<u>LETTERS</u>

Concerns with regard to an article

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We have read with interest and concern the article titled "Consultations on human infection studies in India: Do people's voices really count" (1) by Sandhya Srinivasan and Veena Johari. The article expresses the opinions of two persons who have not visited CMC, nor have spoken to anyone concerned, to ascertain the authenticity of the information published or with regard to the purported research in CMC. Therefore, we would like to point out some very apparent factual errors alluded to in this article with regard to the involvement of Christian Medical College, Vellore.

While it is indeed true that researchers from CMC have attended the workshops at Vellore and Bangalore for engagement in National level discussions on CHIMS, their participation in these meetings was entirely out of their own individual interest and not as representatives of the institution. Participation of these researchers in these meetings did not reflect the views of the institution or imply any intention on the part of the institution to get involved in Controlled Human Infection Model (CHIM) studies.

The two persons from CMC (in their individual capacity) visited the Oxford Vaccine Group's Laboratory facility in the United Kingdom, on the invitation of Dr Pollard to see a typical Controlled Human Infection Model (CHIM) facility. Decisions with regard to Controlled Human Infection Models (CHIM) have to be made by professionals who are fully aware of the various processes involved. The mere attendance at these meetings did not imply any plans to conduct Controlled Human Infection. It should also be pointed out that there were participants from other institutions and a Central Government Department who visited the Oxford Vaccine Group's Laboratory at the same time.

The article states and I quote "The Oxford centre has carried out many CHIM trials including one of a typhoid vaccine developed by CMC along with Bharat Biotech with support from the Wellcome Trust and the Bill and Melinda Gates Foundation." This statement is factually incorrect as CMC was not involved in the development of the typhoid vaccine along with Bharat Biotech as stated in the article.

The article further states that "Second, CMC is apparently working on building capacity to do 'first in human trials' including upgrading facilities for waste treatment and containment. These facilities would also be needed for CHIM trials, 'So that if and when they are allowed, they are prepared', a participant mentioned in a post workshop conversation. And finally, a proposal for typhoid research using CHIM is also being developed." It would have been very useful for the authors if they had made an effort to talk to people directly involved with research within the institution to clarify the position of CMC as an institution rather than making foregone wild conclusions based on conversations with a participant [whom we assume was not representing CMC at that workshop]. We would like to reiterate that the Administration, the Research Office and the Department of Bioethics of CMC Vellore have not made any plans for upgrading facilities in our Institution for Controlled Human Infection Model (CHIM) studies and have not endorsed these studies in our institution. We would also like to state that these studies are unlikely to be performed in CMC in the near future.

CMC Vellore as an institution wishes to place on record the factual inaccuracies in the article both with regard to its involvement in the research referred to and the participation of the two persons in the above deliberations as representatives of the institution.

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Reference

1. Srinivasan S, Johari V. Consultations on human infection studies in India: Do people's voices really count? *Indian J Med Ethics*. Published online on March 22, 2019. DOI:10.20529/IJME.2019.011

Response of the authors to the Letter "Concerns with regard to an article" published online on April 5, 2019 (DOI: 10.20529/IJME.2019.014) on the IJME website.

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We have read the letter by Dr Biju George and Dr Anna Pulimood (1) in response to our report on consultations on human infection studies (2) in India, and emerging issues. Their concerns are not so much with the content of our published report, as with their interpretation of it.

Their concern that we did not visit CMC Vellore seems to be unwarranted, as the information in the report is clear, specific and based on what transpired in various meetings. We have not drawn any foregone wild conclusions, but have merely stated that some facilities at CMC Vellore are being upgraded, which has not been denied by CMC Vellore in their letter.

It is good that CMC Vellore have clarified that the persons from their institute who attended the meetings and related programmes with regard to CHIM trials were not representing the institute, and were attending out of their own interest and