HUMAN VACCINES & IMMUNOTHERAPEUTICS
2023, VOL. 19, NO. 1, 2168947
https://doi.org/10.1080/21645515.2023.2168947

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LETTER

Safety of mRNA BNT162b2 COVID-19 (Pfizer-BioNtech) vaccine in children aged 5–11 years: Author's reply to correspondence

Giancarlo Ripabelli[a], Angelo Salzo[b], and Manuela Tamburro[a]

[a]Department of Medicine and Health Sciences "Vincenzo Tiberio", University of Molise, Campobasso, Italy; [b]Local Health Agency of Molise Region, Campobasso, Italy

ABSTRACT

Dear Editor, We would like to reply to "Safety of mRNA BNT162b2 COVID-19 (Pfizer-BioNtech) vaccine in children aged 5–11years: Correspondence" regarding our article entitled "Safety of mRNA BNT162b2 COVID-19 (Pfizer-BioNTech) vaccine in children aged 5–11years: Results from an active pharmacovigilance study in central Italy."

Author's reply

Dear Editor,

We would like to reply to "Safety of mRNA BNT162b2 COVID-19 (Pfizer-BioNtech) vaccine in children aged 5–11 years: Correspondence" regarding our article entitled "Safety of mRNA BNT162b2 COVID-19 (Pfizer-BioNTech) vaccine in children aged 5–11 years: Results from an active pharmacovigilance study in central Italy."

The first comment is regarding a history of previous diseases among children who have undergone COVID-19 vaccination. In Italy, information on health status of children, as for adults, was collected by health professionals through a standardized format and procedure before undergoing vaccination.[1] In case of significant uncertainties or specific health concerns, including dengue fever, the medical doctor would make the final decision amongst vaccination, exemption, rescheduling and possible consultation of other specialists. Of note, dengue fever is endemic in more than 100 countries in Africa, the Americas, South-East Asia, the Western Pacific, and the eastern Mediterranean, but generally in Europe only imported cases are reported by travelers returning from these areas.[2] Indeed, according to latest surveillance data from 2010 to present provided by the European Centre for Disease Control and Prevention,[2] in our country, including the Molise region, dengue fever may also occur as an imported disease.

With respect to the second comment regarding COVID-19 vaccination in asymptomatic subjects, according to the *interim* clinical considerations by the Centers for Disease Control and Prevention,[3] COVID-19 vaccination is recommended for everyone ages 6 months and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection, and it was proved to be safe considering different age population groups.[3,4] In addition, there are no contraindications for subjects with previous SARS-CoV-2 infection (symptomatic or asymptomatic) to get vaccinated against COVID-19 according to both Italian Ministry of Health and Italian Medicines Agency,[5,6] and it is possible to consider the administration of a single dose that should be preferably received within 6 months after infection diagnosis and not over 12 months of recovery. Since the information related to a previous SARS-CoV-2 infection is collected at time of vaccination through a self-certification model, it is recommended to have evidence of a documented SARS-CoV-2 infection. In the absence, it is recommended that the anamnestic information on a previous infection is collected in the most complete and detailed way. Anyway, viral testing for acute SARS-CoV-2 infection, or serologic testing to assess for prior infection, is not recommended for vaccine decision-making.[7]

Lastly, with respect to the comment related to recipient genetic background connected to immunological responses, the paradigm of personalized medicine has been already applied in the study of SARS-CoV-2 to understand the large inter-individual clinical differences, in which host genetics factors were proven to contribute and modulate response to infection.[8,9] Responses to vaccination could be also different, including adverse reactions or lack of responses, and these are thought to be influenced by host genetic factors because polymorphisms of the innate and adaptive immune system genes could theoretically influence the vaccines response.[10] Indeed, personalized approaches would contribute to identify genetic markers as predictors of SARS-CoV-2 infection and vaccine response, and could guide health-care providers in the process of selecting the best treatment, and the most suitable vaccine for an individual or a specific population group.

Disclosure statement

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

Funding

The author(s) reported there is no funding associated with the work featured in this article.

CONTACT Giancarlo Ripabelli ripab@unimol.it Department of Medicine and Health Sciences "Vincenzo Tiberio", University of Molise, Campobasso, Italy.

ORCID

Giancarlo Ripabelli http://orcid.org/0000-0002-9953-7769

Ethics statement

For this study, ethical approval was not requested as no experimental procedure was applied, and the information were retrospectively provided by participants after signing an informed consent. Furthermore, all data presented were de-identified, coded and were analyzed anonymously in accordance with ethics guidelines.

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