


# Author response to comment on: Premenstrual and menstrual changes reported after COVID-19 vaccination: The EVA project

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First of all, we thank your interest in our study. Nonetheless, we have some concerns to reply to your letter below:

Regarding your statement about the population's opinion about vaccines, and your suggestion that our study promotes fear of vaccination, we clearly emphasize just the contrary, as we reflect in the discussion section:

“... although the vaccine may be associated with mild menstrual disorders, it should be noted that SARS-CoV-2 infection may not only cause menstrual cycle disturbances but can also severely affect a wide range of organs and systems in the human body.”

In fact, we highly recommend vaccination along the text. For instance, in the final conclusions, we state that this study could be useful to eliminate the fear of serious alterations in menstruation after the administration of the vaccine, being able to adequately inform women.<sup>1</sup>

In relation to the definition of *cross-sectional study*, we refer to the one offered by the National Library of Medicine's MeSH terms:<sup>2</sup> “Studies in which the presence or absence of disease or other health-related variables are determined in each member of the study population or in a representative sample at one particular time.” In this research, data from more than 14,000 women at one point in time were used. It is, therefore, a cross-sectional study. Indeed, most of the studies that have been published (11/14) on menstrual changes after COVID-19 vaccine administration are cross-sectional, and with a similar methodology.<sup>3</sup>

Regarding the statement about potential selection biases, we do include them as limitations of our study: “The present results are based on self-reported data provided by volunteers, which can result in a bias error (i.e. women who perceived changes in their menstrual cycle might have been more prone to participate).”<sup>1</sup>

In relation to the e-survey, it was promoted through the media and social networks. The time required to completely answer the questionnaire was estimated based on tests previously carried out by the researchers. However, there was no time limit to complete it.

The author is correct that the best way to test the effect of the vaccine on menstrual disturbances it would be through a clinical trial. However, because of ethical issues, a pure clinical trial cannot be done in a global pandemic. This information should have been recorded in vaccine development clinical trials. At present, it would be difficult to extract non-observational data.

Finally, self-perception of menstrual symptoms has previously been shown to have high specificity and sensitivity, especially for heavy bleeding,<sup>4</sup> which was the most reported menstrual change in our study.

## Declarations

### *Ethics approval and consent to participate*

Not applicable.

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### Consent for publication

Not applicable.

### Author contribution(s)

**Laura Baena-García:** Conceptualization; Methodology; Project administration; Writing – original draft.

**Virginia A Aparicio:** Data curation; Formal analysis; Methodology; Supervision; Writing – review & editing.

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### Availability of data and materials

Not applicable.

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### References

1. Baena-García L, Aparicio VA, Molina-López A, et al. Premenstrual and menstrual changes reported after COVID-19 vaccination: the EVA project. *Womens Health* 2022; 18. DOI: 10.1177/17455057221112237.
2. NCBI. Cross-sectional studies. *MeSH – NCBI*, <https://www.ncbi.nlm.nih.gov/mesh?Db=mesh&Cmd=DetailsSearch&Term=%22Cross-Sectional+Studies%22%5BMeSH+Terms%5D> (accessed 27 August 2022).
3. Nazir M, Asghar S, Rathore MA, et al. Menstrual abnormalities after COVID-19 vaccines: a systematic review. *Vacun*. Epub ahead of print 19 July 2022. DOI: 10.1016/j.vacun.2022.07.001.
4. Magnay JL, O'Brien S, Gerlinger C, et al. A systematic review of methods to measure menstrual blood loss. *BMC Womens Health* 2018; 18: 1–13.