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

RAJYA SABHA
STARRED QUESTION NO. 153
TO BE ANSWERED ON THE 10TH DECEMBER, 2024

SUDDEN DEATH DUE TO COVID VACCINE

153 SHRI VIVEK K. TANKHA:

Will the Minister of Health and Family Welfare be pleased to state:

(a) whether any investigations are underway to assess reports of sudden deaths potentially linked to COVID-19 vaccines and whether any preliminary findings are available;

(b) whether Government is establishing an independent review board to ensure transparent and scientific scrutiny of vaccine-related adverse events and fatalities;

(c) whether Government will consider using the PM CARES Fund to provide financial compensation to families of individuals who may have experienced sudden deaths after vaccination, pending thorough verification; and

(d) the measures in place to improve public awareness regarding vaccine side-effect reporting and to ensure timely medical intervention for affected individuals?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

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

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. 153 * FOR 10TH DECEMBER, 2024

(a) Indian Council of Medical Research (ICMR) has informed that 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/Union Territories of India during May- August 2023. Cases were apparently healthy individuals 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 neighbourhood. 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 / interviewed controls.

A total of 729 sudden death cases and 2916 controls were included in the analysis. It was observed that receipt of any dose of COVID-19 vaccine reduced the odds for unexplained sudden death. Receiving two doses of COVID-19 vaccine significantly reduced the odds of unexplained sudden death. 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 increased the odds of sudden death.

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 behaviours increased the likelihood of unexplained sudden death.

(b) Covid-19 Vaccine Administration Cell has informed that a robust Adverse Event Following Immunization (AEFI) surveillance system has been in place, under the guidance of the National AEFI Committee, comprising of experts from diverse fields, such as paediatricians, obstetricians, cardiologists, neurologists, pathologists, forensic medicine, microbiologist and public health specialists to evaluate each vaccine-related adverse events and fatalities reported. These independent experts make decisions on the causality of the Adverse Events based on available details of the case and scientific evidence.

(c) The study mentioned at part (a) has conclusively documented that COVID-19 vaccination did not increase the risk of unexplained sudden death among young adults in India, and it has instead lowered the odds for unexplained sudden death.

(d) Government of India has implemented several strategies to raise public awareness regarding vaccine side-effects reporting and to ensure timely medical interventions for affected individuals.

1. Guidelines were issued to States/UTs to direct district immunization officers to strengthen reporting of Adverse Events Following Immunization (AEFIs) following COVID-19 vaccination.
2. For the reporting of COVID-19 vaccine AEFIs, the SAFEVAC (a web-based application for AEFI) has been integrated into Co-WIN for reporting of AEFIs. The Co-WIN SAFEVAC has the provision of reporting AEFIs by the vaccinator, district immunization officer and the beneficiary themselves.
3. Frequently Asked Questions with details of Adverse effects of COVID-19 vaccines is available on Ministry of Health and Family Welfare (MOHFW) website.
4. Information, Education and Communication (IEC) material with information related to AEFI have been shared with the States/UTs for translation into local language and display at the vaccination session sites.
5. Awareness on AEFI related information and messages were also amplified through social media and engagement of various immunization partners.
6. To ensure timely medical interventions for affected individuals, preventive measures have been put in place like compulsory observation of vaccine recipients for 30 minutes at session site for any adverse events after vaccination, availability of anaphylaxis kit at each vaccination site and immediate referral to Adverse Event Following Immunization (AEFI) management centre for timely treatment. The AEFI management of such cases has been provided free of cost treatment in Public Health facilities.

*****