

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

Date: 26th August, 2021
Nirman Bhawan, New Delhi

Causality assessment results of 78 reported Serious Adverse Events Following Immunization (AEFI) cases following COVID-19 vaccination approved by National AEFI Committee on 3rd August 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 78 cases completed on 3rd August 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).

48 out of 78 cases for which Causality assessment has been done were found to have consistent causal association to vaccination. Of these 48 cases, 28 cases were vaccine product related reaction and 20 cases were immunization anxiety related reaction. 22 cases have inconsistent causal association to vaccination (coincidental - not linked to vaccination), including 7 death cases. 7 cases were in indeterminate category including 2 death cases. There was 1 death case in unclassifiable 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 78 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 03 AUG 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)DLSWE21001 | 2021 | 35 | FEMALE | SEVERE AND RECOVERED | 23-01-2021 | COVISHIELD | ALLERGIC REACTION | A1 | 03-08-2021 |
| 2 | IND(CO-AEFI)DLSWE21002 | 2021 | 46 | FEMALE | SEVERE AND RECOVERED | 18-01-2021 | COVISHIELD | ALLERGIC REACTION | A1 | 03-08-2021 |
| 3 | IND(CO-AEFI)TSRJS21003 | 2021 | 41 | FEMALE | HOSPITALIZATION AND RECOVERED | 19-01-2021 | COVISHIELD | FEVER WITH VOMITING | A1 | 03-08-2021 |
| 4 | IND(CO-AEFI)WBNPG21001 | 2021 | 53 | FEMALE | HOSPITALIZATION AND RECOVERED | 02-02-2021 | COVISHIELD | ANXIETY REACTION | A4 | 03-08-2021 |
| 5 | IND(CO-AEFI)WBTML21001 | 2021 | 44 | FEMALE | HOSPITALIZATION AND RECOVERED | 27-01-2021 | COVISHIELD | HYPERTENSION | C | 03-08-2021 |
| 6 | IND(CO-AEFI)GUAMC21001 | 2021 | 25 | FEMALE | HOSPITALIZATION AND RECOVERED | 16-01-2021 | COVISHIELD | FEVER WITH CHILLS | A1 | 03-08-2021 |
| 7 | IND(CO-AEFI)KAKPP21001 | 2021 | 34 | FEMALE | HOSPITALIZATION AND RECOVERED | 17-02-2021 | COVISHIELD | ALLERGIC REACTION | A1 | 03-08-2021 |
| 8 | IND(CO-AEFI)WBCAL21016 | 2021 | 34 | MALE | HOSPITALIZATION AND RECOVERED | 20-02-2021 | COVISHIELD | SEIZURE | B2 | 03-08-2021 |
| 9 | IND(CO-AEFI)ASDBR21001 | 2021 | 19 | FEMALE | HOSPITALIZATION AND RECOVERED | 05-02-2021 | COVISHIELD | FEVER WITH INJECTION SITE PAIN | A1 | 03-08-2021 |
| 10 | IND(CO-AEFI)ORB5R21001 | 2021 | 32 | FEMALE | HOSPITALIZATION AND RECOVERED | 18-01-2021 | COVISHIELD | ANXIETY REACTION | A4 | 03-08-2021 |
| 11 | IND(CO-AEFI)ORJSP21001 | 2021 | 45 | FEMALE | HOSPITALIZATION AND RECOVERED | 19-01-2021 | COVISHIELD | MIGRAINE HEADACHE | C | 03-08-2021 |
| 12 | IND(CO-AEFI)BIKHA21001 | 2021 | 40 | FEMALE | HOSPITALIZATION AND RECOVERED | 16-01-2021 | COVISHIELD | VASOVAGAL PRESYNCOPE | A4 | 03-08-2021 |
| 13 | IND(CO-AEFI)BISAR21001 | 2021 | 41 | FEMALE | HOSPITALIZATION AND RECOVERED | 16-01-2021 | COVISHIELD | ANXIETY REACTION | A4 | 03-08-2021 |
| 14 | IND(CO-AEFI)BUJM21001 | 2021 | 56 | FEMALE | HOSPITALIZATION AND RECOVERED | 25-01-2021 | COVISHIELD | ANXIETY REACTION | A4 | 03-08-2021 |
| 15 | IND(CO-AEFI)WBBKR21001 | 2021 | 26 | FEMALE | HOSPITALIZATION AND RECOVERED | 28-01-2021 | COVISHIELD | ANAPHYLAXIS | A1 | 03-08-2021 |
| 16 | IND(CO-AEFI)DLSOU21002 | 2021 | 57 | MALE | HOSPITALIZATION AND RECOVERED | 28-01-2021 | COVAXIN | ANXIETY REACTION | A4 | 03-08-2021 |
| 17 | IND(CO-AEFI)BISAR21002 | 2021 | 39 | FEMALE | HOSPITALIZATION AND RECOVERED | 16-01-2021 | COVISHIELD | DIZZINESS | A1 | 03-08-2021 |
| 18 | IND(CO-AEFI)UPBJN21001 | 2021 | 22 | FEMALE | HOSPITALIZATION AND RECOVERED | 28-01-2021 | COVISHIELD | ANAPHYLAXIS | A1 | 03-08-2021 |
| 19 | IND(CO-AEFI)KEKLM21001 | 2021 | 51 | FEMALE | DEATH | 28-01-2021 | COVISHIELD | ACUTE INFERIOR WALL MI WITH RIGHT VENTRICULAR INFARCTION, ATRIAL FIBRILLATION AND CARDIOGENIC SHOCK | C | 03-08-2021 |
| 20 | IND(CO-AEFI)UPGBN21002 | 2021 | 26 | FEMALE | HOSPITALIZATION AND RECOVERED | 29-01-2021 | COVISHIELD | ANAPHYLAXIS | A1 | 03-08-2021 |
| 21 | IND(CO-AEFI)TSPDP21001 | 2021 | 42 | FEMALE | HOSPITALIZATION AND RECOVERED | 21-01-2021 | COVISHIELD | COVID 19 DISEASE | C | 03-08-2021 |
| 22 | IND(CO-AEFI)DLWES21005 | 2021 | 24 | MALE | HOSPITALIZATION AND RECOVERED | 30-01-2021 | COVAXIN | ALLERGIC REACTION | A1 | 03-08-2021 |
| 23 | IND(CO-AEFI)DLNOR21001 | 2021 | 31 | FEMALE | HOSPITALIZATION AND RECOVERED | 02-02-2021 | COVISHIELD | ANAPHYLAXIS | A1 | 03-08-2021 |
| 24 | IND(CO-AEFI)DLSOE21001 | 2021 | 44 | FEMALE | HOSPITALIZATION AND RECOVERED | 03-02-2021 | COVISHIELD | HYPERTENSION | C | 03-08-2021 |
| 25 | IND(CO-AEFI)DLSOU21003 | 2021 | 43 | FEMALE | HOSPITALIZATION AND RECOVERED | 02-02-2021 | COVAXIN | ANXIETY REACTION | A4 | 03-08-2021 |
| 26 | IND(CO-AEFI)DLSOU21004 | 2021 | 39 | FEMALE | HOSPITALIZATION AND RECOVERED | 28-01-2021 | COVAXIN | FEVER WITH ARTHRALGIA | B1 | 03-08-2021 |
| 27 | IND(CO-AEFI)KADHA21001 | 2021 | 54 | FEMALE | HOSPITALIZATION AND RECOVERED | 18-01-2021 | COVISHIELD | GBS | B1 | 03-08-2021 |
| 28 | IND(CO-AEFI)MHTHN21005 | 2021 | 47 | FEMALE | HOSPITALIZATION AND RECOVERED | 04-02-2021 | COVISHIELD | SEIZURE | C | 03-08-2021 |
| 29 | IND(CO-AEFI)PBSAN21004 | 2021 | 52 | FEMALE | HOSPITALIZATION AND RECOVERED | 22-01-2021 | COVISHIELD | COVID 19 DISEASE | C | 03-08-2021 |

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| 30 | IND(CO-AEFI)GUJMC21009 | 2021 | 23 | FEMALE | HOSPITALIZATION AND RECOVERED | 28-01-2021 | COVISHIELD | FLU LIKE ILLNESS | A1 | 03-08-2021 |
| 31 | IND(CO-AEFI)WBDMD21006 | 2021 | 32 | FEMALE | HOSPITALIZATION AND RECOVERED | 06-02-2021 | COVISHIELD | FEBRILE ILLNESS | A1 | 03-08-2021 |
| 32 | IND(CO-AEFI)RJGGN21001 | 2021 | 26 | FEMALE | HOSPITALIZATION AND RECOVERED | 25-01-2021 | COVISHIELD | ANAPHYLAXIS | A1 | 03-08-2021 |
| 33 | IND(CO-AEFI)MHBM21003 | 2021 | 47 | FEMALE | HOSPITALIZATION AND RECOVERED | 29-01-2021 | COVISHIELD | MILD COVID 19 DISEASE | C | 03-08-2021 |
| 34 | IND(CO-AEFI)WBUDJ21001 | 2021 | 48 | FEMALE | HOSPITALIZATION AND RECOVERED | 03-02-2021 | COVISHIELD | ACUTE RESPIRATORY TRACT INFECTION | C | 03-08-2021 |
| 35 | IND(CO-AEFI)CGJHP21002 | 2021 | 29 | FEMALE | HOSPITALIZATION AND RECOVERED | 06-02-2021 | COVISHIELD | HYSTERICAL CONVERSION REACTION | C | 03-08-2021 |
| 36 | IND(CO-AEFI)GUJMC21005 | 2021 | 20 | FEMALE | HOSPITALIZATION AND RECOVERED | 28-01-2021 | COVISHIELD | FEVER | A1 | 03-08-2021 |
| 37 | IND(CO-AEFI)GUJMC21003 | 2021 | 24 | FEMALE | HOSPITALIZATION AND RECOVERED | 28-01-2021 | COVISHIELD | ACUTE FEBRILE REACTION | A1 | 03-08-2021 |
| 38 | IND(CO-AEFI)GUJMC21008 | 2021 | 46 | MALE | HOSPITALIZATION AND RECOVERED | 28-01-2021 | COVISHIELD | RIGHT FACIAL NERVE PALSY | B1 | 03-08-2021 |
| 39 | IND(CO-AEFI)PBSAN21003 | 2021 | 26 | FEMALE | HOSPITALIZATION AND RECOVERED | 22-01-2021 | COVISHIELD | NUMBNESS IN LEFT HAND | C | 03-08-2021 |
| 40 | IND(CO-AEFI)PBLDN21002 | 2021 | 32 | FEMALE | HOSPITALIZATION AND RECOVERED | 28-01-2021 | COVISHIELD | ANAPHYLAXIS | A1 | 03-08-2021 |
| 41 | IND(CO-AEFI)PBLDN21003 | 2021 | 23 | FEMALE | HOSPITALIZATION AND RECOVERED | 28-01-2021 | COVISHIELD | FEVER | A1 | 03-08-2021 |
| 42 | IND(CO-AEFI)WBCAL21006 | 2021 | 36 | FEMALE | HOSPITALIZATION AND RECOVERED | 25-01-2021 | COVISHIELD | FEVER AND VOMITING | A1 | 03-08-2021 |
| 43 | IND(CO-AEFI)KAUDU21003 | 2021 | 46 | FEMALE | HOSPITALIZATION AND RECOVERED | 22-02-2021 | COVISHIELD | ANXIETY REACTION | A4 | 03-08-2021 |
| 44 | IND(CO-AEFI)MHBM21021 | 2021 | 52 | MALE | HOSPITALIZATION AND RECOVERED | 16-01-2021 | COVISHIELD | ACUTE FEBRILE ILLNESS WITH VOMITING | A1 | 03-08-2021 |
| 45 | IND(CO-AEFI)UPBRL21002 | 2021 | 40 | FEMALE | SEVERE AND RECOVERED | 29-01-2021 | COVISHIELD | ANXIETY REACTION | A4 | 03-08-2021 |
| 46 | IND(CO-AEFI)UPBRL21005 | 2021 | 30 | FEMALE | SEVERE AND RECOVERED | 29-01-2021 | COVISHIELD | ANXIETY REACTION | A4 | 03-08-2021 |
| 47 | IND(CO-AEFI)WBBDN21001 | 2021 | 48 | FEMALE | HOSPITALIZATION AND RECOVERED | 10-03-2021 | COVISHIELD | FEVER AND DIARRHEA | A1 | 03-08-2021 |
| 48 | IND(CO-AEFI)HPMND21001 | 2021 | 74 | FEMALE | HOSPITALIZATION AND RECOVERED | 09-03-2021 | COVISHIELD | BENIGN PAROXYSMAL POSITIONAL VERTIGO WITH UNDERLYING HYPERTENSION/ DIABETES MELLITUS/ HYPOTHYROIDISM | C | 03-08-2021 |
| 49 | IND(CO-AEFI)WBBDN21002 | 2021 | 42 | FEMALE | SEVERE AND RECOVERED | 16-01-2021 | COVISHIELD | ALLERGIC REACTION | A1 | 03-08-2021 |
| 50 | IND(CO-AEFI)PBLDN21005 | 2021 | 23 | MALE | HOSPITALIZATION AND RECOVERED | 17-02-2021 | COVISHIELD | FEVER | A1 | 03-08-2021 |
| 51 | IND(CO-AEFI)DLNDL21003 | 2021 | 56 | MALE | SEVERE AND RECOVERED | 13-02-2021 | COVISHIELD | ALLERGIC REACTION | A1 | 03-08-2021 |
| 52 | IND(CO-AEFI)WBCAL21022 | 2021 | 31 | FEMALE | HOSPITALIZATION AND RECOVERED | 16-03-2021 | COVISHIELD | FEVER AND VOMITING | A1 | 03-08-2021 |
| 53 | IND(CO-AEFI)WBDMD21009 | 2021 | 64 | MALE | HOSPITALIZATION AND RECOVERED | 10-04-2021 | COVISHIELD | VERTIGO | A4 | 03-08-2021 |
| 54 | IND(CO-AEFI)HHJMT21002 | 2021 | 70 | MALE | DEATH | 17-04-2021 | COVISHIELD | SUDDEN UNEXPLAINED DEATH | D | 03-08-2021 |
| 55 | IND(CO-AEFI)RJALW21007 | 2021 | 71 | FEMALE | DEATH | 03-04-2021 | COVISHIELD | SUDDEN CARDIAC DEATH | C | 03-08-2021 |
| 56 | IND(CO-AEFI)HPMND21007 | 2021 | 71 | MALE | HOSPITALIZATION AND RECOVERED | 19-05-2021 | COVISHIELD | ISCHEMIC STROKE | B1 | 03-08-2021 |
| 57 | IND(CO-AEFI)TNCNI21015 | 2021 | 54 | MALE | DEATH | 13-04-2021 | COVISHIELD | ATYPICAL PNEUMONIA WITH PULMONARY EMBOLISM | C | 03-08-2021 |
| 58 | IND(CO-AEFI)TNKKM21001 | 2021 | 62 | MALE | DEATH | 01-02-2021 | COVISHIELD | COVID 19 DISEASE (SEVERE) | C | 03-08-2021 |

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|--------|------------------------|------|----------------|--------|-------------------------------|----------------------------------|------------|---|--|---|
| 59 | IND(CO-AEFI)MEWJH21001 | 2021 | 79 | MALE | DEATH | 13-05-2021 | COVISHIELD | SUDDEN CARDIAC DEATH | B1 | 03-08-2021 |
| 60 | IND(CO-AEFI)WBAPD21011 | 2021 | 49 | FEMALE | HOSPITALIZATION AND RECOVERED | 18-01-2021 | COVISHIELD | ANXIETY REACTION | A4 | 03-08-2021 |
| 61 | IND(CO-AEFI)WBAPD21012 | 2021 | 54 | FEMALE | HOSPITALIZATION AND RECOVERED | 22-01-2021 | COVISHIELD | ANXIETY REACTION WITH UNDERLYING HYPERTENSION | A4 | 03-08-2021 |
| 62 | IND(CO-AEFI)GUJMC21010 | 2021 | 68 | FEMALE | SEVERE AND RECOVERED | 06-04-2021 | COVISHIELD | HYPERTENSION | C | 03-08-2021 |
| 63 | IND(CO-AEFI)RJPR21012 | 2021 | 22 | MALE | HOSPITALIZATION AND RECOVERED | 16-05-2021 | COVISHIELD | ANXIETY REACTION | A4 | 03-08-2021 |
| 64 | IND(CO-AEFI)WBMLD21002 | 2021 | 60 | FEMALE | SEVERE AND RECOVERED | 15-02-2021 | COVISHIELD | ANXIETY REACTION | A4 | 03-08-2021 |
| 65 | IND(CO-AEFI)RJUN21003 | 2021 | 32 | FEMALE | HOSPITALIZATION AND RECOVERED | 22-02-2021 | COVISHIELD | LOWER RESPIRATORY TRACT INFECTION | C | 03-08-2021 |
| 66 | IND(CO-AEFI)WBMLD21003 | 2021 | 66 | MALE | DEATH | 22-03-2021 | COVISHIELD | CHRONIC DIARRHOEA WITH SEVERE MALNUTRITION | C | 03-08-2021 |
| 67 | IND(CO-AEFI)WBCAL21029 | 2021 | 39 | FEMALE | HOSPITALIZATION AND RECOVERED | 01-06-2021 | COVISHIELD | VASOVAGAL PRESYNCOPE | A4 | 03-08-2021 |
| 68 | IND(CO-AEFI)WBDJL21006 | 2021 | 28 | FEMALE | SEVERE AND RECOVERED | 23-02-2021 | COVISHIELD | DIARRHOEA AND VOMITING | A1 | 03-08-2021 |
| 69 | IND(CO-AEFI)WBDJL21015 | 2021 | 68 | FEMALE | HOSPITALIZATION AND RECOVERED | 06-04-2021 | COVAXIN | COVID-19 DISEASE | C | 03-08-2021 |
| 70 | IND(CO-AEFI)TNCNI21017 | 2021 | 69 | FEMALE | DEATH | 30-04-2021 | COVISHIELD | SUDDEN CARDIAC DEATH | B1 | 03-08-2021 |
| 71 | IND(CO-AEFI)WBASN21007 | 2021 | 64 | MALE | DEATH | 03-05-2021 | COVISHIELD | ACUTE CORONARY SYNDROME | C | 03-08-2021 |
| 72 | IND(CO-AEFI)WBDJL21019 | 2021 | 36 | FEMALE | HOSPITALIZATION AND RECOVERED | 22-01-2021 | COVISHIELD | NON-SPECIFIC JOINT PAIN | C | 03-08-2021 |
| 73 | IND(CO-AEFI)WBDJL21020 | 2021 | 52 | MALE | SEVERE AND RECOVERED | 28-01-2021 | COVISHIELD | ANXIETY REACTION | A4 | 03-08-2021 |
| 74 | IND(CO-AEFI)WBDJL21021 | 2021 | 31 | FEMALE | SEVERE AND RECOVERED | 22-01-2021 | COVISHIELD | FEVER WITH INJECTION SITE PAIN | A1 | 03-08-2021 |
| 75 | IND(CO-AEFI)WBDJL21022 | 2021 | 41 | FEMALE | SEVERE AND RECOVERED | 19-01-2021 | COVISHIELD | ANXIETY REACTION | A4 | 03-08-2021 |
| 76 | IND(CO-AEFI)TNCNI21018 | 2021 | 63 | FEMALE | DEATH | 18-03-2021 | COVISHIELD | COVID 19 DISEASE | C | 03-08-2021 |
| 77 | IND(CO-AEFI)TSHYD21001 | 2021 | 46 | MALE | SEVERE AND RECOVERED | 09-02-2021 | COVAXIN | VASOVAGAL ATTACK | A4 | 03-08-2021 |
| 78 | IND(CO-AEFI)MPRTM21002 | 2021 | 35 | FEMALE | HOSPITALIZATION AND RECOVERED | 07-06-2021 | COVISHIELD | ANXIETY REACTION | A4 | 03-08-2021 |

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

Verified by Dr Anju Seth and Dr Anil Gurtoo on 13th August 2021