LETTER TO THE EDITOR



Authors' Reply to Mungmunpuntipantip et al.'s Comment on "Description of Frequencies of Reported Adverse Events Following Immunization Among Four Different COVID-19 Vaccine Brands"

Agnes Kant¹ · Florence van Hunsel¹

Accepted: 20 June 2022 / Published online: 15 July 2022 © The Author(s), under exclusive licence to Springer Nature Switzerland AG 2022

Dear Editor,

We read the response by Mungmunpuntipantip and Wiwanitkit [1] on our article "Description of Frequencies of Reported Adverse Events Following Immunization Among Four Different COVID-19 Vaccine Brands" [2]. Because experienced common adverse events following immunization (AEFIs) were asked for in predefined questions to all participants in the cohort we do not assume there is a high chance of underreporting. It is correct that not all mentioned events will be adverse reactions. That is incorporated in the definition of an AEFI: *adverse event following immunization is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship* [3]. An experienced AEFI can also be due to nocebo effect, or background incidence.

Yours sincerely Agnes Kant and Florence van Hunsel (Corresponding Author)

Declarations

Funding Funding for the cohort event monitoring of COVID-19 vaccine safety was granted by the Dutch Ministry of Health, Welfare and Sport (Grant 331.880). The Dutch Ministry of Health, Welfare and Sport had no role in the study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the article for publication.

This reply refers to the comment available online at https://doi.org/ 10.1007/s40264-022-01205-z.

Florence van Hunsel f.vanhunsel@lareb.nl

¹ Netherlands Pharmacovigilance Centre Lareb, Goudsbloemvallei 7, 5237 MH 's Hertogenbosch, The Netherlands **Conflict of interest** The authors AK and FH declare no relevant conflicts of interest.

Ethics approval If a study in the Netherlands is subject to the Medical Research Involving Human Subjects Act (WMO), it must undergo a review by an accredited Medical Research Ethics Committee or the central committee on research involving human subjects (CCMO). After submission to an accredited review committee (METC Brabant), this study was deemed not to fall under the WMO act.

Consent to participate Participants in the study provided a written statement of consent to participate at the time of registration.

Consent for publication Participants in the study provided a written statement of consent at the time of registration for their data to be used for the purpose of this research and publication of study results.

Availability of data and material The datasets for this manuscript are not publicly available because of the Lareb data protection policy. Requests to access the datasets should be directed to the first author and will be granted upon reasonable request.

Code availability The SQL statements for the data used in this article are not publicly available because of the Lareb data protection policy. Requests to access the datasets should be directed to the first author and will be granted upon reasonable request.

Authors' contribution This response letter was drafted by both AKT and FHL and both approved the final version.

References

- Mungmunpuntipantip R, Wiwanitkit V. Comment on "Description of Frequencies of Reported Adverse Events Following Immunization Among Four Different COVID-19 Vaccine Brands". Drug Saf. 2022. https://doi.org/10.1007/s40264-022-01205-z.
- Kant A, Jansen J, van Balveren L, van Hunsel F. Description of frequencies of reported adverse events following immunization among four different COVID-19 vaccine brands. Drug Saf. 2022;21:1–13. https://doi.org/10.1007/

s40264-022-01151-w (Epub ahead of print. PMID: 35314943; PMCID: PMC8936041).

3. World Health Organization. Adverse events following immunization (AEFI) https://www.who.int/teams/regulation-prequalifi cation/regulation-and-safety/pharmacovigilance/health-profession als-info/. Accessed 19 Apr 2022.