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

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UNSTARRED QUESTION NO. 277
TO BE ANSWERED ON 02ND DECEMBER, 2025

LONG-TERM SIDE EFFECTS OF COVID-19 VACCINES

277. SHRI A. A. RAHIM:

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

(a) whether the Ministry has conducted or commissioned any longitudinal or post-marketing surveillance studies to assess the long-term side effects of COVID-19 vaccines administered in the country;
(b) if so, the details of such studies, including the agencies involved, methodology adopted, and preliminary findings, if any;
(c) whether reports of vaccine-related adverse events have been compiled and analysed by age group, gender, and vaccine type; and
(d) if the study is not conducted, whether Government is ready to conduct a comprehensive study?

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

(a) to (d): The Covid-19 Vaccine Administration Cell, Department of Health & Family Welfare has informed that the Adverse Event Following Immunization (AEFI) are monitored through AEFI surveillance system. Causality assessment of all serious and severe AEFIs are done by the designated AEFI committee to determine if AEFI is related to vaccine or vaccination process or otherwise. The assessment is done by age, gender and vaccine type. The Indian Pharmacopoeia Commission has informed that the National Coordination Centre for Pharmacovigilance Programme of India (PvPI) also receives Adverse Event reports associated with Vaccines (not limited to COVID-19 vaccines) which are regularly communicated to AEFI Secretariat under Immunization Technical Support Unit who is the main custodian of vaccine related Adverse Event reports.

Indian Council of Medical Research (ICMR) has informed that it commissioned two studies through National Institute of Epidemiology (ICMR-NIE) to investigate rising anecdotal reports of sudden unexplained deaths and factors associated with thrombotic events among young adults in India. The first study was conducted among apparently healthy adults aged 18–45 years in India. The multicentric matched case–control study spanned 47 tertiary hospitals across India and

recruited 726 cases, including healthy adults with no known comorbidities who died suddenly within 24 hours between 1 October 2021 and 31 March 2023. The study included four matched controls per case by age, gender, and neighbourhood. Trained investigators collected detailed information on recent COVID-19 vaccination (within 42 days), COVID-19 infection and post-COVID conditions, family history of sudden death, smoking, recreational drug use, alcohol consumption and binge drinking, and vigorous physical activity in the 48 hours preceding death or interview. Key findings of the study are given below –

i. Receiving one or more doses of the COVID-19 vaccine was found to significantly reduce the risk of unexplained sudden death in young adults, with two doses offering greater protection.

ii. Previous hospitalization due to COVID-19 was linked to a higher risk of sudden unexplained death by four-fold.

iii. Other risk factors included a family history of sudden death, binge drinking within 48 hours, and vigorous physical activity shortly before death.

The study clearly shows that COVID-19 vaccines do not cause sudden unexplained deaths; rather, they are protective.

The second study was a multicentric hospital-based matched case–control study in 25 tertiary hospitals across India to determine the association between COVID-19 vaccination, lifestyle, medical risk factors and thrombotic events among young adults. This study included adults aged 18–45 years hospitalized with new arterial or venous thrombotic events, with four hospital controls per case matched by admission date. Among 292 cases (199 myocardial infarctions, 67 ischemic strokes, and 26 venous events) and 1,168 controls, cases were mostly male and aged 31–45 years. The key finding of the study are listed below-

i. Thrombotic events in young adults were mainly associated with comorbidities, prior thrombotic history, smoking, and previous hospitalization due to COVID-19.

ii. No definitive association between thrombotic events was observed after one or two doses of Covishield™ or Covaxin™.

iii. In young adults, thrombotic events were driven by traditional risk factors and prior COVID 19 illness.

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