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Editorial

COVID 19 Pandemic Vaccination Drive: Adverse Event Following Immunization Protocol.

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The COVID 19 Pandemic is one of the deadliest ongoing global pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) which is a single linear RNA segment (positive-sense-single–stranded RNA). Till date, more than 129 million cases were confirmed and it attributed around 2.81 million deaths due to COVID-19.[1] The virus mainly spreads amongst near contacts through air as it leaves from infected person's breathe, sneeze, cough or speak. Usual entry points are nose, mouth, or eyes. There are chances of spread of virus from contaminated surfaces. The important preventive measures include wearing masks over face covering nose and mouth, following social distancing norms, avoiding crowded places, frequent hand washing, sanitization of infected areas, self-monitoring and self-isolation measures.[2]

Vaccines are considered as one of important preventive measures against this deadly virus. Many vaccines have shown efficacy around 95% in phase III trial. The vaccination drives are launched in many countries in phased manner with prioritizing high risk groups such as health care workers, elderly people with co-morbidities, etc. In India, various laboratories are trying to develop an effective vaccine against COVID 19. The Drug Controller General of India (DCGI) given approval to two vaccines viz. **Covishield** vaccine on 1st of January 2021[3] and **Covaxin** on 2nd January 2021[4] for conditional and emergency use. In India, the national vaccination drive started at 3006 vaccination centre on 16th January 2021.[5] With the background of COVID-19 vaccination, there is need for identification of AEFI (adverse events following immunisation) as well as adverse events of special interest by the surveillance teams.[6]

Adverse Event Following Immunisation (AEFI):

Adverse event following immunization (AEFI) includes various untoward medical occurrence followed by vaccination. It may not have a direct causal relationship with use of vaccine. Such events need to be dealt effectively at the earliest to avoid the dramatic consequences due to loss of faith in vaccination drive. The prompt investigations into the incidences of such untoward medical occurrences facilitates research to identify the reasons and further appropriate needed action. WHO has established a Global Advisory Committee on Vaccine Safety to dealt efficiently, promptly towards the vaccine safety issues.[7] In 2012, Council for International Organisations of Medical Sciences (CIOMS) given revised classification relevant to cause-specific categorisation of AEFI as follows:

Cause-specific categorisation of AEFI (CIOMS/WHO 2012):

1. Vaccine product-related reaction
2. Vaccine quality defect-related reaction
3. Immunization error-related reaction
4. Immunization anxiety-related reaction
5. Coincidental event.

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The various types of Adverse Effect Following Immunization in accordance with the severity and frequency are as follows:

1. **Common Minor AEFIs:** Recipient's immune system react to the vaccine leading to events like fever, local reaction, etc.
2. **Severe AEFIs:** AEFIs which are not included as minor events but it also not leading to hospitalisation, disability or death.
3. **Serious AEFIs:** AEFIs leading to hospitalization, disability or death are included in Serious AEFIs.
4. **Cluster:** When two and more adverse effects following immunizations (AEFIs) occur in relation to time, place or vaccine termed as cluster. It usually associated with particular health facility, vaccine manufacturer, or vaccine vial. Such cluster occur mainly due to immunization error or anxiety-related reactions when vaccines administered on massive scale.
5. **Signal:** It is information received from multiple sources suggesting causal association between set of related events. Such information may be adverse or beneficial.

As the vaccination drive for COVID-19 is on larger scale, there is very high possibility of errors during immunization and as it involves subjects of all ages, anxiety related reactions will be on higher side. The government should be in position to tackle the clusters as compared to routine vaccination. [6]

Reporting: All serious/severe AEFI need to be reported after filling Case Report Form (CRF). The report needs to be sent to District Immunization Officer (DIO) within 24 hours who after verification of the case details in next 24 hours, forwards the information to the state and national level committee.[6] Co-WIN software have been used for reporting of AEFI as well as action for events subsequent to vaccination (SAFEVAC). [8]

AEFI Investigation[9]:

The District Immunization Officer (DIO) usually lead the case investigation with support of team members from District AEFI Committee. Various steps in investigation includes confirmation of information stated in report; investigate and collect data about patient, event, suspected vaccine and other people; assess immunization service; specimen collection as needed **(refer table no. 1)** and conclude investigation.

Table 1: Specimen collection from Patient

Sr No	Event	Specimen from Patient
1	Severe Local Reaction	Blood
2	CNS symptoms with no paralysis	Cerebrospinal fluid, Blood.
3	CNS symptoms with paralysis	Stool
4	Lymphadenitis	Blood
5	Anaphylaxis	Blood
6	Toxic shock syndrome	Blood
7	Abscess	Swab, blood.
8	Death	Postmortem Tissue Specimen

Investigation of reported AEFI Deaths:

Death is a serious AEFI event and hence prompt field investigation is necessary. It may cause dramatic community consequences about faith in vaccine and may affect the vaccination drive severely. An AEFI death reports are notified at all administrative level including National AEFI Secretariat of Immunization Division in Ministry of Health and Family Welfare (MoHFW).

The investigation in reported AEFI Deaths carried out by a multi-speciality team which includes clinician, laboratory and forensic experts. All necessary information on event needs to be made available to the concerned team. Various potential sources of information include verbal autopsy, medical consultation and hospital records, lab investigation reports, home visits, community visits by team, interactions with treating physician and vaccinator, etc. There is need of timely, methodical and comprehensive investigation to dealt such event promptly.[9]

In AEFI pertaining to COVID 19, it is needed to note the name of brand, manufacturer and batch numbers so as to relate the type of vaccine used in the country. WHO recommends Vigiflow AEFI line list to collect the particulars in the reporting form COVID-19. It is mandatory for every country to launch causality assessment processes before beginning the vaccination drive. As the age group of the persons undergoing vaccination is spread throughout, AEFI causality assessment committees must be comprising of multiple specialities.[6]

AEFI causality assessment committee should take into consideration the issues pertaining to COVID 19 vaccine. Few live attenuated vaccines can cause vaccine-associated enhanced disease. There is possible risk of getting affected by COVID 19 disease in severe form subsequent to COVID 19 vaccination on exposure to COVID 19 virus. Till date, deaths occurring following COVID 19 vaccination are not known to linked with it. Even if the complications arising are mild in nature which can be controlled by the medication. [6]

AEFI Deaths- Autopsy guidelines[9]:

Autopsy is mandatory in all such AEFI deaths to exclude any other coincidental cause of death. It is necessary to conduct Post-mortem examination on such deceased at the earliest (within 72 hours) to avoid tissue damage, development of post-mortem artefacts due to decomposition process, and adrenal gland lysis altering diagnosis. The District Immunization Officer need to provide detailed patient's history and all relevant information on the event to the autopsy surgeon.

Autopsy need to be performed by a multi-speciality experts team comprised of Forensic specialist, pathologist, clinician, etc. The autopsy is conducted abiding the guidelines given in **annexure 17** of the AEFI Surveillance and Response Operational guidelines 2015 as soon as possible within 72 hours.[7] Various tissue samples need to be preserved and sent for histopathological, virological, genetic testing and toxicological examination to concerned approved and accredited Government reference laboratories. In case the autopsy is not performed, comprehensive verbal autopsy to be done and findings obtained to be sent to National AEFI committee. [10]

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