T.13020/08/2018-IMM
Government of India
Ministry of Health and Family Welfare
(Immunization Division)

Nirman Bhawan, New Delhi
Dated: 21st August, 2024

To

1. President, Indian Academy of Paediatrics, Mumbai
2. National President, Indian Medical Association, New Delhi
3. President, The Association of Physicians of India, Mumbai
4. President, Federation of Obstetrics and Gynaecological Societies of India, Mumbai
5. President, Trained Nurses Association of India, New Delhi

Sub: Reporting of Adverse Events Following Immunization (AEFI) – Advocacy and sensitization efforts- reg.

Sir/Madam,

As you are aware, the Government of India's Universal Immunization Programme (UIP) is one of the largest public health programme gobally. Vaccines are also administered by the private sector to various populations, including infants, children, pregnant women, the elderly, vulnerable patients (e.g., those on immunosuppressants), professionals in certain fields (e.g., forest guards, food industry workers and international travelers, covering diseases such as Influenza, Rabies, Typhoid, Cholera, Kyasanur Forest Disease, Yellow Fever and Meningococcal infections.

An Adverse Event Following Immunization (AEFI) surveillance system is in place to monitor the safety of all vaccines, including those listed above and those administered in the private sector. Over the past decade, the reporting, investigation and causality assessment of AEFIs have been significantly strengthened. In January 2024, the revised National AEFI Surveillance and Response Operational Guidelines – 2024 were released, with representatives from your organization participating in the national dissemination workshops.

We seek your support in enhancing AEFI reporting by members of your association through advocacy and awareness activities aimed at increasing the reporting of AEFIs to the District Immunization Officer (or DRCHO in certain states). Enclosed, please find a note detailing activities to advocate for AEFI reporting through various channels. Additionally, Annexure A, which contains the guidelines for AEFI reporting, is attached for display on your association's website.

For further details, please contact Dr Deepak Polpakara (Mob:9868878721; deepak_polpakara@in.jsi.com ; aefiindia@gmail.com).

Yours faithfully,

21.08.2024

(Dr Pawan Kumar)
Additional Commissioner (IMM)

Copy to:

1. MD-NHM, all States/UTs
2. SEPIOs, all States/UTs
3. Dr. Deepak Polpakara, Team Lead – AEFI, AEFI Secretariat

NOTE

Role of professional associations and bodies in enhancing reporting of Adverse Events Following Immunization (AEFI)

Professional associations and bodies can support the Government in enhancing AEFI reporting by:

1. Requesting state/district/local chapters of the association/body to
    a. Engage with the DIO/DRCHO and Surveillance Medical Officer of WHO-NPSP by inviting the DIO/DRCHO/SMO to take a session on AEFI surveillance in monthly meetings of local/district/state chapters
    b. Including AEFI surveillance as a topic in CMEs, workshops, and trainings.

2. Advocate reporting of AEFIs on home page of official websites by
    a. Displaying a message for reporting AEFIs (**see Annexure A**)
    b. Providing a
        i. downloadable blank Case Reporting Form on the website for reporting serious and severe AEFIs
        ii. Link to the website for the national AEFI surveillance guidelines of 2024 and link for the CRF

Annexure A

Guidelines for reporting serious / severe AEFIs

Why should AEFIs be reported?

1. Every AEFI reported (and subsequently investigated and causally assessed) contributes to vaccine safety surveillance. AEFI surveillance provides the evidence to show that the vaccines being administered to the beneficiaries are safe, thus assuring public confidence in vaccines.
2. It helps to identify events which are due to errors in handling, storage and administration and manufacturing issues which are preventable; ensure expected reactions occur within the expected rate; and inform the community that coincidental events are not related to vaccination.

What to report?

1. An AEFI can be a case brought for treatment to your clinic/institution after vaccination in another place or vaccinated in your own clinic /institution.
2. Ask for vaccination history in all cases and write in treatment records.
3. Adverse events suspected to be caused due to vaccination should be reported.
4. Adverse events known to occur following vaccination such as febrile seizures following DwPT/pentavalent vaccine or anaphylaxis following any vaccination or anxiety reactions also need to be reported.
5. Report any death/hospitalization/congenital anomaly/disability or events occurring in clusters following any vaccination

Whom to report?

1. Report immediately to the District Immunization Officer/District RCH Officer.

How to report?

1. Report using the Case Reporting Format (CRF) which is available at the following links:
   i. On the association website
   ii. https://itsu.org.in/wp-content/uploads/2022/10/Case-Reproting-Form-CRF-1.pdf
   iii. On page 213-214 (Annexure 6) of the National AEFI Surveillance Operational Guidelines – 2024 available at https://mohfw.gov.in/sites/default/files/National%20AEFI%20Surveillance%20and%20Response%20Operational%20Guidelines%202024.pdf and https://itsu.org.in/wp-content/uploads/2024/03/National-AEFI-Surveillance-and-Response-Operational-Guidelines-2024.pdf
2. Send the hard copy to the DIO/DRCHO by hand/post or scanned version by Whatsapp/email.
3. If CRF is not available, inform the DIO/DRCHO or to the Surveillance Medical Officer of WHO-NPSP by telephonic call/SMS/Whatsapp/email/letter, etc. with the following details: Name, age, gender, contact number of the case, address of vaccination site, vaccines administered, symptoms/ signs, sequence of events and outcome.

What happens after reporting an AEFI?

1. On receiving the information regarding the AEFI, the DIO may contact you for clarifications and more details such vaccine batch details, outcome of the case, etc.
2. The DIO may request support in investigation by asking for treatment records of the case so that valid diagnosis can be made.
3. All information is kept confidential and used for causality assessment of the case by expert committee.

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