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LETTER

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Response to Mr. Somovilla del Saz's letter to the editor regarding "Risk of all-cause and cardiac-related mortality after vaccination against COVID-19: A meta-analysis of self-controlled case series studies"

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ABSTRACT

This is a response to Mr. Somovilla del Saz's letter to the editor regarding Marchand et al.'s article, "Risk of all-cause and cardiac-related mortality after vaccination against COVID-19: A meta-analysis of self-controlled case series studies." The response is on behalf of all authors clarifying misconceptions about the work.

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Dear Editors and Mr. Somovilla del Saz,

We have read Mr. Somovilla del Saz's letter[1] in response to our study[2] published in August 2023. We appreciate the response as well as the interest in discussing our findings further. We could not be more pleased that our work has sparked important academic debate. We'll take the liberty of discussing Mr. Somovilla del Saz's comments in order. Given that Mr. Somovilla del Saz may not have extensive experience with meta-analyses, we'll aim to clarify these points in straightforward terms.

First, we'd like to address Mr. Somovilla del Saz's claim regarding Dr. Joseph Ladapo's study, suggesting it is "non-peer-reviewed." Contrary to this assertion, the study by Ladapo et al. has undergone a review process and is indeed peer-reviewed, making it suitable for inclusion in a meta-analysis. This research is an official publication of the Florida Health Department. It's worth noting that major governmental health organizations, including the Florida Health Department, have established internal review mechanisms. These mechanisms often involve relevant boards and physician members overseeing the publication processes, which aligns with the concept of peer review in the context of a meta-analysis. Similarly, publications from other prominent medical entities, like the CDC, undergo comparable review processes.

Nevertheless, it's important to highlight that non-peer-reviewed articles are frequently incorporated into systematic reviews and are often regarded as valid and reliable sources of evidence. We have conducted a meticulous assessment of the evidence to ensure its credibility and relevance.

While we concur that an independent or even blinded review is ideal, it's essential to recognize that neither Cochrane, PRISMA, nor other authoritative bodies in meta-analysis explicitly mandate this as the sole criterion for peer review.

Second, Mr. Somovilla del Saz's observation regarding the absence of a sensitivity analysis is not at all accurate. While sensitivity analyses are indeed valuable in meta-analyses, the feasibility of conducting such an analysis depends on the number of available studies. For all-cause mortality, we had sufficient studies to perform a sensitivity analysis to identify the source of heterogeneity. However, for cardiac-related mortality, we were limited to only two studies, making a sensitivity analysis unfeasible. In situations with a limited number of studies, a widely accepted and Cochrane-recommended approach is the "leave-one-out" analysis. This method serves as a form of sensitivity analysis and was aptly applied in our study for all-cause mortality. We are eager to conduct a more extensive sensitivity analysis on this topic in the future, but this would necessitate the publication of additional studies!

Lastly, we note Mr. Somovilla del Saz's concerns regarding the study by Ladapo et al., suggesting it was "altered to emphasize an increase in COVID vaccine-related effects." Such claims are significant, and it's essential that they are backed by evidence. The Florida Health Department is responsible for the health and safety of 21.8 million Floridians and oversees the licensure and conduct of over 89,000 physicians. Should Mr. Somovilla del Saz possess concrete evidence supporting his claims, we urge him to

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present it to the Florida Department of Health for a comprehensive review. As of now, we are not privy to any such evidence. We regard Ladapo et al.'s study as a methodically conducted research, employing the unique design of a self-controlled case series. It's crucial to approach scientific discourse with evidence-based critiques. Baseless allegations can hinder genuine scientific publishing and inadvertently spread misinformation. In today's age, ensuring accurate information dissemination is paramount.

We hope this clears up any misconceptions regarding our work.

Thank you sincerely, on behalf of all authors

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