

ATTN: Editorial and publishing management team

Dear Sir or Madam,

We are writing to make a formal complaint about the process followed, and scientific judgment relied upon by the Editor(s) of the BMC journal, BMC Public Health, with regard to their intended retraction of our article (<https://doi.org/10.1186/s12889-022-14341-z>). Because the subject(s) of the complaint is/are the Editor(s) of the journal, we request this complaint to be handled independently by the editorial and publishing management team of Springer Nature. Our complaint concerns the impending retraction of our article for purported methodological issues raised in an anonymous Letter. We feel that the retraction is inappropriate, as we not only addressed these considerations during peer review, but also responded to them even more thoroughly in post-publication correspondence with the Editor(s), through additional sensitivity analyses and reference to other published work. For transparency, we have made all relevant materials available on OSF (<https://doi.org/10.17605/OSF.IO/FZTNK>) and on PubPeer (<https://pubpeer.com/publications/0C19CEA0C329F1C95FC0884C7A4AE1>), which we will refer to in the following. These events were also covered by Retraction Watch (<https://retractionwatch.com/2023/07/27/exclusive-public-health-journal-says-it-will-retract-vaping-paper-for-questions-authors-say-were-addressed-in-peer-review/>).

For context, in October 2022, BMC Public Health published our article (<https://doi.org/10.1186/s12889-022-14341-z>; handling Editorial Board Member: Tarang Parekh) showing population-level evidence for substitution between cigarettes and e-cigarettes among US adults, following two rounds of peer review with two referees and revisions responsive to those reviews (see 'Peer Reviews.pdf' file on OSF at <https://doi.org/10.17605/OSF.IO/FZTNK>). In May 2023, the journal shared with us an anonymous Letter to the Editor, the content of which mostly consisted of a complaint about our funding source, JUUL Labs Inc, despite us having disclosed this funding source in the article and at every step of the peer review process following BMC guidelines (see Section 2 of the 'Correspondence.PDF' file on OSF at <https://doi.org/10.17605/OSF.IO/FZTNK>). This Letter was forwarded by BMC Public Health to a single anonymous Editorial Board Member, who agreed with the Letter writer(s) and who questioned one of the parameters of the model in our article (explained below).

We responded with a justification of our choice of parameter, and pointed to sensitivity analyses (in the original published article) showing that our overall findings are robust to this parameter choice. As neither the Editors, nor the Letter writer, nor the Editorial Board Member had made any mention of retraction to us, we were under the impression that the criticism and

our response would be published as correspondence in the journal, consistent with standard practice and COPE guidelines on methodological disagreements. However, based on the anonymous Letter and the single anonymous Editorial Board Member's comment, which was itself subject to no scientific review that we are aware of, the journal informed us in July that it intended to retract our article. We believe that this decision was flawed both on scientific grounds and on process.

On scientific grounds:

- Neither the Letter writer(s), nor the Editorial Board Member, nor anybody else at BMC Public Health have demonstrated that our overall findings – that e-cigarette use uptake correlates with declines in cigarette smoking – are unreliable, or that any error had been made in our analysis, or that any change to our methods would result in a different finding.
- The anonymous Editorial Board Member focused on our choice for one of the model parameters, namely, the year in which, in our model, prevalence of current e-cigarette use is assumed to be negligible. As background, e-cigarettes were only introduced in 2007 in the US, and use prevalence remained extremely low for several years thereafter; thus, current e-cigarette use prevalence *had* to have been approximately 0% around this time. We chose 2010 as the cutoff year, i.e. the last year in which current e-cigarette use prevalence was approximately 0%, consistent with other published literature; but knowing the exact cutoff year is uncertain, we included sensitivity analyses in our original published paper which vary the cutoff year (using 2009 and 2011).
- Importantly, the Editorial Board Member, in criticism of this choice, provided citations for *lifetime* e-cigarette use in 2010 and *current* e-cigarette use in years *after* 2010. There is a real and important distinction between lifetime use, which refers to having ever tried an e-cigarette (even just one puff) in one's entire life, and *current* use which is defined by CDC as use on 'every day' or 'some days', i.e., ever using e-cigarettes vs regularly using e-cigarettes. Ever use of e-cigarettes in 2010, as cited by the Editorial Board Member, is *not relevant* to our statistical model, which assessed *current* e-cigarette use prevalence over time. In fact, we *have* provided the journal with a citation for current e-cigarette use prevalence in 2010, and it is negligible (0.3% of all US adults), completely consistent with our use of either 2010 or 2009 for the model parameter in our analysis (see Section 13 of the 'Correspondence.PDF' file on OSF at <https://doi.org/10.17605/OSF.IO/FZTNK>).
- We also pointed out that in our original article, 2010 was identified objectively using an empirical inflection or 'knee' point detection algorithm (<https://doi.org/10.1109/ICDCSW.2011.20>). Other published articles on this topic have also used a cutoff at/near 2010 for examining the impact of e-cigarette use prevalence on cigarette smoking prevalence (<https://doi.org/10.3390/ijerph18094876>; <https://doi.org/10.1063/5.0063593>). Thus, the main criticism of our article (the one criticism mentioned in the proposed retraction notice wording) is based on a

misunderstanding of the literature and is not backed by evidence; to the contrary, the evidence strongly supports our contentions.

- This question around the model parameter was addressed during the original peer reviews of our article by providing sensitivity tests for the years around 2010, the results of which were completely consistent with one another (see 'Peer Reviews.pdf' file on OSF at <https://doi.org/10.17605/OSF.IO/FZTNK>). In other words, even with variations in the choice of cutoff year, all of our analyses confirm our original article's conclusions that e-cigarette uptake correlates with a shortfall in cigarette smoking.
- Not only this, but in subsequent correspondence with the journal, we went even further to test the model parameter for all years between 2006 and 2011 (inclusive), which once again showed absolutely no change in the outcome of the model (see Section 10 of the 'Correspondence.PDF' file on OSF at <https://doi.org/10.17605/OSF.IO/FZTNK>).
- The anonymous Editorial Board Member acknowledged that the sensitivity analysis results are consistent but stated that the "sensitivity analysis has no real value if the initial assumption was wrong," which is incorrect in two respects, first because as we have shown, the initial assumption was not "wrong," and second because that's not how sensitivity tests work; if extensive sensitivity tests support an assumption, then there is no issue with that assumption.
- Another criticism raised by the anonymous Editorial Board Member is that the subgroup analyses by age were only statistically significant in the 18-34 age group. Again, this criticism represents a fundamental misunderstanding of our findings. It does not represent a scientific flaw. The fact that the effect is not observed in the Editorial Board Member's preferred subgroup (older adults) does not invalidate the relevance of it being observed among younger adults. In fact, as we have attempted repeatedly to convey to the journal, e-cigarettes cannot impact smoking in groups who are *not* using e-cigarettes, namely the older adult cohorts. This is not a weakness. It is a strength of the findings that the observed association only exists in subgroups one could *expect* it to exist in, i.e., those widely using e-cigarettes. If we had observed a significant association in cohorts not using e-cigarettes widely, that actually would raise questions about the effect.
- Our findings are consistent with many other similar scientific articles (see Section 6 of the 'Correspondence.pdf' file on OSF at <https://doi.org/10.17605/OSF.IO/FZTNK>), including:
  - Other population-level prevalence modelling studies consistently showing that e-cigarette use is associated with more rapid declines in cigarette smoking (<https://doi.org/10.3390/ijerph18094876>; <https://doi.org/10.1063/5.0063593>; <https://doi.org/10.3310/RPDN7327>).
  - Studies of objectively-assessed sales trends showing the same result (<https://doi.org/10.1007/s10603-022-09533-4>).

- Other econometrics literature showing economic substitution between cigarettes and e-cigarettes (e.g. <https://doi.org/10.1016/j.jhealeco.2022.102676>), which is the gist of our conclusion.
- Thus, our findings are not controversial, but confirm and extend a substantial body of existing work.
- Posted in the PubPeer comments on our article, in response to the Retraction Watch piece on our article, 23 independent tobacco control experts wrote to the journal in support of our work, seriously questioning the journal's decision to retract our article (<https://pubpeer.com/publications/0C19CEA0C329F1C95FC0884C7A4AE1#3>). The journal did not notify us of it having received any Letter in support of our article, only the original Letter critiquing our article, nor did the journal make any scientific response to the 23 independent tobacco control experts' Letter that we are aware of. This seems to prioritize the view of one Editorial Board Member over the views of 23 world-class experts in the area.

On process:

- We believe the decision is inconsistent with Committee on Publication Ethics (COPE) guidelines, which state that a retraction should only be issued if there is "clear evidence that the findings are unreliable, either as a result of major error (e.g., miscalculation or experimental error), or as a result of fabrication (e.g., of data) or falsification (e.g., image manipulation)." None of these apply to our article; as shown in the above, there has been no demonstration that our findings are unreliable. On the contrary, our sensitivity tests on the year parameter completely support the findings.
- Further, the journal could have taken a scientifically robust approach to challenging our findings, by requesting that the Letter writer(s) or Editorial Board Member present what they considered to be a more appropriate analysis of the data, which are publicly available. Neither the journal nor those individuals took this scientific approach. If the Letter writer(s) and Editorial Board Member feel that we have made a "major error," one would think they would have some duty to demonstrate this using the underlying data. We are also not aware of any public peer-review of the comments by the Letter writer(s) and Editorial Board Member.
- COPE's mandate to support post-publication debate states that "Journals must allow debate post publication either on their site, through letters to the editor, or on an external moderated site, such as PubPeer." We have suggested repeatedly to the journal that consistent with COPE's mandate, the journal should publish the original Letter to the Editor it received, as well as the Editorial Board Member's comments and our response, so that interested readers can decide for themselves which conclusion best fits the available data. By retracting the paper, the journal denies readers this opportunity, and credits one side of a discussion while suppressing the other in a way that is incongruous with the pursuit of scientific knowledge. The journal has not explained why it does not consider publishing the correspondence to be an option.

- The journal has previously afforded other authors it has published the opportunity to publish a post-publication revision of their article, e.g. Lowrie et al. (<https://doi.org/10.1186/s12889-018-5602-7>). The journal has not offered us this opportunity, which we could easily use to add the additional sensitivity tests we provided the journal to address the Editorial Board Member's comments. The journal has not explained to us why it also does not consider this to be an option.
- Throughout, the journal has made vague reference to a "review," but we have only seen anonymised comments from a single Editorial Board Member, relayed to us by an Associate Editor. The journal has offered no detailed explanation of the steps by which it conducted its review, the people involved, or the protocol being followed.

In summary, we conclude that the journal has taken an extreme decision against our article without providing a scientific basis, without following COPE guidelines, and without providing us with transparency throughout the process.

We hope that you take this formal complaint seriously, and we remain hopeful that Springer Nature will come to science-based solution in accordance with COPE guidelines.

We look forward to hearing from you.

Thanks, and kind regards,

Floe Foxon, Dr Arielle Selya, Joe Gitchell, and Dr Saul Shiffman.