weaknesses

The strength of this study is that it provides quantitative and qualitative data on physicians' experiences with COI disclosure in a national database. To our knowledge, no such evidence exists for any European transparency regulation in medicine. The investigated sample was stratified to their disclosing behaviour. Due to the otherwise random selection of participants, our sample comprises a great bandwidth of age, disciplines, and workplaces. The study, however, also has several limitations. A common problem in survey methods, answers may be skewed by social desirability.[35] The answers to a controversially discussed subject may be even more skewed: Physicians may be more motivated to respond to the survey if they have strong opinions on transparency, or if they experienced extreme reactions towards their disclosure. We tried to counter this by our efforts to increase the response rate. Additionally, the questionnaire we used was only constructed for this study, so our data cannot be directly compared to other data.

Meaning of the study

Physicians in our sample reported to be concerned about reputational damage and public exposure. Those who did not disclose payments had various reasons. Mandatory transparency could approach these issues: Firstly, if disclosure is mandatory, it will no longer feel "unfair" that some disclose information and some hide this information. Secondly, if conducted in a standardized form, everyone's information is available, and therefore the disclosed information is easier to compare and better to interpret, which will lessen the risk of unfair reputational damage and might enable a fair discussion between pharmaceutical companies, physicians, researchers, and the public.

Currently, the consent rate to disclose payments by pharmaceutical companies in Germany is low, compared to other countries.[12,13] In our study we observed that even if

physicians consented to disclosure, our participants mainly appear not to have used the database nor checked their entries. Therefore, we propose that disclosers need to be educated about the background of transparency regulations and the concept of COI to raise commitment.

For the management of financial COI in medicine, transparency is by now seen as a necessary, but not sufficient, measure.[7,10,36] Managing the influence of COI involves further higher action, e.g. people with relevant COI being excluded from guideline development groups.[1,36] Voluntary transparency regulations do not serve this aim, but may paint a distorted picture of the actual situation. The voluntary database investigated in this study is a good example: Only 24% of HCPs decided to disclose information about pharmaceutical payments in 2016, [13] which means that the publicly visible amount of payments and number of HCPs who receive payments very probably greatly underestimates the actual amount of payments and the actual number of HCPs. Voluntary transparency regulations may fuel discussion and raise awareness for the interaction of pharmaceutical companies with HCPs, however this may backfire if information is not contextualized, and the regulation is not driven forward.

Unanswered questions and future research

In this sample, reasons for non-disclosure were heterogeneous. More research is needed about the motives for and against voluntary disclosure to improve current transparency policies. Our data show that there are more issues that need to be considered about the experiences with transparency guidelines, such as the fear of reputational damage. Broad evaluations of transparency guidelines including all involved persons are needed to get a full picture of the current situation.

CONCLUSION

The study at hand was the first survey of physicians who disclosed voluntarily in a nation-wide transparency database. We found no significant predictors for future disclosure behaviour and no statistically significant difference in the reactions to disclosures between the first year and the second year of the database. The exploratory results of this study show preliminary evidence that although German HCPs experienced only few reactions by patients, colleagues or in private, they are concerned that disclosing payments in a public database will result in reputational damage. Considering public opinion and media exposure was the most frequent reason for non-disclosure in this subsample. We propose that

mandatory disclosure could be a solution to this problem by creating a standardized environment for an open discussion.

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Note: This paper contains extended passages from the dissertation by Marlene Stoll [29].

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REFERENCES

1. Institute of Medicine Committee on Conflict of Interest in Medical Research. 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; 2009.
2. Chimonas S, Mammor M, Zimbalist S, Barrow B, Bach PB, Korenstein D. BMJ. 2021 Nov 3; 375:e066576
3. Lundh A, Lexchin J, Mintzes B, et al. Industry sponsorship and research outcome: systematic review with meta-analysis. Intensive Care Med. 2018 Oct 1;44(10):1603–12 https://doi.org/10.1007/s00134-018-5293-7.
4. Mitchell AP, Trivedi NU, Gennarelli RL, et al. Are Financial Payments From the Pharmaceutical Industry Associated With Physician Prescribing? Ann Intern Med. 2021 Mar 16;174(3):353–61 https://doi.org/10.7326/M20-5665.
5. Nejstgaard CH, Bero L, Hróbjartsson A, et al. Association between conflicts of interest and favourable recommendations in clinical guidelines, advisory committee reports, opinion pieces, and narrative reviews: systematic review. BMJ. 2020 Dec 9;371:m4234 https://doi.org/10.1136/bmj.m4234.
6. Thompson D. Understanding financial conflicts of interest. N Engl J Med. 1993.
7. Fabbri A, Santos A, 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 Mar 14;7(6):504–9 https://doi.org/10.15171/ijhpm.2018.20.
8. 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 May 1;122(5):509–18 https://doi.org/10.1016/j.healthpol.2018.03.015.
9. 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
10. Bradley SH, DeVito NJ, Lloyd K, Richards GC, Rombey T, Wayant C, Gill PJ. Reducing bias and improving transparency in medical research: a critical overview of the problems, progress and suggested next steps. J R Soc Med. 2020 Nov 1;113(11):433-443. https://doi.org/10.1177/0141076820956799
11. Open Payments [Website]. Available from: https://www.cms.gov/openpayments (accessed 19 Nov 2021).
12. Mulinari S, Martinon L, Jachiet P-A, et al. Pharmaceutical industry self-regulation and non-transparency: country and company level analysis of payments to healthcare professionals in seven European countries. Health Policy. 2021 Jul 1;125(7):915–22 https://doi.org/10.1016/j.healthpol.2021.04.015.
13. 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 Sep 1;10(9):e037395 http://dx.doi.org/10.1136/bmjopen-2020-037395.

14. Loewenstein G, Sah S, Cain DM. The Unintended Consequences of Conflict of Interest Disclosure. JAMA. 2012 Feb 15;307(7):669–70 https://doi.org/10.1001/jama.2012.154.
15. Sah S, Loewenstein G, Cain DM. Insinuation Anxiety: Concern That Advice Rejection Will Signal Distrust After Conflict of Interest Disclosures. Pers Soc Psychol Bull. 2019;45(7);1099-1112 https://doi.org/10.1177/0146167218805991.
16. Loewenstein G, Sunstein CR, Golman R. Disclosure: Psychology Changes Everything. Annu Rev Econ. 2014;6:391–419 https://doi.org/10.1146/annurev-economics-080213-041341.
17. Chimonas S, DeVito NJ, Rothman DJ. Bringing Transparency to Medicine: Exploring Physicians' Views and Experiences of the Sunshine Act. Am J Bioeth. 2017 Jun 3;17(6):4–18 https://doi.org/10.1080/15265161.2017.1313334.
18. Boytchev WB. Warum Ärzte schweigen. 2016 Jul 17; Available from: https://correctiv.org/aktuelles/euros-fuer-aerzte/2016/07/17/warum-aerzte-schweigen (accessed 19 Nov 2021).
19. Licurse A, Barber E, Joffe S, Gross C. The impact of disclosing financial ties in research and clinical care: a systematic review. Arch Intern Med. 2010;170(8):675-82. https://doi.org/10.1001/archinternmed.2010.39
20. Riedl EM, König J, Koch C, Lieb K. Einstellungen und Erwartungen von Patienten in Bezug auf Interessenkonflikte ihrer behandelnden Ärzte. Z Evid Fortbild Qual Gesundheitswes. 2016 Jan 1;110-111;45-53 https://doi.org/10.1016/j.zefq.2015.12.002
21. Pham-Kanter G, Mello MM, Lehmann LS, et al. Public Awareness of and Contact With Physicians Who Receive Industry Payments: A National Survey. J Gen Intern Med. 2017 Jul 1;32(7):767–74 http://dx.doi.org/10.1007/s11606-017-4012-3.
22. Young PD, Xie D, Schmidt H. Towards Patient-Centered Conflicts of Interest Policy. Int J Health Policy Manag. 2017 Oct 29;7(2):112–9 https://dx.doi.org/10.15171%2Fijhpm.2017.128.
23. Chung A, Rimal RN. Social norms: a review. Rev Commun Res. 2016;4:1–28 https://doi.org/10.12840/issn.2255-4165.2016.04.01.008.
24. Lapinski MK, Rimal RN. An Explication of Social Norms. Commun Theory. 2005 May 1;15(2):127–47 https://doi.org/10.1111/j.1468-2885.2005.tb00329.x.
25. Freiwillig Selbstkontrolle für die Arzneimittelindustrie e.V. FSA-Transparenzkodex. 2019. Available from: https://www.fsa-pharma.de/de/kodizes/sk_fsa_transparenzkodex_13.03.2019.pdf (accessed 19 Nov 2021).
26. Richter, F. "Euros für Ärzte"-Datenbank beendet. 2021 Jan 14; Available from: https://correctiv.org/aktuelles/2021/01/14/euros-fuer-aerzte-datenbank-beendet/ (accessed 19 November 2021).

27. CORRECTIV. Euros für Ärzte. 2021. Available from: https://correctiv.org/aktuelles/euros-fuer-aerzte (accessed 19 November 2021).

28. Elmer C, Stotz P. Warum Ärzte schweigen. 2016 Jul 14; Available from: https://www.spiegel.de/gesundheit/diagnose/euros-fuer-aerzte-datenbank-wie-viel-hat-mein-arzt-bekommen-a-1102819.html (accessed 19 November 2021).

29. Stoll M. Unintended Consequences of Conflict of Interest Disclosure: a Psychological Perspective [Internet]. Johannes Gutenberg-Universität Mainz; 2021 [cited 2021 Jul 28]. Available from: https://openscience.ub.uni-mainz.de/handle/20.500.12030/5731

30. Green SB. How Many Subjects Does It Take To Do A Regression Analysis. Multivar Behav Res. 1991 Jul 1;26(3):499–510 https://doi.org/10.1207/s15327906mbr2603_7.

31. Mayring P. Qualitative content analysis: theoretical foundation, basic procedures and software solutions [Internet]. Social Science Open Access Repository; 2014 [cited 2021 Nov 19]. Available from: https://nbn-resolving.org/urn:nbn:de:0168-ssoar-395173

32. JASP Team. JASP (Version 0.10.2). 2019.

33. R Core Team. R: A Language and Environment for Statistical Computing. 2019. Available from: https://www.R-project.org

34. Sah S, Loewenstein G. Nothing to Declare: Mandatory and Voluntary Disclosure Leads Advisors to Avoid Conflicts of Interest. Psychol Sci. 2014;25(2):575-584 https://doi.org/10.1177%2F0956797613511824.

35. Barclay S, Todd C, Finlay I, et al. Not another questionnaire! Maximizing the response rate, predicting non-response and assessing non-response bias in postal questionnaire studies of GPs. Fam Pract. 2002 Feb 1;19(1):105–11 https://doi.org/10.1093/fampra/19.1.105.

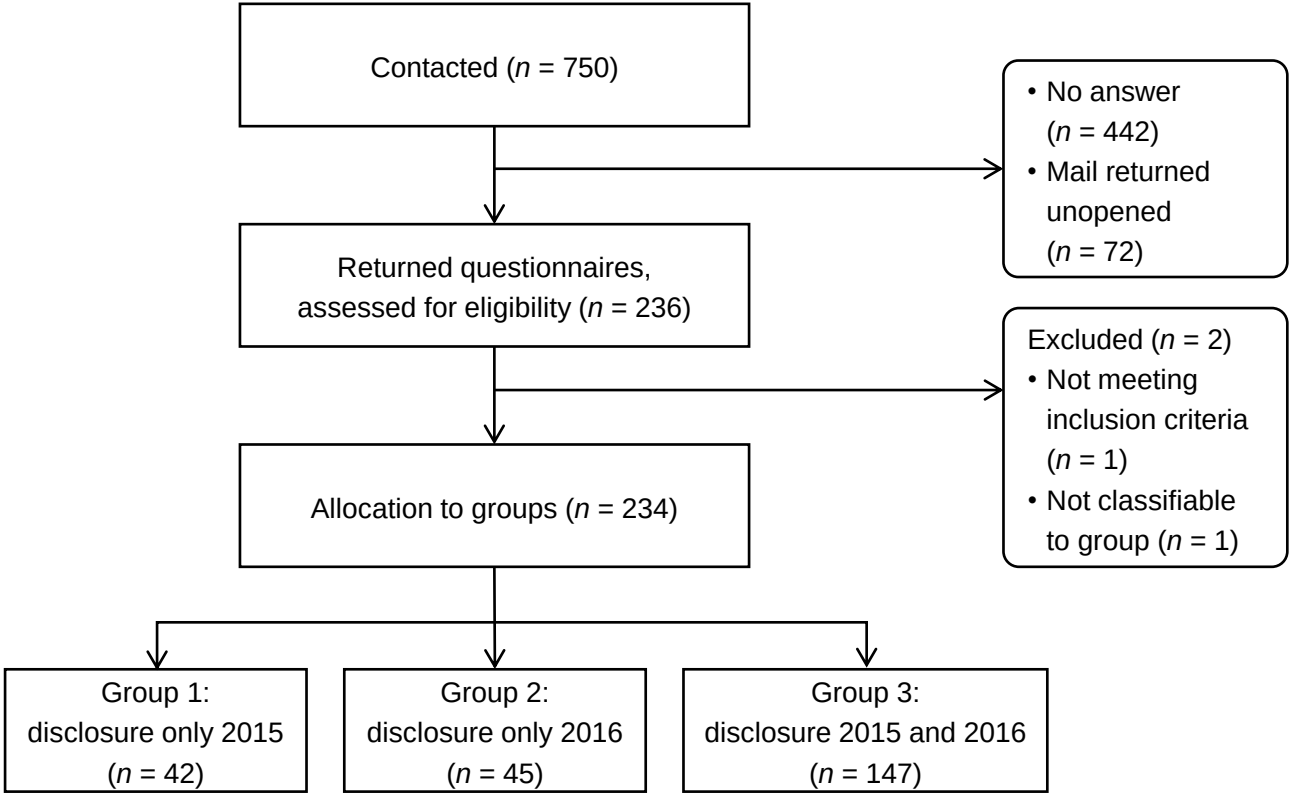
36. Lexchin J, Fugh-Berman A. A Ray of Sunshine: Transparency in Physician-Industry Relationships is not Enough. J Gen Intern Med. 2021 Oct 1;36(10):3194-3198 https://doi.org/10.1007/s11606-021-06657-0

Figures

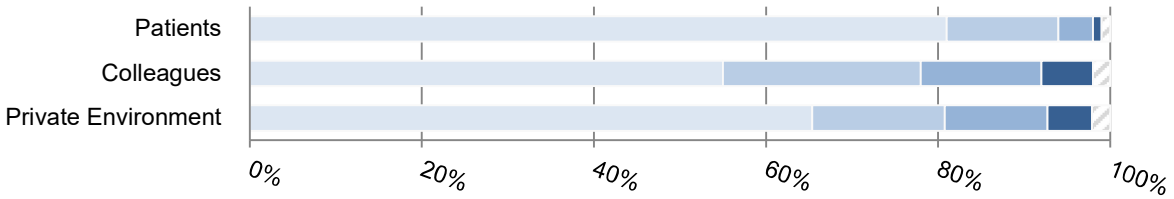
Figure 1. Participant Flow Chart.

Figure 2. Relative Frequencies of Item Answers for Frequency, Content, and Pleasantness of Reactions from Recipients, N = 234.

Figure 3. Factors Considered for Decision Against Disclosure.

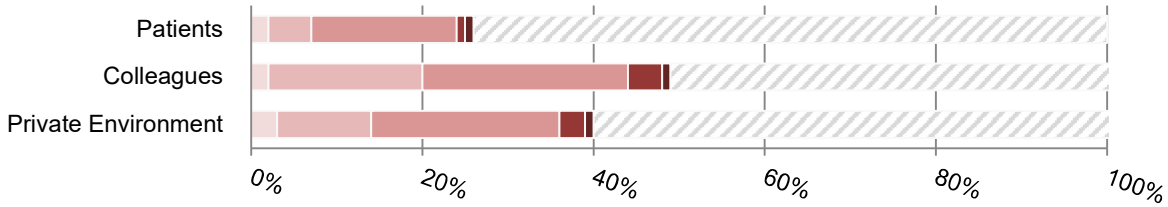

Contacted (n = 750)
• No answer (n = 442)
• Mail returned unopened (n = 72)
Returned questionnaires, assessed for eligibility (n = 236)
Excluded (n = 2)
• Not meeting inclusion criteria (n = 1)
• Not classifiable to group (n = 1)
Allocation to groups (n = 234)
Group 1: disclosure only 2015 (n = 42)
Group 2: disclosure only 2016 (n = 45)
Group 3: disclosure 2015 and 2016 (n = 147)

Frequency of Reactions



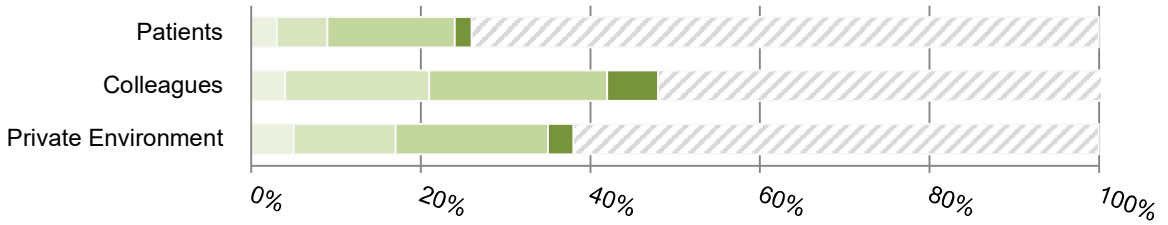
	Private Environment	Colleagues	Patients
none	65%	55%	81%
very few	15%	23%	13%
rather few	12%	14%	4%
rather many	5%	6%	1%
many	0%	0%	0%
NA	2%	2%	1%

Content of Reactions

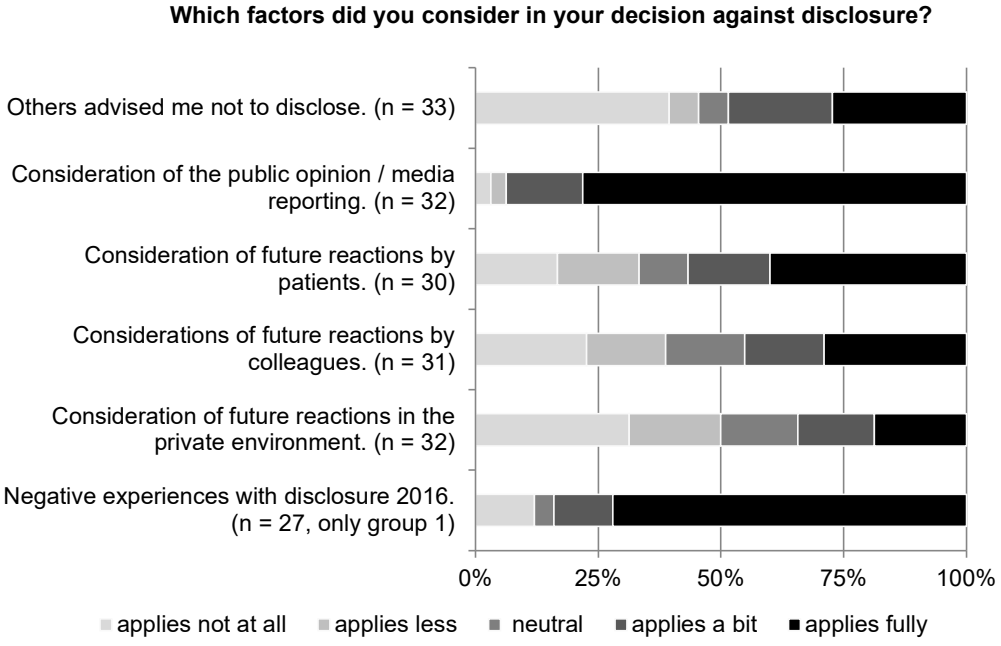


	Private Environment	Colleagues	Patients
very negative	3%	2%	2%
negative	11%	18%	5%
neutral	22%	24%	17%
positive	3%	4%	1%
very positive	1%	1%	1%
NA	61%	52%	74%

Pleasantness of Reactions



	Private Environment	Colleagues	Patients
very unpleasant	5%	4%	3%
rather unpleasant	12%	17%	6%
neutral	18%	21%	15%
rather pleasant	3%	6%	2%
very pleasant	0%	0%	0%
NA	62%	53%	74%



Supplement A
Translated Questionnaire (not formatted)

1) Discipline:
[open format]

2) Gender:
- ❑ male
- ❑ female

3) Age:
[open format]

4) Do you work in a hospital?
- ❑ yes, university hospital
- ❑ yes, non-university hospital
- ❑ no

5) If yes: Which position do you have?
- ❑ head
- ❑ senior
- ❑ resident

6) If no: How do you work?
- ❑ licensed
- ❑ employed
- ❑ other

7) How much of your working hours (in %) do you spend on patient care?
[open format]

8) How much of your working hours (in %) do you spend on research?
[open format]

9) Please tick every box that resembles a research area that you have been actively working in in the last five years (multiple responses are possible).
- ❑ non-interventional post-marketing studies
- ❑ clinical studies on behalf of pharmaceutical companies
- ❑ clinical studies investigated by yourself
- ❑ own, academical research
- ❑ other: _____
- ❑ I do not work in research.

10) What percentage of German physicians do you estimate consented to disclose in the database?

In 2016 for disclosure 2015: [open format]

In 2017 for disclosure 2016: [open format]

11) Do you know the actual percentage approximately, for example from the media?

2016:

- ❑ yes
- ❑ no

2017:

- ❑ yes
- ❑ no

12) Have your information about payments been correctly reported in the database? "Euros for Doctors"?

[groups 1, 3-5] In 2017 for 2016:

- ❑ yes
- ❑ no
- ❑ I don't know

[groups 2-5] In 2016 for 2015:

- ❑ yes
- ❑ no
- ❑ I don't know

13) In the summer of 2016, first data were disclosed in the database. How much do the following statements apply to you?

- I looked into the database.
- I followed media coverage about the database.
- I searched for persons in the database.

scale:

- ❑ applies not at all
- ❑ applies less
- ❑ neutral
- ❑ applies a bit
- ❑ applies fully

14) How high is the amount of money you disclosed, compared to the other disclosed payments?

- ❑ definitely below average
- ❑ somewhat below average
- ❑ average
- ❑ somewhat above average
- ❑ definitely above average

15. 1) [group 1, 3-5] You disclosed data in 2015. We are interested in how your environment reacted to this entry.
15.2) [group 2] You disclosed data in 2015. We are interested in how your environment reacted to this entry.

How many reactions did you get from …

- **patients?**
- **colleagues?**
- **your private environment?**

scale:

- ❑ none
- ❑ very few
- ❑ rather few
- ❑ rather many
- ❑ many

16) If there were reactions, how was their content? Reactions from …

- **patients**
- **colleagues**
- **your private environment**

scale:

- ❑ very negative
- ❑ somewhat negative
- ❑ neutral
- ❑ somewhat positive
- ❑ very positive

17) If there were reactions, how did you perceive them? Reactions from …

- **patients**
- **colleagues**
- **your private environment**

scale:

- ❑ very unpleasant
- ❑ rather unpleasant
- ❑ neutral
- ❑ rather pleasant
- ❑ very pleasant

18) Was there anything that bothered you about the reactions?
[open format]

19.1) [group 1] You do not have an entry in the database in the year 2016. Why?
19.2) [group 2] You do not have an entry in the database in the year 2015. Why?

- ❑ I have not received any payments.
- ❑ I was not asked for my consent to disclose.
- ❑ I forgot to answer the inquiry for disclosure consent.
- ❑ I consciously decided against disclosure.

20.1) [group 1] In case you decided consciously against disclosure: Which factors did you consider in your decision against disclosure?

- Others advised me not to disclose.
- Consideration of the public opinion / media reporting.
- Consideration of future reactions by patients.
- Consideration of future reactions by colleagues.
- Consideration of future reactions in the private surrounding.
- Negative experiences with disclosure 2015.

scale:

- ❑ applies not at all
- ❑ applies less
- ❑ neutral
- ❑ applies a bit
- ❑ applies fully

20.2) [group 2] In case you decided consciously against disclosure: Which factors did you consider in your decision against disclosure?

- Others advised me not to disclose.
- Consideration of the public opinion / media reporting.
- Consideration of future reactions by patients.
- Consideration of future reactions by colleagues.
- Consideration of future reactions in the private surrounding.

scale:

- ❑ applies not at all
- ❑ applies less
- ❑ neutral
- ❑ applies a bit
- ❑ applies fully

20.3) [groups 3-5] In 2016, you decided to disclose a second time. Please state how much the following statements apply to you.

- [groups 3-5] Coming to decision whether or not to disclose was easier for the second year than for the first year.
- [groups 4,5] My payments shifted because the opportunities by the pharmaceutical companies changed.
- [group 4] My payments shifted because I consciously accepted more money.
- [group 5] My payments shifted because I consciously accepted less money.

scale:

- ❑ applies not at all
- ❑ applies less
- ❑ neutral
- ❑ applies a bit
- ❑ applies fully

21) To what extent do you agree with the following statements:

- Payments by pharmaceutical companies are a risk for the independence of clinical practice and research.
- Disclosure of payments increases patients' trust in me.
- Receiving payments is fine if regulation measures (disclosure, exclusion from committees) are adopted.
- In principle, I approve of transparency.
- Disclosure leads to a wrong impression in the public.
- Collaboration with pharmaceutical companies and receiving payments by those companies is part of the medical profession.
- Some payments should be avoided, while others are indispensable.
- Without good alternatives in research and training, nothing about financial interactions in the medical sector will change.
- Disclosure of payments should be more nuanced.

In case you are working in research:

- Transparency guidelines impede my scientific work.
- I have been confronted with disclosures within the context of a published study at least once.
- My research results were criticized because of my disclosures at least once.
- If I do not cooperate with the industry, the research that is relevant for me lacks financial resources.
- The undifferentiated displaying of the disclosures brings science into disrepute.

scale:

- ❑ strongly disagree
- ❑ disagree
- ❑ neutral
- ❑ agree
- ❑ strongly agree

22) In your opinion: Disclosure of financial payments is more important in which area?

- ❑ definitely in patient care
- ❑ rather in patient care
- ❑ equally important
- ❑ rather in research
- ❑ definitely in research

Supplement B

Sample Characteristics

Characteristic		*n*	%
Gender	Female	48	21
	Male	185	79
	NA	1	0
Field	General and internal medicine	129	55
	Psychiatry, neurology and psychosomatics	33	14
	Surgery	31	13
	Other	38	16
Workplace	University hospital	67	29
	Non-university hospital	51	22
	Of which position: Head	*49*	*42*
	Senior	*53*	*19*
	Resident	*11*	*9*
	NA	*5*	*4*
	Practice	113	48
	Of which: Licensed	*104*	*92*
	Employed	*9*	*8*
	NA	3	1

Note. N= 234

Supplement C

Investigating non-disclosure, regression analysis.

To answer the first research question, we investigated data of those participants who disclosed in 2015 (n = 189) to predict whether they disclosed again in 2016 (n = 147, 78%) or did not disclose again in 2016 (n = 42, 22%). Response rate per item differed: For the items attitude, descriptive norm 2015, and pleasantness of reactions 2015, data were available from 188, 174, and 107 participants, respectively. For pleasantness of reactions 2015, we thus only had data of 22 people who did not disclose in 2016. All variables were significantly non-normal: all W = 0.52 - 0.92, all p < .01.

In regression model 1, the predictors were the three variables X1: pleasantness of reactions, X2: descriptive norm and X3: attitude. This model did not significantly improve the model fit compared to the null model, $\chi 2$ = 1.0, p = .792. Regression model 2 included the three variables as well as the interaction terms X3*X2 as well as X3*X1. This second model also did not significantly improve the model fit compared to the null model, $\chi 2$ = 12.66, p = .027. Effect sizes, pseudo-R^2-values and variance inflation factors (VIF) of regression model 1 and 2 can be seen in Table C1. The pseudo-R^2-values, being very low, indicate that this prediction model is of poor quality. We further explored the data by investigating whether participants who disclosed in 2016 had systematically different values on the main outcomes from the participants who did not disclose in 2016. Results from the performed Wilcoxon tests provided no indication for systematic differences between the groups (all p < .01).

Table C1

Logistic Regression Coefficients and Effect Sizes of Regression Model 1 and 2

	B (SE)	*p*	*OR*
Regression model 1: Only main effects			
Intercept	1.54 (0.28)	.000	4.66
Pleasantness of reactions	0.24 (0.27)	.373	1.27
Descriptive norm	0.13 (0.37)	.717	1.14
Attitude	-0.10 (0.32)	.753	0.90
Regression model 2: Main effects and interaction terms			
Intercept	2.31 (0.60)	.000	10.11
Pleasantness of reactions	0.61 (0.42)	.142	1.84
Descriptive norm	-0.06 (0.46)	.891	0.94
Attitude	-1.57 (1.08)	.145	0.21
Attitude*pleasantness of reactions	-1.27 (0.64)	.048	0.28
Attitude*descriptive norm	0.98 (0.67)	.140	2.67

Note. Model fit regression model 1: R^2 = .01 (Hosmer-Lemeshow), .01 (Cox-Snell), .02 (Nagelkerke); model 1 compared to null model: $\chi^2(3) = 1.04$, $p = .792$, all *VIF* < 10*;* Model fit regression model 2: R^2 = .01 (Hosmer-Lemeshow), .01 (Cox-Snell), .02 (Nagelkerke); model 2 compared to null model: $\chi^2(5) = 12.66$, $p = .027$; model 2 compared to model 1: $\chi^2(2) = 11.63$, $p = .003$, all *VIF* < 10.

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
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	4-6
Objectives	3	State specific objectives, including any pre-specified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	7-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7-9
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	7-8
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9
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	8-9, Supplement A
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	8

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
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	7, 10
		(b) Give reasons for non-participation at each stage	10
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10, Supplement B
		(b) Indicate number of participants with missing data for each variable of interest	10-14
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	10-11, Figure 2
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	11-13
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11-15
Discussion			
Key results	18	Summarise key results with reference to study objectives	15-16
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	16
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16-17
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	21

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.
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.