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Side effects of SARS-CoV-2 vaccines should be assessed by unbiased professionals on-site

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Letter to the Editor

We read with interest the article by Cheng et al. about a study on the adverse events among Chinese health care workers (HCWs) who had undergone a compulsory vaccination program using the Chinese brands Aikewei and CoronaVac.[1] Data were collected by means of a self-administered questionnaire delivered to HCWs in the field of perinatal medicine respectively obstetric gynecology during two nation-wide congresses, one held between 9-21 June 2021 in Taiyuan and the other between 5-11 June 2021 in Nanjing.[1] The overall incidence of mild adverse events in the two surveys was 38.2% and 31% respectively and the incidence of moderate adverse events 1.9% and 0.9% respectively.[1] None of the participants reported severe adverse events and none required hospitalization.[1] It was concluded that the results are useful to overcome vaccine hesitancy and concerns about the safety of SARS-CoV-2 vaccines.[1] The study is appealing but has some limitations that raise concerns requiring discussion.

The results of the index study are in strong contrast to reports about severe side effects mainly of the Astra Zeneca vaccine (AZV), the Biontech Pfizer vaccine (BPV), the Moderna vaccine (MOV), and the Johnson and Johnson Vaccine (JJV).[2,3] Vector-based as well as mRNA-based vaccines carry a potential risk of severe, particularly immunological side effects, why it is surprising that no severe side effects were observed with the Chinese preparations. However, at least one patient with Guillain-Barre syndrome (GBS) following a vaccination with the CoronaVac vaccine had been reported.[4] Regarding the Aikewei vaccine only three patients with severe side had been reported.[5] The reason for the discrepancy between the safety profile of Chinese vaccines and the AZV, BPV MOV, and JJV could be that Chinese vaccines generally carry a lower risk of side effects or that severe side effects were not published due to political, economical, or personal reasons.

A general disadvantages of studies relying on self-reported data are that the provided data are not checked, that not necessarily the patient but a third person responds, that unwillingness to consent and to contribute may bias the study, and that those severely ill, either due to the investigated condition or due to other disease, may not be able to participate. Therefore, the data collected may be biased regarding the severity of side effects, regarding the completeness of the data, and regarding the reliability of the information provided. Studies following such a design need to be compared with studies collecting the data in an on-site setting.

Another bias that should not be neglected concerns the fear of HCWs working in public institutions when reporting side effects about a measure the employer propagates and which was compulsory. Not to get into troubles with the employer, employees may hold back what they truly experienced. Though the study may guarantee anonymity, there is of course no certainty about the anonymity of the provided data. In this regard, it should be communicated how anonymity of the participants was guaranteed.

Another limitation of the study is that those not attending the congress and those not able to respond may have been missed. Particularly, vaccinees who had to be hospitalized because of severe side effects to the vaccines or due to other causes may be unable to respond to the questionnaire within the timeframe of the survey. Therefore, we should know the reason why those not responding did not participate. It should be told how many of the HCWs in question were hospitalized during the study period.

Overall, the interesting study has limitations which challenge the results and their interpretation. Side effects of SARS-CoV-2 vaccines should be assessed by unbiased specialized doctors face to face with the vaccinee.

Author's contribution

JF: design, literature search, discussion, first draft, critical comments, final approval.

Consent to participate

Consent to participate was obtained from the patient.

Data availability statement

All data are available from the corresponding author.

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Disclosure statement

No potential conflict of interest was reported by the author(s).

Ethics approval

Ethics approval was in accordance with ethical guidelines. The study was approved by the institutional review board.

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