Universal Health Organisation (UHO)

PEOPLE'S HEALTH IN PEOPLE'S HANDS

To,
The Director,
Indian Council of Medical Research.

Date: 21 May 2024

Subject: ICMR should lead high quality research on vaccine safety, desist from academic censorship – an open letter

Dear Dr. Rajiv Bahl,

A recent research study [link] was published on 13 May 2024 in the Journal of Drug Safety by a research group from IMS-BHU. This filled an important gap in terms of field data analyzing the long-term safety of the widely administered Covid vaccine Covaxin. While we were hoping and expecting a research institution of repute such as ICMR to build upon this study, address its shortcomings, and elevate the standards of vaccine safety, we are aghast to come across letters sent by ICMR (a) asking for the retraction of the paper, and (b) threatening the authors of the study. Several aspects are amiss in this context.

1. In its letters, ICMR has pointed out that the published study lacks a control group. This is indeed a shortcoming of the study – but is admitted in the study itself, in the "limitations" section. No scientific study is without limitations, and the study must be used to further improve vaccine safety studies. To the contrary, calling for its retraction is unbecoming of a scientific institution of ICMR's stature.
2. While a study with a control group would certainly be of higher quality, this immediately points to the fact that it is researchers from ICMR who have access to the data with the control group, i.e. the original phase-3 trials of Covaxin – as well publicized in "The Vaccine War" movie. ICMR thus owes it to the people of India, that it publishes the long-term follow-up of phase-3 trials. It is to be noted that *interim* results [link] of the phase-3 trial, also cited by Dr. Priya Abraham in "The Vaccine War" movie, had a mere *56 days* of safety follow-up, much shorter than the one-year follow-up in the IMS-BHU study. Furthermore the ICMR phase-3 trial study did not include adolescents below 18 years, which the IMS-BHU study does. While Bharat Biotech has claimed in the media [link] that "safety monitoring was continued", neither Bharat Biotech nor ICMR has published the long-term safety results.
3. In Sep 2022, Bharat Biotech, the manufacturer of Covaxin, had published a study on Covaxin for ages 2-18 [link]. This study too lacked a control group. Furthermore, it had a mere 175 adolescents in the 12-18 age-group, likely around just 80-90 in the 15-18 age-group, and it too had only *56 days* of follow-up. In comparison, the IMS-BHU study has 635 adolescents in the 15-18 age-group followed-up for a year. These aspects further underscore the intrinsic value of the IMS-BHU study despite its stated limitations.
4. Privately addressed letters to the authors and the journal editor have been leaked to the press and in social media. This amounts to harassment and intimidation of the study authors. ICMR must investigate this transgression of professional conduct.
5. The letter addressed to the authors is spreading a falsehood about the first author Dr. Upinder Kaur. Dr. Kaur has not acknowledged ICMR at all. While "The Vaccine War" movie is celebrating women scientists, this ICMR letter is spreading a falsehood about a woman researcher. ICMR must thus issue a note of apology in this regard to Dr. Kaur.

6. On the issue of use of telephonic interview for safety follow-up, it is certainly a limitation, as also admitted by the authors in the "limitations" section. However, it is to be noted that the same research group also published a safety follow-up study on Covishield in Jul 2021 [link]. This study was later cited by a study on Covishield with several authors from ICMR [link], including the then director Dr. Balram Bhargava. Therefore, ICMR researchers acknowledged then that telephonic interview is a valid process, although not most desirable. Furthermore, telephonic interviews for follow-up is part of ICMR's own Covaxin rollout plan [link]. Thus, citing telephonic interviews as a reason to call for retraction of the IMS-BHU study is unsound and inconsistent.
7. The issue of author acknowledgement itself has been blown out of proportion. If ICMR does not wish to be acknowledged, it can communicate this privately to the authors and the editor and an erratum can be issued – a routine matter in scientific publications.
8. The above appears all the more stark in light of the following. On 29 Aug 2022, the Hon'ble Supreme Court of India had issued a notice [link] to ICMR, in the case of "Rachana Gangu & ANR vs Union of India & ORS", involving Covid vaccine safety. However, even after nearly 21 months, ICMR has not found time to respond to this notice, while it has found time within a few days to raise issue with author acknowledgement in a publication. ICMR must invert its priorities and give more weightage to the notice from the Indian Supreme Court.

In summary, we reiterate that ICMR must lead the country in giving vaccine safety its due priority. It must publish data from the original phase-3 trial with long-term follow-up, as well as lead other high quality research studies on long-term safety. It must certainly desist from academic censorship of the already small number of studies on Covaxin long-term safety. ICMR owes this to the lakhs of Indian children to whom Covaxin has been administered, for these children have their entire life ahead of them.

In anticipation of a positive response,

Yours Sincerely,

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An electronic copy of this open letter is available at:
https://uho.org.in/files/covaxin-safety-icmr-letter.pdf