

The fallacy of science is science: the impact of conflict of interest in vaping articles

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ABSTRACT

Objective. To explore the association between reporting conflict of interest (COI) and having a positive outcome toward vaping in scientific articles.

Methods. A cross-sectional study that analyzed a sample of 697 articles published between 2017 and 2020 regarding vaping. Information on the reporting of COI, type of COI (no conflict, conflict with the tobacco industry, pharmaceutical industry, or other), and country of publication were collected. To explore the association between reporting COI and having a positive result for vaping, two logistic regression models were fitted, both adjusted by country of publication.

Results. From 88 articles that reported COI, 23 reported COI with the tobacco industry, 44 with the pharmaceutical industry, and 21 reported another type of conflict. We found that reporting any type of COI increased by 4.7 times the odds (OR 4.70; 95% CI [2.89, 7.65]) of having a positive result for vaping. Additionally, compared to other countries, manuscripts published in England had 2 times higher odds (OR 2.40; 95% CI [1.16, 4.98]) of reporting a positive result for vaping. Reporting COI with the tobacco and pharmaceutical industries increased the odds of favorable results by 29 times (OR 29.95; 95% CI [9.84, 90.98]) and 2 times (OR 2.87; 95% CI [1.45, 5.69]), respectively.

Conclusions. In scientific articles, reporting COI and having positive results for vaping are highly associated. COI should be considered and caution should be exercised when using data for policy-making.

Keywords

Conflict of interest; public health; electronic nicotine delivery systems; tobacco industry; policy making.

Nowadays, there is no doubt regarding the harms that tobacco poses to public health (1). Worldwide, there have been many global efforts to reduce tobacco consumption, led by the World Health Organization's Framework Convention on Tobacco Control (WHO-FCTC), proposed in 2005 and signed by 182 parties (2). Thanks to tireless efforts, tobacco consumption trends have decreased around the world (3), although the 30% reduction in the prevalence expected for 2025 may not be achieved (4). Recently, new products like heat-not-burn and vaping devices have emerged, posing a threat to the achievements made through the implementation of the WHO-FCTC

and the ongoing tobacco control policies, in addition to being a potential health risk for the population, especially vulnerable groups like children and youth (5).

These new products have been advertised as "harm reduction" and a powerful tool to help smokers quit tobacco (6, 7). Since their launch, a body of scientific evidence has risen in support of these devices, facilitating their commercialization in many countries (8). However, it is important to take a closer look at the evidence supporting these arguments, as the tobacco industry (TI) has a 44% market control in these new products (9). While some of the arguments have come from independent

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sources, others have originated due to sponsorship or ties with the TI, either directly or indirectly, and through TI-sponsored research groups such as the Foundation for a Smoke-Free World, which constitutes a conflict of interest (COI) (10). This and other TI activities to undermine or subvert tobacco control efforts have been around for a long time, and Article 5.3 of the WHO-FCTC has established clear guidelines to identify and manage TI interference (11).

COI is a set of conditions in which professional judgment concerning a primary interest (patient welfare or the validity of research) tends to be or appears to be unduly influenced by a secondary interest (financial or non-financial gain) (12). COI leads to the commercialization of science with serious secondary effects to public health, like the support for potentially harmful products in order to obtain funding, direct financial benefits, and/or public recognition. According to the TI, if the scientific method is correctly used, all results are equally valid, and their funding source or relationships of the researchers with the industry should not matter (13). However, the TI has historically used funds to stimulate scientific controversy about the health effects of their products by actively disqualifying and silencing researchers or funding their own research, preventing the advance of public health policies (11, 14). The aim of this study is to explore the association between reporting COI and having a positive outcome toward vaping.

MATERIALS AND METHODS

For this cross-sectional analysis, we used the information collected for the “ENDS Repository.” The ENDS Repository is a study that consisted of a search of all the available scientific evidence from national and international observational studies focused on electronic nicotine delivery systems (ENDS) published from mid-2017 to the beginning of 2020. More details on the ENDS Repository have been published elsewhere (15). The initial sample of the ENDS Repository was 700 articles; however, 3 articles were excluded because they did not meet the inclusion criteria. A total of 697 articles were included in the analysis, with diverse information on vaping, such as cessation, dual use, flavors, physical harm, marketing, social media, among others.

Outcome

The dependent variable was treated as a dichotomous variable that reflected the overall position of the article as positive or negative toward vaping. Those articles that recommended the use of vapers as cessation tools, as harm reduction devices, or with a general positive tone toward the use of vapers were classified as positive, while those that did not recommend or had a general negative tone were classified as negative. The information for this variable was retrieved from the results and discussion sections of the articles.

Exposures

Two variables were collected as main exposures; the first was the report of any type of COI as a dichotomous variable (yes/no). This variable was constructed using the information reported by the authors in the COI section of each manuscript, and it was collected for the first author, corresponding author,

and coauthors. If any of the authors reported COI, the article was considered as having COI, otherwise the article was considered as not having COI. The second exposure was a categorical variable of the type of COI reported, categorized as follows: (a) no conflict reported; (b) conflict with TI reported (including tobacco and vaping industry, and nongovernmental organizations financed by the TI); (c) conflict with the pharmaceutical industry; and (d) other (reported COI due to involvement in court cases or funding from health institutes).

Country of publication information was collected as covariate. It was categorized into four categories according to the highest number of publications, as: United States of America, England, Switzerland, and others that included various countries from all the regions.

Statistical analysis

Frequencies and percentages were calculated for the descriptive analysis. For the association analysis, two logistic regressions were fitted: (1) to estimate the association between having a positive result toward vaping and having reported COI; and (2) to estimate the association between a positive result toward vaping and the specific type of COI (with TI, pharmaceutical industry, or other COI). Both analyses were adjusted by country of publication. Statistical significance level was considered <0.05 . All analyses were performed using the statistical software Stata v.17 (16).

RESULTS

A total of 121 manuscripts had positive results for vaping, and 31.4% of those reported COI. From a total of 88 articles that reported COI, 23 reported COI with the TI, 44 with the pharmaceutical industry, and 21 reported another type of conflict. Most of the manuscripts reviewed were published in the United States of America, followed by England (Table 1).

Compared to those articles with no reported COI, those that reported any COI had 4 times (odds ratio [OR] 4.70; 95% CI [2.89, 7.65]) higher odds of having a favorable result for vaping. Manuscripts published in England had 2 times (OR 2.40 95% CI [1.16, 4.98]) higher odds of presenting a favorable result, compared to manuscripts published in other countries (Table 2).

Compared to those articles with no reported COI, those that reported having COI with the TI had 29 times higher odds (OR 29.95; 95% CI [9.84, 90.98]) of having a positive result for vaping, while those with COI with the pharmaceutical industry had 2 times (OR 2.87; 95% CI [1.45, 5.69]) higher odds of having a favorable result. In this model, being published in England had also 2 times (OR 2.48; 95% CI [1.17, 5.27]) higher odds of presenting a favorable result, compared to manuscripts published in other countries (Table 3).

DISCUSSION

COI is not solely financial, it can also be professional, personal, political, or legal, and it can compromise the integrity of the research, undermine the trust in science, and affect the decision-making process (17). From a total of 697 articles, 88 reported COI, most of them with pharmaceutical companies ($n = 44$) and TI ($n = 23$), and 30.1% of them favored vaping. In general, studies have shown that there is a strong positive

TABLE 1. Description of the sample by negative or positive stance toward vaping (n = 697)

	Negative (%) (n = 576)	Positive (%) (n = 121)
Conflict of interest		
No	91.3	68.6
Yes	8.7	31.4
Type of conflict reported		
No conflict reported	91.3	68.6
With tobacco industry	0.7	15.7
Pharmaceutical	5.2	11.6
Other*	2.8	4.1
Country of publication		
United States of America	57.8	52.1
England	20.3	30.6
Switzerland	5.6	7.4
Netherlands	5.6	3.3
Other**	10.7	6.6

Notes: * Includes funding from national health institutes, trials involvement, or journals.
****** Includes: Australia, Argentina, Brazil, Belgium, Canada, China, France, Germany, Greece, Hungary, Ireland, Israel, Japan, Republic of Korea, Mexico, Poland, Spain, and Thailand.
Source: Table prepared by the authors based on published data.

TABLE 2. Association between having a reported conflict of interest and a positive result toward vaping (n = 697)

	OR (95% CI)	p-value
Conflict of interest (reported)		
No	Reference	
Yes	4.70 (2.89, 7.65)	<0.001
Country of publication		
Others*	Reference	
United States of America	1.53 (0.78, 3.01)	0.349
England	2.40 (1.16, 4.98)	0.017
Switzerland	1.87 (0.69, 5.04)	0.218

Notes: OR, odds ratio; bold type indicates statistical significance.
***** Australia, Argentina, Brazil, Belgium, Canada, China, France, Germany, Greece, Hungary, Ireland, Israel, Japan, Republic of Korea, Mexico, Netherlands, Poland, Spain, and Thailand.
Source: Table prepared by the authors based on published data.

correlation between the source of funding and the results of research (17). Our results showed 4 times higher probability of having positive results toward vaping if the articles reported any COI. This is not surprising, as industry-sponsored studies tend to be biased in favor of the sponsor’s products (10). The bias generated by the COI may affect the research from the design to the reporting of results, sometimes even bending or breaking the rules of science to suit their purposes (17).

The TI has a long history of misleading the public about the risks associated with its products (18). Nowadays, the TI has a large body of evidence that supports its claims regarding the alleged lower harm of vaping and other new tobacco products (19). However, much of this evidence has been funded by the TI, either directly or indirectly through the Foundation for a Smoke-Free World, which despite the claims of independence by its founders, constitutes a clear COI as stated by the World Health Organization (10). Our results showed that articles that reported COI with the TI had 29 times higher probability of having positive results toward vaping. The latter has enormous implications for public health, as the TI is used to interfering with tobacco control by political lobbying, campaign contributions,

TABLE 3. Association between reporting a specific type of conflict of interest and a positive result toward vaping (n = 697)

	OR (95% CI)	p-value
Type of conflict of interest reported		
No conflict reported	Reference	
With tobacco industry	29.95 (9.84, 90.98)	<0.001
Pharmaceutical	2.87 (1.45, 5.69)	0.002
Other*	1.90 (0.67, 5.40)	0.225
Country of publication		
Others**	Reference	
United States of America	1.55 (0.77, 3.14)	0.217
England	2.48 (1.17, 5.27)	0.018
Switzerland	1.94 (0.69, 5.45)	0.204

Notes: OR, odds ratio; bold type indicates statistical significance.
***** Includes funding from national health institutes, trials involvement, or journals.
****** Australia, Argentina, Brazil, Belgium, Canada, China, France, Germany, Greece, Hungary, Ireland, Israel, Japan, Republic of Korea, Mexico, Netherlands, Poland, Spain, and Thailand.
Source: Table prepared by the authors based on published data.

or the financing of research (20), causing laws and regulations to be delayed, withdrawn, or not even voted on.

Nowadays, England has one of the most comprehensive smoking regulations, including—but not limited to—smoke-free places, plain packaging, health warnings, and cessation aid programs (21). Around 2007, the Royal College of Physicians issued a report that advocated for alternative sources of medicinal nicotine available to smokers (22). Since then, e-cigarettes have become part of their smoking reduction strategy, and Public Health England has recommended these as a cessation tool (23). Public Health England has reported that e-cigarettes are currently the most popular cessation aid, even surpassing nicotine replacement therapy (27.2% vs 18.7%) (24). This could be an explanation why those manuscripts published in England had increased odds of being favorable toward vaping, as this supports the current policy. Nevertheless, it is important to notice that the risk reduction and e-cigarette cessation programs are part of a larger effort, based on the MPOWER measures.

This study has limitations that must be mentioned. First, only self-reported COI was evaluated, meaning that those manuscripts which failed to declare COI despite the existence of one were misclassified. However, this would only lead to an underestimation of our estimates. Second, the analytical time frame covers only mid-2017 to the start of 2020, leaving out most of the evidence regarding the use of ENDS and COVID-19—a period in which the TI funded a large amount of research. Third, due to the limited variability of the sample, we had low statistical power, which contributed to wide confidence intervals in our estimates. Finally, this was a cross-sectional study, therefore causality cannot be established. Nevertheless, to our knowledge this is the first study to explore the association between reporting COI and presenting positive results for the use of e-cigarettes. It contributes to the development of a line of research and the start of a conversation on the importance of COI and its possible effect on results.

In all settings, COI can have serious consequences; however, when it comes to research and public health it can affect millions of lives. There are still many unknowns about vaping and its potential harms; however, the research needed to fill the gaps should not be funded or linked to the TI. As stipulated in the guidelines of Article 5.3 of WHO-FCTC, there is an

irreconcilable conflict between the TI and public health interests, and those working with the TI should be accountable and transparent. Regarding tobacco and its new products, there is a need to be aware and analyze who is presenting the information and what possible interests they may have; keeping in mind that the industry is not going to be neutral when it comes to their own products. Research must adhere to ethical principles from funding to publication, especially if it is involved in public health regulations. When presenting or using evidence, researchers, stakeholders, legislators, and any other person involved in the decision-making process, must ensure that the evidence presented is independent and free from COI. Further research on the implications of COI and strict regulations should be considered in scientific research.

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La falacia de la ciencia es la ciencia: el efecto del conflicto de intereses en los artículos sobre el vapeo

RESUMEN

Objetivo. Explorar la relación entre notificar la existencia de conflictos de intereses y tener un resultado positivo con respecto al vapeo en los artículos científicos.

Métodos. Se realizó un estudio transversal que analizó una muestra de 697 artículos sobre vapeo publicados entre 2017 y 2020. Se recopiló información sobre la notificación de la existencia de conflictos de intereses, los tipos de conflicto (sin conflicto o conflicto con la industria tabacalera, con la industria farmacéutica o con otras industrias) y el país de publicación. Para explorar la relación entre notificar la existencia de conflictos de intereses y tener un resultado positivo respecto del vapeo, se adaptaron dos modelos de regresión logística, y ambos se ajustaron por país de publicación.

Resultados. De los 88 artículos en los que se notificó la existencia de conflictos de intereses, 23 informaron sobre conflictos de intereses con la industria tabacalera, 44 sobre conflictos con la industria farmacéutica y 21 sobre otros tipos de conflicto. Se determinó que la notificación de cualquier tipo de conflicto de intereses incrementó en 4,7 veces las probabilidades (OR 4,70; IC del 95 % [2,89; 7,65]) de obtener un resultado positivo con respecto al vapeo. Además, en comparación con otros países, los artículos publicados en Inglaterra mostraron probabilidades 2 veces más altas (OR 2,40; IC del 95 % [1,16; 4,98]) de comunicar un resultado positivo respecto del vapeo. Informar sobre la existencia de conflictos de intereses con las industrias tabacalera y farmacéutica multiplicó las probabilidades de resultados favorables por 29 (OR 29,95; IC del 95 % [9,84; 90,98]) y por 2 (OR 2,87; IC del 95 % [1,45; 5,69]), respectivamente.

Conclusiones. En los artículos científicos, existe una clara relación entre notificar la existencia de conflictos de intereses y tener un resultado positivo con respecto al vapeo. Se debe considerar el conflicto de intereses y actuar con precaución al emplear estos datos para la formulación de políticas.

Palabras clave

Conflicto de intereses; salud pública; sistemas electrónicos de liberación de nicotina; industria del tabaco; formulación de políticas.

A falácia da ciência é ciência: o impacto do conflito de interesses em artigos sobre cigarros eletrônicos

RESUMO

Objetivo. Examinar a associação entre declarar conflitos de interesses e obter resultados favoráveis sobre os cigarros eletrônicos em artigos científicos.

Métodos. Estudo transversal que analisou uma amostra de 697 artigos sobre cigarros eletrônicos publicados entre 2017 e 2020. Foram coletadas informações sobre a declaração de conflito de interesses, tipo de conflito (ausência de conflito, conflito com a indústria tabagista ou farmacêutica, ou outras formas de conflito) e o país de publicação do estudo. Dois modelos de regressão logística foram criados, com ajuste por país de publicação, para examinar a associação entre declarar conflitos de interesses e obter resultados favoráveis para os cigarros eletrônicos.

Resultados. De 88 artigos que continham a declaração de conflitos de interesses, 23 informaram conflitos com a indústria tabagista, 44 com a indústria farmacêutica e 21 outras formas de conflito. Declarar qualquer tipo de conflito de interesses foi associado a uma probabilidade 4,7 vezes maior (OR 4,70; IC 95% [2,89, 7,65]) de obter resultados favoráveis aos cigarros eletrônicos. Quanto aos países de publicação, verificou-se uma probabilidade duas vezes maior de os artigos publicados na Inglaterra (OR 2,40; IC 95% [1,16, 4,98]) informarem resultados favoráveis para os cigarros eletrônicos. Quando se declarou o conflito de interesses com as indústrias tabagista e farmacêutica, a chance de resultados favoráveis nos estudos foi 29 vezes maior (OR 29,95; IC 95% [9,84, 90,98]) e 2 vezes maior (OR 2,87; IC 95% [1,45, 5,69]), respectivamente.

Conclusões. Observa-se uma forte associação entre declarar o conflito de interesses e obter resultados favoráveis para os cigarros eletrônicos em artigos científicos. O conflito de interesses deve ser levado em consideração, recomendando-se cautela ao utilizar os dados de estudos na formulação de políticas.

Palavras-chave

Conflito de interesses; saúde pública; sistemas eletrônicos de liberação de nicotina; indústria do tabaco; formulação de políticas.
