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Original article

What are the rates and validity of French authors' conflicts of interest disclosures in Orthopaedics & Traumatology: Surgery & Research? Analysis of the year 2017 with comparison versus the Transparence.sante.gouv.fr database

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Abstract

Introduction

Authors are responsible for their own Disclosure of Interests in submitting to Orthopaedics & Traumatology: Surgery & Research (OTSR). Disclosure may be incomplete or false, by deliberate or unintended omission. Omission may impact the analysis of results or at least the reader's perception of it. The rate of validity of disclosure in OTSR is not known, and we therefore conducted a bibliometric study on articles published in 2017, in order to: 1) determine the proportion of articles in

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which authors disclose interests, and 2), when interests are disclosed, to assess their validity by comparison against the Transparence.gov.fr database.

Hypothesis

Disclosure rates exceed 75%.

Material and Method

We analyzed all articles published in OTSR in 2017, and extracted those with at least one French author. We also analyzed data from the Transparence.gouv.fr corporate declaration database, for comparison with the authors' own disclosures in each article. Significant interest was defined by a €1,000 threshold, although higher thresholds (>€5,000, >€10,000 and >€100,000) were also investigated.

Results

In 2017, 337 articles were published in OTSR, 210 of which had at least 1 French author. Of these, 201 (95.7%) had at least 1 author with significant interest (>€1,000) according to the Transparence data. In 189 of these 201 articles (94%), authors had failed to disclose at least 1 direct or indirect conflict of interest. This omission rate fell to 22/45 (48.9%) for more substantial interests, which were more faithfully disclosed. At the €1,000 threshold, in only 8/201 articles (4%) did authors disclose all their interests with perfect validity, but this rate increased up to 25/45 (55.5%) at higher thresholds. At the €1,000 threshold, 66 of the 201 articles cited the trade-name of interest, resulting in 54/66 (82%) correct disclosure of direct interest; this rate increased up to 25/26 (96%) at higher thresholds.

Discussion

At a threshold of €1,000, the rate of complete and valid disclosure was 4% and the rate of omission 94%. At higher thresholds, rates were better, with just 48.9% omission and, above all, 55.5% validity,

even if these rates were lower than hypothesized (75%). Authors and editors need to take greater care. Disclosures were often made, but incompletely, and authors need reminding that they must disclose not only interests related to the article in question but also all interests that might directly or indirectly influence their interpretation of the results reported, allowing readers to make up their own minds.

Level of evidence: IV; systematic retrospective study

Keywords: conflicts of interest, bibliometrics, Orthopaedics & Traumatology: Surgery & Research

1. Introduction

Authors of scientific articles often receive perks of various sorts from industry: royalties, payments, consulting fees, or in kind. Orthopedic surgery, like most medico-surgical specialties, is no exception [1]. These relations could be a cause of confusion. The French Decree n°2020-730 of June 15, 2020 concerning remunerations by health product and service manufacturers or suppliers now defines a strict framework for relations between industry and health professionals. A decree of October 1, 2020 specified modalities and payment thresholds for contracts requiring either declaration or prior authorization from the health professional's official body [2]. What some consider an interest, others do not [3]. A relation of interest can bias the interpretation of scientific results [4–7], and this applies equally in orthopedics [8–10]. In France, since 2015, industry systematically declares the various sorts of payment and the information is available on a government website [11], to promote transparency (notably for patients), impartiality and proof of independence when publishing scientific reports , or at least to provide the reader with details of the relationship. Recent news stories show that this information is often taken up by the media, and that particular vigilance is therefore mandatory [12].

In the journal Orthopaedics & Traumatology: Surgery & Research (OTSR), disclosure of interest is the responsibility of the author when submitting for publication [13]. For this, each author uses the ICMJE (International Committee of Medical Journal Editors) declaration form, and the data are

summarized at the end of the article. This disclosure of interest might be incomplete or false, by deliberate or unintended omission. Such omission could bias the interpretation of the results, or at least the reader's perception [14]. As the rate of validity of the disclosures of interest in OTSR is not known, we conducted a bibliometric study on articles published in 2017, in order to: 1) determine the proportion of articles in which authors disclose interests, and 2), when interests are disclosed, to assess their validity by comparison against the Transparence.gov.fr database. The study hypothesis was that declaration rates exceed 75%.

2. Material and Methods

2.1 Material

We analyzed all articles published in OTSR in 2017 and extracted those with at least 1 French author. We also analyzed data on the www.transparence.sante.gouv.fr health industry transparency website of the French government for comparison with the disclosures of interest made by the authors of each article. Homonyms were searched for and grouped together manually. All analyses were made by 2 investigators (RE and TH), so as to double-check data, with discussion in case of disagreement (in 3 cases).

2.2 Methods

Authors were deemed to have made correct disclosure of direct interest (in direct relation with the article) when the disclosure included companies mentioned in the article that had declared annual sums of ≥€1,000€ on Transparence.gouv.fr. Indirect interest (no related to the article) was defined as payments exceeding €1,000€ but unrelated to any trade-name cited in the article. Sums received were assessed based on the Transparence.gouv.fr data. Authors' disclosures did not distinguish between monetary payments and payments in kind, and only the source was mentioned, without declaring the amounts. Classification in terms of perks, payment or contract was based on the

Transparence website's classification. We analyzed amounts received at the time of publication up to December 31, 2017, from January 1, 2015, the main study endpoint being sums received before the December 31, 2017 deadline.

We defined interests according to increasing payment thresholds: ≥€0, >€1,000, >€5,000, >€10,000 and >€100,000. These thresholds, going from very small to very considerable amounts, enabled analysis of whether disclosure validity was associated with the amount of payment. They corresponded to the thresholds reported in the Transparence database for each activity declared by a company; thus a given author could have different interests at different thresholds for a given company.

2.3 Statistics

Analyses used Stata v15 software (StataCorp, College Station, Texas, USA). Results were reported as number and percentage for qualitative and categoric variables and as mean ± standard deviation for continuous variables.

3. Results

The results flowchart is shown in figure 1. We studied 1,078 French authors in the 210 articles with ≥1 French author, for a mean 5.1 authors per article.

3.1 Qualitative assessment of articles

In cases of interest exceeding €1,000, distribution according to "perks, contracts, payments" showed predominance of perks, at 58% ± 26% of the total sum, compared to 25% ± 23% for payments and 17% ± 16% for contracts. In cases of omission of disclosure of interest exceeding €1,000, distribution was broadly similar: 67% ± 26%, 18% ± 20% and 16% ± 16%, respectively.

In 2017, 337 articles were published in OTSR, 210 (60.4%) of which had ≥1 French author. Eighty-two articles (39.0%) mentioned ≥1 laboratory or company (Figure 1). In the 210 articles, 1,078 relations of direct or indirect interest were identified on the Transparence.gouv.fr website: 847 (78.6%) ≥€0 (with

some interests disclosed for amounts corresponding to €0), 740 (68.6%) >€1,000, 461 (42.8%) >€5,000, 336 (31.2%) >€10,000 and 72 (6.7%) >€100,000.

Table 1 shows interests and their validity according to threshold. The greater the amount received, the better the validity. Small amounts, generally in the forms of perks, were poorly disclosed. A given author could have interests at different thresholds: e.g., an interest of €10 and another of €50,000: only the latter might be duly disclosed, and this author would then be classified with poor validity at the >€0 threshold and good validity at the €50,000 threshold. This helped reveal that larger interests were more willingly disclosed.

Two hundred and one of the 210 articles with ≥1 French author (95.7%) included ≥1 author with >€1,000 interests, but in 189 of these 201 articles (94%) authors had failed to disclose at least 1 relation of direct or indirect interest. At the €1,000 threshold, 66 of the 201 articles included a trade-name, with correct disclosure of a direct relationship in 54 cases (81.8%) (Table 1). Disclosure was valid for both direct and indirect interests in only 8 of the 201 articles (4%).

One hundred and seventy of the 210 articles with ≥1 French author (81.0%) included ≥1 author with >€5,000 interests, but in 142 of these 170 articles (83.5%) authors had failed to disclose at least 1 relation of direct or indirect interest (Table 1). At the €5,000 threshold, 63 of the 170 articles included a trade-name, with correct disclosure of a direct relationship in 57 cases (90%). Disclosure was valid for both direct and indirect interests in only 14 articles (8.2%)

One hundred and forty five of the 210 articles with ≥1 French author (69.0%) included ≥1 author with >€10,000 interests, but in 109 of these 145 articles (75.1%) disclosure was incomplete and authors had failed to disclose at least 1 relation of direct or indirect interest (Table 1). At the €10,000 threshold, 60 of the 145 articles included a trade-name, with correct disclosure of a direct relationship in 54 cases (90%). Disclosure was valid with respect to the Transparence data for both direct and indirect interests in only 20 articles (13.7%).

Forty five of the 210 articles with ≥1 French author (21.4%) articles included ≥1 author with >€100,000 interests, but in 22 of these (48.9%) disclosure was incomplete and authors had failed to disclose at least 1 relation of direct or indirect interest (Table 1). At the €100,000 threshold, 26 of the 45 articles included a trade-name, with correct disclosure of a direct relationship in 25 cases (96%). Disclosure was valid with respect to the Transparence data for both direct and indirect interests in only 25 articles (55.5%).

4. Discussion

With 94% non-disclosure of €1,000 amounts and a 4% validity rate, the disclosure and validity rates in OTSR were low, and the study hypothesis was not confirmed. At higher thresholds, however, rates were better, with only 48.9% non-disclosure and, above all, 55.5% overall validity and 96% validity for disclosure of direct interests. In 2019, the systematic use of the ICMJE form was made mandatory on the OTSR submissions website, which should improve these findings. Non-disclosure mainly concerned small sums, suggesting that authors receiving small amounts considered them negligible and/or without impact on their objectivity with respect to the company mentioned (for direct interest) or not mentioned in the article (indirect interest). Disclosure was much better for direct interests, with a rate of 82% at the €1,000 threshold and 96% at the highest threshold. However, the ICMJE rule is to disclose any direct or indirect relation of interest over the previous 36 months [15]. It should be borne in mind that surgeons do not necessarily check companies' declarations on the Transparence.gov.fr website, and that the system does not work in the same way as in other countries: the French system includes relations that would probably not be deemed significant in other health systems. Most non-disclosed interests concerned perks rather than direct payments. Under French law, any sum received must be declared. We set an arbitrary threshold of €1,000, but this cannot be recommended; we did so because many sums of just a few euros are declared on Transparence.gov.fr and usually concern presenting a product in exchange for a coffee or a sandwich. What disclosure threshold would be relevant for such a perk? Is it really worth mentioning a €15

meal in a disclosure of interest? On the other hand, any threshold would be open to dispute, and the ICMJE guidelines do not set any floor [15].

Sums were mainly quite small, but in some cases amounted to several hundred thousand euros. The largest undisclosed amount concerned a laboratory, with equipment mentioned in the article at a cost of €69,909, which ought to have been declared. These figures show that the amounts received by practitioners from industry in our profession are not negligible. Interest is not only financial: a dominant position in a scientific society, journal or public body are strong interests that should be disclosed. These points were not analyzed here as they are difficult to check, but it would have been useful to be able to take them into account.

The strong point of the present article was to study relations of interest specifically with regard to the trade-names mentioned in the articles, which is not usually done [1,4,5,8]: studies more often focus on relations of interest in general, rather than being specific to a given article. Publicizing data for conflicts of interest may seem like hanging out one's dirty washing and be badly received by both practitioners and the public, but it has the advantage of enabling comparison between journals, although it also facilitates media exposure.

Comparison with the literature reveals that disclosure rates in OTSR were relatively low. In 2020, Somersom et al. [16] reported >90% disclosure in the Journal of Shoulder and Elbow Surgery. Other journals find poorer rates, as in the present study. In 2021, Tisherman et al. [17] reported a disclosure rate of just 16.6% In Injury. In hand surgery, in 2020, Ross et al. [18] reported 58% non-disclosure in the American Journal of Hand Surgery. In spine surgery, in 2020, Tisherman et al. [19] reported 41% correct disclosure in Spine. Direct or indirect payments from industry are also found in the pharmaceutical sector [20] and for journal editors [21]. The authors themselves are often unaware of the possibility of checking their conflicts of interest via websites [22].

The International Committee of Medical Journal Editors (ICMJE) has put a new Word format conflicts of interest form on-line (http://www.icmje.org/downloads/coi_disclosure.docx), which does not so

clearly distinguish interests related or unrelated to the article being submitted; it is less precise in this respect than the previous form, in PDF format (http://www.icmje.org/downloads/coi_disclosure.zip), which is no longer accessible on the ICMJE website. The older form had the advantage of providing an automatic detailed summary of the author's interests in relation to the article. The OTSR editorial board decided to keep and promote the use of this older PDF form, which remains accessible on the OTSR website (https://www.em-consulte.com/getInfoProduit/OTSR/instructionsAuteurs/OTSR.pdf).

The present study had certain limitations. 1) Only 1 year was studied; other years could confirm the present findings and perhaps reveal progression. The study will therefore be updated in a few years to assess progression, especially since the ICMJE forms became mandatory on the OTSR submissions site in 2019. 2) The Transparence.gouv.fr website may not be exhaustive, so that certain conflicts of interest may have been overlooked, especially when surgeons use professional associations to receive payments from industry; but this was not feasibly quantifiable. Conversely, some amounts may be mistakenly declared on the Transparence website, as the surgeon's confirmation is not required. In the present study, all sums disclosed in the articles could be traced on the Transparence website, suggesting a certain exhaustiveness. On the other hand, there were many homonyms requiring considerable analysis ahead of data interpretation. Another website, Euros For Docs (https://www.eurosfordocs.fr/explore), also details conflicts of interest, but we did not make use of this as it is not an official site. Despite these limitations, the present study highlighted the importance of vigilance with respect to articles published in OTSR. This relies on the authors' honesty and care taken by the editorial board to check exhaustive disclosure. The present study did not assess the validity of the actual articles, and casts no aspersions on the quality of the studies published [23–26]: the spotlight was solely on disclosure of interest.

5. Conclusion

At the €1,000 threshold, the rate of complete and valid disclosure was 4% and the non-disclosure rate was 94%; at higher thresholds, rates were better, with only 48.9% non-disclosure and, above all, 55.5% validity, although these values were lower than the 75% hypothesized. Authors and editors need to take greater care. Disclosure is often made, but incompletely, and authors need reminding that they should disclose not only interests in relation to the article in question but also all direct and indirect interests liable to influence study results, allowing readers to make up their own minds.

Disclosure of interest: Roger Erivan received >€1,000€ perks from Zimmer and Depuy for registration fees and accommodation for congresses. Stéphane Boisgard is a consultant for Zimmer, without relation to the present study, and received >€1,000 for registration fees, travel and accommodation for congresses. Stéphane Descamps is a consultant for SERF, EUROS and Depuy, without relation to the present study, and received >€1,000 from Zimmer, Domortho and Mathys for registration fees, travel and accommodation for congresses. Guillaume Villatte was a consultant for FH Orthopedics without relation to the present study, and received >€1,000 from Biomet et Depuy for registration fees and accommodation for congresses. Julien Dartus received >€1,000 perks from Orthofix for registration fees and accommodation for congresses; other payments and perks were <€1,000. Thomas Hacquart received >€1,000 perks from Leo Pharma for registration fees and accommodation for congresses; other payments and perks were <€1,000.

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Author contributions: Roger Erivan: study design, data collection, statistics, writing, re-editing. Thomas Hacquart: study design, data collection, statistics. Guillaume Villatte: study design, writing, re-editing. Julien Dartus: writing, re-editing. Stéphane Descamps: study design, re-editing. Stéphane Boisgard: study design, re-editing.

Figure legend

Figure 1: Flowchart

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Table 1: Authors' disclosures in OTSR in 2017 (only the 210 articles with at least 1 French author were analyzed).

Interest thresholds	**≥€0**	**>€1,000**	**>€5,000**	**>€10,000**	**>€100,000**
Total number of articles	337	337	337	337	337
Number of articles with at least 1 French author	210	210	210	210	210
Assessment of direct and indirect interest					
Number of articles with at least 1 relation of interest according to Transparence.gov.fr	206	201	170	145	45
Number of articles with at least 1 undisclosed interest that should have been disclosed	199/206 (96.6%)	189/201 (94.0%)	142/170 (83.5%)	109/145 (75.2%)	22/45 (48.9%)
Number of articles with partially disclosed interests	7/206 (3.4%)	12/201 (6.0%)	28/170 (16.5%)	49/145 (33.8%)	23/45 (51.1%)
Number of articles with at least 1 author fully disclosing interest at the various thresholds	0/206 (0%)	8/201 (4.0%)	14/170 (8.2%)	20/145 (13.7%)	25/45 (55.5%)
Assessment of direct interest					
Number of articles with at least 1 trade-name (laboratory, manufacturer) mentioned	66	66	63	60	26
Number of articles with authors with undisclosed direct interest in a trade-name mentioned in the article	NC	12/66 (18%)	6/63 (10%)	6/60 (10%)	1/26 (4%)
Number of articles with authors with correctly disclosed direct interest in a trade-name mentioned in the article	NC	54/66 (82%)	57/63 (90%)	54/60 (90%)	25/26 (96%)

NC: non-calculable. The thresholds are those of the Transparence.gov.fr for each activity declared by a company; thus a given author may have interests at more than one threshold with the same company.
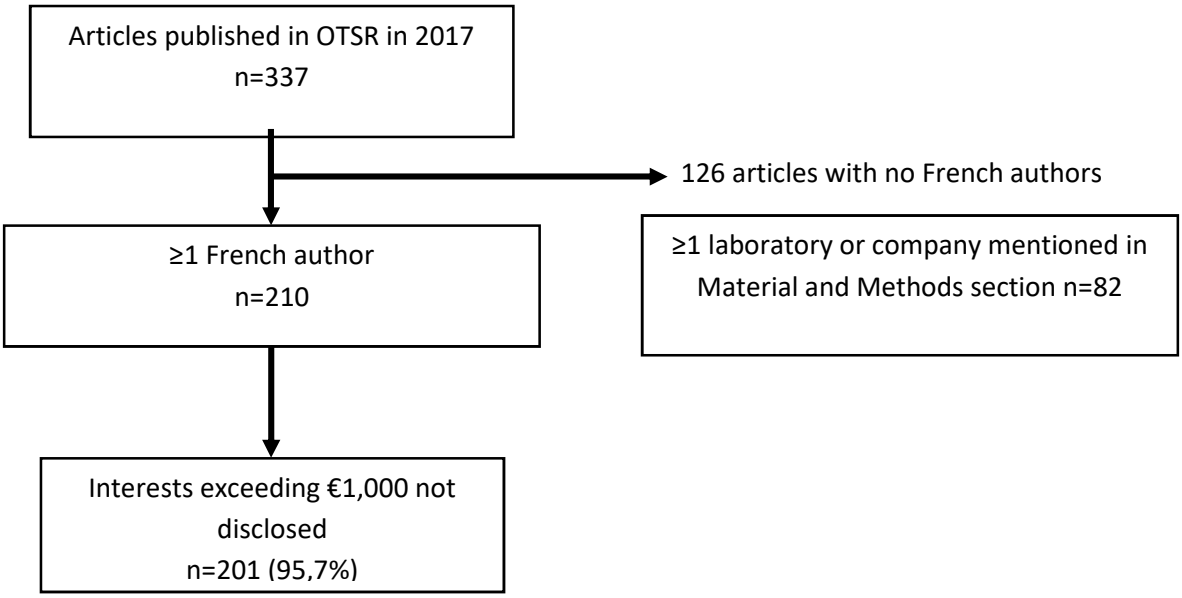
Figure 1: Flowchart