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Dear Drs. London, Eitzman, Weinberg and Harrington,

JAHA paper on e-cigarettes and myocardial infarction

In June, the *Journal of the American Heart Association* published “Electronic cigarette use and myocardial infarction among adults in the US Population Assessment of Tobacco and Health [PATH],” by Dharma N. Bhatta and Stanton A. Glantz.¹

We are concerned that the primary finding of the study is based on a critical error. Brad Rodu of the University of Louisville has provided a strong critique of this study, which we summarize as follows.

Many of the myocardial infarctions (MI) used in the calculation of the association between e-cigarette use and MI risk occurred *before* subjects first used e-cigarettes. The PATH survey includes timing data for MI and first e-cigarette use that the authors should have used to exclude these cases from the analysis. Further, the authors went on to conclude that the association was causal and made policy recommendations regarding smoking cessation practice on that basis. When the cases in which the MI occurred before e-cigarette use are excluded, the analysis does not show an association. Any residual association is, in any case, likely due to incomplete adjustment for almost complete confounding by smoking history. It follows that the conclusion is not supported by the underlying data and, therefore, the published findings could mislead practitioners and policymakers.

These concerns have been put directly to the journal in the expectation that the journal would investigate and correct the record as appropriate. Rodu and his colleague wrote two letters to the JAHA editorial team explaining the problems and asking the journal “*to take appropriate action on this article, including retraction*”.^{2,3} The flaws in the study were raised in the national press in an article in USA Today in July.⁴ Most recently, on November 27, the Bhatta-Glantz



paper was discussed in a blog post by Andrew Gelman, a widely respected professor of statistics and director of the Applied Statistics Center at Columbia University.⁵ Professor Gelman states:

It seems like a real article with a data issue that Rodu found, and the solution would seem to be to perform a corrected analysis removing the data from the people who had heart problems before they started vaping

Gelman's contribution is important because it recognizes the data problem with the paper and recommends addressing this with the same approach that Rodu and his colleague have used. The authors' approach of only including MIs that occurred after 2007 does not do this adequately (subjects may have started vaping, for example, in 2014 after an MI in 2013 – a plausible patient response). But the data is available to perform the analysis that both Gelman and Rodu recommend. If that is done, the association disappears, and the authors' conclusion is invalidated. It is clear that the authors knew of the PATH survey questions that establish the respective timings of MI and e-cigarette uptake because they refer to these questions in the discussion section of their paper. It is a matter of concern, therefore, that the authors did not use these questions to eliminate the MIs that occurred prior to e-cigarette uptake from their analysis.

The journal has not so far provided a substantive response to these concerns. However, according to the journal's Policy and Procedure Manual, the response to such concerns should follow the guidance of Committee on Publication Ethics (COPE). "*The AHA policy reflects the COPE best practices while also allowing for notification of the Scientific Publishing Committee (SPC) Chair and AHA Corporate Counsel.*"⁶

The COPE guidelines on retraction state:⁷

Journal editors should consider retracting a publication if they have clear evidence that the findings are unreliable, either as a result of misconduct (e.g. data fabrication) or falsification (eg image manipulation) or honest error (e.g. miscalculation or experimental error).

Further, the COPE guidelines on handling concerns about scientific soundness raised directly by external 'whistleblowers' such as Rodu require a proper investigation and response.⁸

The analysis provided by Professors Rodu and Gelman strongly suggests that the published findings are unreliable and that there is a case to answer.

We respectfully request that the journal initiates the relevant COPE procedures. It is time this paper received proper critical scrutiny and that the published record is corrected as appropriate.

We would appreciate a reply indicating what steps the journal will take next. Given the interest in this paper, we expect to make this letter public in due course.

Yours sincerely

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The signatories write in a personal capacity and declare no competing interests with respect to tobacco or e-cigarette industries. Full ICMJE disclosures are available on request.

References

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- ⁶ American Heart Association, Policy and Procedure Manual – Scientific Publishing. [Ethical Conduct in Authorship and Publication](#). May 2017
- ⁷ Committee on Publication Ethics (COPE), [Retraction guidelines 2019](#). 2019.
- ⁸ Committee on Publication Ethics (COPE), [How to respond to whistle blowers when concerns are raised directly](#). 2019.