

Z-16025/05/2012 Imm p/f
Government of India
Ministry of Health & Family Welfare
Immunization Division

Nirman Bhawan, New Delhi
Date: 05th November 2021

Causality assessment results of 22 reported Serious Adverse Events Following Immunization (AEFI) cases following COVID-19 vaccination approved by National AEFI Committee on 18th October 2021.

The Immunization Division, MOHFW has taken several steps to strengthen the national AEFI surveillance system for COVID-19 vaccinations. Considering the importance and critical nature of the task, steps were taken to include medical specialists, cardiologists, neurologists, pulmonary medicine specialists, obstetrician-gynecologist as members of the causality assessment sub-committee at the national level. A Special Group has been framed to conduct causality assessment of AEFIs following COVID-19 vaccination. The results of causality assessment done by this Special Group is discussed in the national AEFI committee meeting for final approval.

The results of the causality assessment for 22 cases completed on 18th October 2021 after thorough review, deliberation and approval by the National AEFI Committee is given in the annexure (anonymized line list of the causality assessment done by the National AEFI Committee).

09 out of 22 cases for which Causality assessment has been done were found to have **consistent causal association to vaccination**. Of these 09 cases, 05 cases were vaccine product related reaction and 04 cases were immunization anxiety related reaction. 12 cases have inconsistent causal association to vaccination (**coincidental - not linked to vaccination**), including 05 death cases. There was 01 case (death) in indeterminate category.

Vaccine product related reactions are expected reactions that can be attributed to vaccination based on current scientific evidence. Examples of such reactions are allergic reactions and anaphylaxis, etc.

Indeterminate reactions are reactions which have occurred soon after vaccination but there is no definitive evidence in current literature or clinical trial data that this event could have been caused due to the vaccine. Further observations, analysis and studies are required.

Unclassifiable events are events which have been investigated but there is not enough evidence for assigning a diagnosis due to missing crucial information. When this relevant information becomes available, the case may be reconsidered for causality assessment.

Coincidental events are events that are reported following immunization but for which a clear cause other than vaccination is found on investigation.

Overall, the benefits of vaccination are overwhelmingly greater than the small risk of harm. However, as a measure of utmost precaution, all emerging signals of harm are being constantly tracked and reviewed periodically.

**CAUSALITY CLASSIFICATION OF 22 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE
ON 18 OCT 2021- (NEW DELHI)**

A1 - VACCINE PRODUCT RELATED REACTION

A2 - VACCINE QUALITY DEFECT RELATED REACTION

A3 - IMMUNIZATION ERROR RELATED REACTION

A4 - IMMUNIZATION ANXIETY RELATED REACTION

B1 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT

B2 - REVIEWING FACTORS RESULT IN CONFLICTING TRENDS OF CONSISTENCY AND INCONSISTENCY WITH CAUSAL ASSOCIATION TO IMMUNIZATION

C - COINCIDENTAL - UNDERLYING OR EMERGING CONDITION(S), OR CONDITIONS CAUSED BY EXPOSURE TO SOMETHING OTHER THAN VACCINE

D - UNCLASSIFIABLE

S. NO.	NATIONAL ID	YEAR	AGE (IN YEARS)	SEX	REASON FOR REPORTING/ OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	VACCINE	DIAGNOSIS	CLASSIFICATION* BY NATIONAL AEFI COMMITTEE	DATE OF APPROVAL BY NATIONAL AEFI COMMITTEE
1	IND(CO-AEFI)KABMP21002	2021	42	FEMALE	HOSPITALIZED AND RECOVERED	18-01-2021	COVISHIELD	ANXIETY REACTION	A4	18-10-2021
2	IND(CO-AEFI)KACDG21001	2021	50	FEMALE	HOSPITALIZED AND RECOVERED	18-01-2021	COVISHIELD	ANXIETY REACTION	A4	18-10-2021
3	IND(CO-AEFI)KEKZK21001	2021	44	FEMALE	HOSPITALIZED AND RECOVERED	21-01-2021	COVISHIELD	FEVER, HEADACHE AND VOMITING	A1	18-10-2021
4	IND(CO-AEFI)MPMDS21001	2021	26	MALE	HOSPITALIZED AND RECOVERED	16-01-2021	COVISHIELD	ANXIETY REACTION	A4	18-10-2021
5	IND(CO-AEFI)ORBGH21003	2021	28	FEMALE	HOSPITALIZED AND RECOVERED	16-01-2021	COVISHIELD	PNEUMONIA (COVID POSITIVE)	C	18-10-2021
6	IND(CO-AEFI)TSRJS21002	2021	36	FEMALE	HOSPITALIZED AND RECOVERED	18-01-2021	COVISHIELD	NON CARDIAC CHEST PAIN	C	18-10-2021
7	IND(CO-AEFI)MPBHP21001	2021	45	MALE	DEATH	17-02-2021	COVISHIELD	COVID 19 DISEASE	C	18-10-2021
8	IND(CO-AEFI)ORGJM21001	2021	30	FEMALE	HOSPITALIZED AND RECOVERED	19-02-2021	COVISHIELD	CVA (MULTIPLE INFARCTS) IN KNOWN CASE OF TAKAYASU ARTERITIS	C	18-10-2021
9	IND(CO-AEFI)ORSUN21004	2021	25	MALE	HOSPITALIZED AND RECOVERED	18-01-2021	COVISHIELD	ALLERGIC RASH	A1	18-10-2021
10	IND(CO-AEFI)WBDMD21007	2021	45	FEMALE	HOSPITALIZED AND RECOVERED	02-03-2021	COVISHIELD	CVA (ACUTE ISCHEMIC INFARCT- LEFT BASAL GANGLIA) WITH HYPERTENSION	C	18-10-2021
11	IND(CO-AEFI)WBMBD21004	2021	21	FEMALE	SEVERE AND RECOVERED	25-01-2021	COVISHIELD	ANAPHYLAXIS	A1	18-10-2021
12	IND(CO-AEFI)WBSPG21001	2021	76	MALE	DEATH	09-03-2021	COVISHIELD	ACUTE CORONARY SYNDROME WITH UNDERLYING DIABETES MELLITUS, HYPERTENSION AND COPD	C	18-10-2021

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13	IND(CO-AEFI)UPMZP21001	2021	46	MALE	DEATH	15-03-2021	COVISHIELD	HEMORRHAGIC CVA WITH HYPERTENSION	C	18-10-2021
14	IND(CO-AEFI)KARMN21001	2021	36	FEMALE	HOSPITALIZED AND RECOVERED	20-01-2021	COVISHIELD	ACUTE GASTRITIS	C	18-10-2021
15	IND(CO-AEFI)WBBDN21005	2021	78	MALE	DEATH	23-03-2021	COVISHIELD	LOBAR PNEUMONIA WITH EMPHYSEMA WITH PULMONARY ALVEOLAR PROTEINACEOUS WITH INTERSTITIAL LUNG DISEASE WITH PROLIFERATIVE GLOMERULONEPHRITIS	C	18-10-2021
16	IND(CO-AEFI)HAKNL21003	2021	45	FEMALE	HOSPITALIZED AND RECOVERED	29-01-2021	COVISHIELD	ANAPHYLAXIS	A1	18-10-2021
17	IND(CO-AEFI)WBDJL21010	2021	73	FEMALE	HOSPITALIZED AND RECOVERED	18-03-2021	COVISHIELD	POST STROKE EPILEPSY	C	18-10-2021
18	IND(CO-AEFI)KACBP21003	2021	27	FEMALE	HOSPITALIZED AND RECOVERED	19-02-2021	COVISHIELD	EPILEPSY	C	18-10-2021
19	IND(CO-AEFI)GUGNR21003	2021	48	FEMALE	DEATH	25-03-2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH DIABETES MELLITUS AND CORONARY ARTERY DISEASE	C	18-10-2021
20	IND(CO-AEFI)GOGOS21018	2021	20	FEMALE	HOSPITALIZED AND RECOVERED	27-06-2021	COVISHIELD	ANAPHYLAXIS	A1	18-10-2021
21	IND(CO-AEFI)GUGNR21006	2021	21	FEMALE	HOSPITALIZED AND RECOVERED	27-07-2021	COVISHIELD	VASOVAGAL REACTION	A4	18-10-2021
22	IND(CO-AEFI)TNCBE21001	2021	20	FEMALE	DEATH	08-06-2021	COVISHIELD	MULTISYSTEM INFLAMMATORY SYNDROME OF CHILDREN	B1	18-10-2021

*Covid vaccine is a new vaccine. The causality may change as more information become available.

Verified by Dr Anil Gurtoo and Dr Anju Seth on 25th October 2021