

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH RESEARCH**

**RAJYA SABHA
UNSTARRED QUESTION NO. 1711
TO BE ANSWERED ON 06TH AUGUST, 2024**

OBJECTION BY ICMR ON RESEARCH PAPER BY BHU

1711. SHRI A.D. SINGH:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether some researchers of Banaras Hindu University (BHU) have published a research paper in a journal regarding study on the side effects of Indian Indigenous Vaccine for Covid – Covaxin;
- (b) if so, the details thereof;
- (c) whether ICMR has taken objection to the research paper and has asked the researchers to retract the study;
- (d) if so, the details thereof and the reasons therefor;
- (e) whether it will not affect the research ecosystem in the country; and
- (f) if not, the response of Government?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI PRATAPRAO JADHAV)**

(a) and (b): Banaras Hindu University had published a research paper on 13th May, 2024 in Springer Nature journal titled “Long-Term Safety Analysis of the BBV152 Coronavirus Vaccine in Adolescents and Adults: Findings from a 1-Year Prospective Study in North India”. The details of the study can be obtained from the following link <https://pubmed.ncbi.nlm.nih.gov/38740691/>

(c) and (d): ICMR reviewed the article and observed that the study had serious methodological flaws such as the following:

- (i) The study had no control arm of unvaccinated individuals for comparing the rates of events between the vaccinated and unvaccinated groups. Hence, the reported events in the study cannot be linked or attributed to COVID-19 vaccination.
- (ii) The study did not provide background rates of observed events in the population, making it impossible to assess the change in incidence of observed events in the post vaccination period. Also, no baseline information regarding the study participants were provided.
- (iii) The tool used in the study was found to be inconsistent with the ‘Adverse Events of Special Interest (AESI)’ definition that was in the reference provided in the paper for AESI.

- (iv) The method of data collection used in the study had a high risk of bias. It was observed that study participants were contacted telephonically one year after vaccination and their responses were recorded without any confirmation with clinical records or by physician examination.
- (v) It was also observed that ICMR had not provided any form of support for the conduct of the study and the authors had unduly acknowledged ICMR for the research support provided for the conduct of the study.

ICMR has not asked researchers to retract the study. Researchers have been asked to immediately remove acknowledgement to ICMR, as ICMR had not provided any financial or technical support, and ICMR cannot be associated with poorly designed study. Also, ICMR has asked the scientific journal to remove the acknowledgement to ICMR and to retract the paper as conclusions made in the paper are not supported by evidence/data. It is expected that good journals only publish papers where conclusions are supported by the data presented in the paper.

(e) and (f): ICMR promotes research that has methodological rigor. Study proposals need to undergo rigorous scientific review before conducting the studies. This will strengthen the research ecosystem in the country.
