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

## LOK SABHA STARRED QUESTION NO. 86 TO BE ANSWERED ON THE 8<sup>TH</sup> DECEMBER, 2023

### LINKAGE BETWEEN COVID-VACCINE AND INCIDENTS OF HEART ATTACKS

#### \*86. SHRIMATI SAJDA AHMED:

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

- (a) whether there has been any reported instances among the people of a linkage between the Covid-vaccine and incidents of heart attacks within the country;
- (b) if so, the details thereof;
- (c) whether the Government has undertaken a comprehensive review of the details and findings related to this potential correlation;
- (d) if so, the details thereof; and
- (e) whether the Government is currently engaged in any ongoing study/review focused on assessing the potential risks associated with the administration of the Covid-vaccine in children and if so, the details thereof?

# ANSWER THE MINISTER OF HEALTH AND FAMILY WELFARE (DR MANSUKH MANDAVIYA)

(a) to (e) A Statement is laid on the Table of the House.

## STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 86 FOR 8<sup>TH</sup> DECEMBER, 2023

(a) to (e) Sudden deaths have been reported in some people after COVID-19. However, sufficient evidence was not available to confirm the cause of such deaths. To ascertain the facts regarding the apprehension of rising cases of cardiac arrest after COVID-19, Indian Council of Medical Research (ICMR)-National Institute of Epidemiology (NIE) conducted a study titled "Factors associated with unexplained sudden deaths among adults aged 18-45 years in India - A multicentric matched case-control study" at 47 tertiary care hospitals located across 19 states/UT of India during May- August 2023. A multi centric matched case control study was conducted. Cases were apparently healthy individuals aged 18-45 years without any known co-morbidity, who suddenly (<24 hours of hospitalization or seen apparently healthy 24 hours before death) died of unexplained causes during 1st October 2021- 31st March 2023. Four controls were included per case matched for age, gender and neighborhood. Information was collected regarding data on COVID-19 vaccination /infection, post-COVID-19 conditions, family history of sudden death, smoking, recreational drug use, alcohol frequency, binge drinking and vigorous-intensity physical activity two days before death among the cases / interview among controls.

A total of 729 cases and 2916 controls were included in the analysis. It was observed that receipt of at least one dose of COVID-19 vaccine lowered the odds for unexplained sudden death, whereas past COVID-19 hospitalization, family history of sudden death, binge drinking 48 hours before death/interview, use of recreational drug/substance and performing vigorous-intensity physical activity 48 hours before death/interview were positively associated. Two doses lowered the odds of unexplained sudden death, whereas single dose did not.

Hence, the study observed that COVID-19 vaccination did not increase the risk of unexplained sudden death among young adults in India. Past COVID-19 hospitalization, family history of sudden death and certain lifestyle behaviors increased the likelihood of unexplained sudden death.

There is a Nationwide National Adverse Event Following Immunization (AEFI) surveillance system under Ministry of Health & Family Welfare in place that continuously monitors through COWIN app, reports of vaccine related AEFI's. These are investigated on a time bound manner at District level and then AEFI causality done at State and National level and analysed by National AEFI Committee on a regular and time bound basis. Prima-facie, to date no direct signal has emerged linking Heart Attack to COVID-19 vaccines.

ICMR is not currently conducting any studies for assessing the potential risks associated with the administration of the Covid-19 vaccines in children.

However, a phase 2/3 open-label, non-randomised, multicentre study on the immunogenicity and safety of the BBV152 vaccine done in six hospitals in India on healthy children (male or female) aged 2–18 years observed that the vaccine was well tolerated with no serious adverse events, deaths, or withdrawals due to an adverse event reported during the study.

Another Prospective Observational study on Corbevax Vaccine Side Effects in Children of Age Group 12–14 Years demonstrated that Corbevax is a safe vaccine with few mild side effects.

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