ABSTRACT

COVID-19 – Health and Family Welfare department – Adverse Event Following Immunization (AEFI) Management Guidelines – Orders – Issued.

HEALTH AND FAMILY WELFARE (P1) DEPARTMENT

G.O.(Ms).No.344

Dated: 06.08.2021
Pilava, Aadi - 21
Thiruvalluvar Aandu – 2052

Read :

1. G.O.(Ms).No.319, Health and Family Welfare (P1) Department dated: 31.08.2020.
2. G.O.(Ms).No.88, Health and Family Welfare (P1) Department dated: 24.02.2021.
3. Mail received from the Director of Public Health and Preventive Medicine, dated:01.08.2021.

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ORDER:-

In Government order first read above, the Government have issued comprehensive guidelines for COVID-19. In Government order second read above, modified comprehensive guidelines have been issued for COVID-19 testing strategy, guidelines for home isolation, demarcation of containment zone, categorization of patients and discharge policy for Covid-19 patients.

2. The Director of Public Health and Preventive Medicine has sent draft AEFI Management Guidelines for approval of the Government.

3. The Government have examined the draft AEFI Management Guidelines prepared and issue the following AEFI Management Guidelines:-

Adverse Event Following Immunization (AEFI) Management Guidelines

An Adverse Event Following Immunization (AEFI) is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.
For the purpose of reporting, AEFIs can be minor, severe and serious.

Minor AEFI	Severe AEFI	Serious AEFI
• Common, self-limiting reactions Examples: pain, swelling at injection site, fever, irritability, malaise etc.	• Can be disabling and rarely life threatening • Do not lead to long-term problems Examples: include non-hospitalized cases of anaphylaxis that has recovered, high fever (>102-degree F), etc.	• Death • Inpatient hospitalization • Persistent or significant disability • Cluster • Significant parental/community concern

AEFI Management Kits

- Ensure recipients wait for 30 minutes at session site after vaccination
- After vaccination, inform the vaccine recipient
- About minor events which may occur - mild to moderate fever, local pain and swelling at injection site, malaise etc.
- Tablet Paracetamol SOS with a minimum interval of 4 hours between two doses
- Visit nearest health facility, if minor adverse event persists beyond 2-3 days
- For any other severe / serious event, immediately refer to a secondary or tertiary care health facility
- Anaphylaxis kit with Inj.Adrenaline within expiry date at outreach session site
- Inform Medical Officer immediately by telephone about serious/severe AEFIs
- Emergency numbers (102, 108, etc.) for transporting case to AEFI management center / higher health facility with vaccinator team

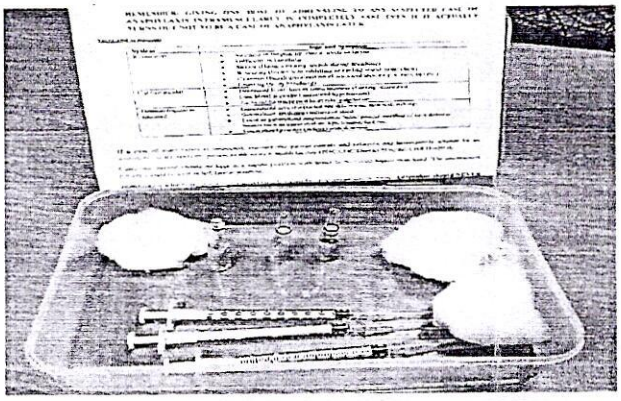
At fixed session sites, an AEFI management kit or an emergency tray should be available for use. The contents of the AEFI Management Kits are

- Inj.Adrenaline (1:1000) (3)
- Inj. Hydrocortisone (3)
- Ringer Lactate/ Normal saline (2)
- IV drip set (2)
- Scalp vein sets or IV cannula (2)
- Disposable syringes – 5 ml with 24/25G IM needle (3 sets)
- Adhesive tape and blank Case Reporting Forms (CRF)

Anaphylaxis Kits

- Job aid for recognizing anaphylaxis
- Dose chart for adrenaline as per age
- 1 ml ampoule of adrenaline (1:1000 aqueous solution)-3 nos.

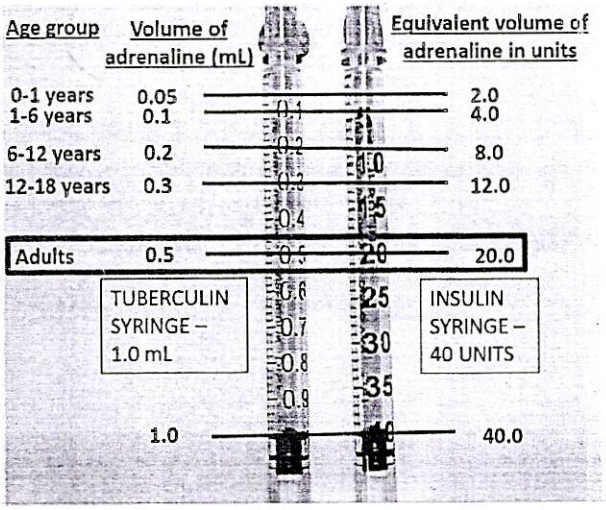
- Tuberculin syringes (1 ml) or insulin syringe (of 40 units, without fixed needle)- 3 nos.



- 24G/25G needles (1 inch)-3nos.
- Swabs – 3 nos.
- Updated contact information of SIO (DDHS), Medical Officers of PHC, referral center and ambulance services
- Certification by Medical Officer for expiry dates of contents.

Initial management of Anaphylaxis
Suspected anaphylaxis:

- Early onset and rapid progression of symptoms
- At least one sign/symptom related to at least two of the following three systems
  - **Respiratory**
  - **Cardiovascular**
  - **Dermatological/mucosal**
- *Adrenaline* is the drug of choice to treat anaphylaxis
- Ensure adequate stock of adrenaline for supplying to sessions



Reporting and Recording

- Any adverse event following COVID-19 vaccination must be reported. There is no time limit (between vaccination and onset of symptoms) for reporting AEFIs. If the health worker or the treating physician or anyone suspects the event to be due to vaccination, it should be reported.
- State and District Authorities (DIO/CMO or the Block MO) should proactively reach out to all health care service providers such as Medical colleges, Hospitals (Public, Autonomous and Private) and individual practitioners and sensitize them to report any adverse event following COVID-19 vaccine as per guidelines.
- Doctors should ask and record history of COVID-19 vaccination in OPD prescriptions, casualty records, clinical treatment sheets, etc. Patients with history of COVID-19 vaccination (any duration) in which onset of symptoms has occurred after COVID-19 vaccination should be considered as AEFIs and reported by the treating doctor to the nearest PHC doctor or District Immunization Officer (DDHS) in Case Reporting Format or telephonically. During investigation conducted by the DIO/ district AEFI committee, all treatment records of the patient must be shared for causality assessment.
- Professional bodies like IAP, IMA, IPHA, partner agencies like WHO-NPSP, UNICEF, UNDP, USAID, PATH and others should also be encouraged to support AEFI surveillance.
- Blank copies of Case Reporting Formats (CRF) should be available with potential reporters to capture AEFI details. The reporter should also know whom to report. Thereafter, the case should be investigated by the district health authorities (DIO with support of the district AEFI committee members.

Immediate Reporting of Serious and Sever AEFIS

A serious or severe AEFI case needs to be reported immediately to the concerned Medical Officer or the appropriate health authorities. Soon after the identification / notification of a serious and serve AEFI, a two –step process must be initiated.

Step:1

Report serious and severe AEFI to the appropriate authority (DIO or the nearest government health facility) in Case Reporting Format.

Step: 2

- Investigation of all reported serious and severe AEFI by District Immunization Officer or District AEFI Committee.
- All serious and severe AEFIs should be treated as a medical emergency and priority should be given to its management followed by its reporting and investigation on the standardized AEFI formats. All serious and severe AEFIs should be documented on a CASE REPORTING FORM (CRF).

Route of Reporting

Reporting through Co-WIN

Co-WIN is a web-based application developed for management of COVID-19 vaccination process including AEFI reporting in the beneficiary module of

Co-WIN, there is a provision for reporting of AEFI cases following COVID-19 vaccines.

- All adverse events (minor, severe and serious) following COVID-19 vaccination must be reported in Co-WIN by
- The vaccinator through vaccinator's module.
- The DIO through district login in Co-WIN.
- Immediately inform severe and serious AEFI cases telephonically by vaccinator to supervisor/medical officer/DIO
- Only basic information is entered in Co-WIN, which is automatically transferred to SAFE-VAC.
- Once the basis case details are entered through Co-WIN, DIO can generate CRF for a serious/severe case. DIO, using a single sign-on through Co-WIN, can access SAFE-VAC for AEFI is related to COVID-19 vaccines and can enter information into CRF, PCIF, FCIF and can upload the documents.

AEFI registers at PHC/block/planning unit levels:
VHNs/ANMs at block/planning unit should notify all AEFIs (serious, severe and minor) of their respective areas on weekly basis and document them in the AEFI register which is being maintained at the centre. Medical Officer in-charge of the block or planning programme errors and inform to District Immunization Officer.

Reporting and investigation of cluster AEFI cases:
Cluster of AEFI cases is a specific condition which warrants immediate investigation because of its nature and seriousness. Each case of an AEFI cluster should be separately reported and investigated as per national AEFI guidelines.
For known anxiety clusters, separate CRFs should be filled for each case of a cluster. In confirmed anxiety clusters ONLY, if symptoms, clinical sequence of events, treatment and outcome are similar in all cases, a single, completely-filled PCIF and FCIF with all critical information recorded can be submitted. In addition, a summary report of the district AEFI committee certifying that this is an anxiety cluster should also be submitted along with the CRFs, PCIF, FCIF, hospital records etc., of the cluster.

Investigation of AEFI Cases
All serious and severe AEFI cases after COVID-19 vaccines must be investigated as per the National AEFI Guidelines. The process of investigation must be expedited for collecting accurate and complete clinical and epidemiological facts so that causality assessment can be completed as soon as possible. Following actions are required in advance as preparation for investigation of cases:

- District AEFI committee meetings must be held at least one month prior to the start of COVID-19 vaccination. All members of the committee must be sensitized, and their services should be utilized, it needed, to investigate the cases.
- The district AEFI committees must include drug inspectors and ensure their support in the investigations.
- Medical Officers of government and private health care facilities, where serious AEFI cases are expected to reach for treatment, must be informed and sensitized about AEFI surveillance for immediate reporting and cooperation in investigations. Their support is also crucial for ensuring availability of medical records and clinical details of the cases which are required for causality assessment of the cases.

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If a death following vaccination is reported, and the case was not hospitalised or clinical records are not available, relatives should be motivated to give consent for post mortem. Post mortems should be conducted to find the pathological cause of death. Any samples sent for laboratory tests should be followed up for obtaining results as soon as possible.

If consent for post mortem is refused, the AEFI verbal autopsy form should be administered as soon as possible.

(BY ORDER OF THE GOVERNOR)

J.RADHAKRISHNAN,
PRINCIPAL SECRETARY TO GOVERNMENT.

To
The Principal Secretary / Commissioner, Greater Chennai Corporation, Chennai – 600 003.
The Director of Public Health and Preventive Medicine, Chennai – 600 006.
The Director of Medical Education, Chennai – 600 010.
The Director of Medical and Rural Health Services, Chennai – 600 006.
All Deans of the Medical Colleges (through the Director of Medical Education, Chennai- 600 010)
All District Collectors.

Copy to:-
The Senior Personal Assistant to Hon'ble Minister (Medical and Family Welfare), Chennai – 600 00
The Principal Private Secretary to Chief Secretary, Chennai – 600 009.
Stock File / Spare Copy / Data Cell.

// FORWARDED BY ORDER //

6/8/21

SECTION OFFICER

6/8/21