



NHMHP-UIP0AEFI/1/2019-10422

National Health Mission

SDA Complex, Kasumpti, Shimla-9

Himachal Pradesh

Dated: Shimla-171009, the 27th December 2020

To,

All the Chief Medical Officers,
in Himachal Pradesh

Dated Shimla-9 the

Subject: Initiatives to strengthen AEFI Surveillance system for COVID 19 Vaccination in the state-matter reg.

Sir/Madam,

This is with reference to D.O. No:T.13020/08/2018-IMM dated 18th November 2020 and DO No. Z-16025/05/2012 Imm p/f dated 22nd December 2020 received from Dr. Manohar Agnani, IAS, Additional Secretary to the Govt. of India on the subject cited above (copies enclosed).

As you are well aware, preparations are underway for conducting COVID-19 vaccination in the State starting with some priority groups. In this connection, some immediate steps need to be taken at district level to strengthen Adverse Events Following Immunization (AEFI) surveillance, following COVID-19 vaccination to maintain confidence in safety of vaccine.

As per GOI instructions the following initiatives need to be implemented at the earliest, so that required changes take place well before the start of COVID 19 vaccination:

- 1. Include Medical Specialists in addition to pediatrician in District AEFI Committee:** The COVID 19 vaccination will be given to adults, many of whom may have co-morbidities, so medical specialist, respiratory medicine specialist, neurologist and cardiologist in addition to pediatrician should be included in district

AEFI committee. The suggestive composition of District AEFI Committee is as follows:

Sr. No.	Designation	Position
1	Chief Medical Officer	Chairman
2	Medical Superintendent of District Hospital/Medical College	Vice-Chairman
3	Medical Officer of Health (MOH)	Member
4	District Immunization Officer	Member Secretary
5	Paediatrician	Member
6	Microbiologist	Member
7	District Surveillance Officer	Member
8	Neurologist	Member
9	Cardiologist	Member
10	Pulmonary Medicine Specialist/Medicine Specialist	Member
11	Obstetrics and Gynaecologist	Member
12	Community Medicine expert	Member
13	Pathologist	Member
14	Drug Inspector	Member

The individual members of the committee (specialists) can be notified from amongst those posted in various Health Institutions including the Medical Colleges in the District. The BMO and/or MO who has investigated the AEFI can also be co-opted as a member on case to case basis. **All Districts must re-notify their District AEFI committees within 5 days and send details to the NHM SHQ along with names and phone numbers of notified members.**

- 2. Training of new committee members/Specialist for investigation and causality assessments:** The new committee members /specialists should be oriented on the immunization program, COVID 19 vaccination, AEFI surveillance and conduction of causality assessments for AEFI cases when they first attend the AEFI committee meeting.
- 3. More frequent meetings of district AEFI committee:** While District AEFI committee is routinely require to meet once a quarter, in view of the need to clear the backlog of existing cases for investigations and causality assessment and to familiarize new members on AEFI surveillance processes and their roles and

also to monitor the preparations for managing AEFI surveillance following COVID vaccination, it is recommended that the AEFI committee meet at least once a month and share meeting minutes with the State Immunization Division.

4. Expanding reporting network of AEFI surveillance for adult vaccinations:

District Immunization Officer (DIO) is required to prepare a list of government and private hospitals and health care facilities, medical colleges, health care facilities of other departments like Railway, Defence, ESIC etc. in the district and contact the head of institutions to identify a Nodal officer (AEFI reporting).

- Ensure that the Nodal Officer (AEFI reporting) conducts one-hour sensitization meeting with all doctors in the institution and they should be able to report AEFIs immediately to the DIO and share clinical record of the case.
- Ensure that an AEFI register is available for all medical officers to record minor, serious and severe AEFI details.
- Share the list of all such institutions and dates of orientations of doctors to the State Immunization Officer for record.

5. Operational PHC AEFI registers- DIO should ensure that AEFI registers are available at all planning units/cold chain points/PHCs/CHCs/District Hospitals and Medical Colleges and ANMs, Medical Officers and other staff are recording details of minor, serious and severe AEFIs in the register. These registers need to be reviewed weekly by the nodal officer (AEFI reporting) or Medical Officer In-charge of the PHC/CHC. All forms and formats for reporting of AEFI cases are available at all health institutions.

6. Ensure involvement of drug inspectors in investigation in the districts: The drug inspector of the district should be a member of the District AEFI committee as mentioned above and may be involved in AEFI investigations, whenever required.

7. Availability of injection adrenaline in Anaphylaxis and AEFI managements kits and training of vaccinators on use of Anaphylaxis kits: The district should ensure that there is enough stock of injection Adrenaline for the coming months for use in Anaphylaxis kits and AEFI management kits. It is important to

note that Adrenaline has short expiry date. It is also important that all vaccinators (including temporary hires for routine immunization and for COVID 19 vaccinations) should be trained on use of the Anaphylaxis kits.

8. **Training on use of Anaphylaxis kits for alternate vaccinators:** While it is expected that all vaccinators involved in UIP vaccinations are trained in use of Anaphylaxis kits (if required re-orientation can be given), and therefore it is requested that all additional/alternate vaccinators including those from the private sector may be trained to identify suspected anaphylaxis and use contents of the Anaphylaxis kit.
9. **The revised list of contents of the AEFI management kit** for use at AEFI Management Centres is as follows:
 - Inj. Adrenaline (1:1000 dilution) - three ampoules
 - Tuberculin/insulin syringes - three
 - 24G/25G one inch needles - three
 - Cotton swab - three
 - Inj. Hydrocortisone - one
 - Ringer lactate/Normal saline - two units
 - 5% dextrose - two units
 - IV drip set - two units
 - Scalp vein sets or IV cannula - two
 - Disposable syringes - 5 ml with 24/25G IM needles - three sets
 - Adhesive tape – one

All Districts must ensure that these AEFI Management kits with revised composition are put in place within the next 10 days and the vaccinators (including alternate vaccinators) are oriented in their use.

10. **AEFI trainings and sensitization meetings:** DIO should initiate sensitization of Medical Officers and health workers in public and health facilities for immediate reporting of serious and severe AEFIs to the DIO and recording of the minor, serious and severe AEFIs in AEFI registers. Monthly and weekly review meetings should be utilized for this purpose. The focus of sensitization should include

AEFIs following adult vaccinations which will become important when COVID 19 vaccinations are initiated. Data entry operators in the office of the DIO should be oriented on SAFEVAC, the online reporting software for AEFIs.

- 11. Communication plans for vaccine safety:** Districts should prepare communication plans to manage rumours and myths regarding vaccine safety and crisis situations following serious AEFIs. Key messages for use in managing crisis situations and myths and rumours may be prepared in advance. Spokespersons may also be identified in advance and oriented on potential vaccine safety issues related to routine vaccines and potential COVID 19 vaccines.

For any additional information or support in implementing the above mentioned interventions, you may contact State Immunization Division or Surveillance Medical Officer, WHO-NPSP state unit/AEFI Secretariat, MoHFW New Delhi. The Chief Medical Officers are requested to ensure that all above mentioned initiatives are taken at the earliest under your direct oversight and same should be discussed during District Task Force meetings. The implementation status of each District shall also be an agenda item in the upcoming State Task Force and State Steering Committee meetings.

Yours faithfully,

**NIPUN
JINDAL**

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Dr. Nipun Jindal, IAS
Mission Director, NHM
Himachal Pradesh, Shimla – 9

Endst. No. As above: Dated Shimla-9 the

Copy to:

1. The Secretary (Health) to the Govt. of Himachal Pradesh for information please.
2. The Director Health Services, Himachal Pradesh, Shimla-9 for information please.
3. The Director Medical Education, Himachal Pradesh for information please
4. All Deputy Commissioners, Himachal Pradesh for information please.
5. The Principals, All Medical Colleges, Himachal Pradesh for information and necessary action please
6. All the District Immunization Officers for information & compliance please.

7. The SMO, WHO, NPSP unit SIHFW campus Parimahal, Shimla-9 for information & necessary action with the directions to track all above mentioned activities closely in all the districts & submit its report to the undersigned regularly keeping in view COVID-19 pandemic vaccination drive in State in near future.
8. The SPO UNDP, Parimahal, Shimla-9 for information please.

**NIPUN
JINDAL**

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Mission Director, NHM
Himachal Pradesh, Shimla – 9



Date	18/11/2020
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MH	CR
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NCD	UIP
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PIO	RKSK
FP	NLEP
Trg.	NUHM

Dr. Manohar Agnani, IAS
Additional Secretary
Tele: 011-23061723
e-mail: jsrch-mohfw@gov.in

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
Government of India
Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi - 110011

D. No: T.13020/08/2018-IMM

Date -18th November 2020

Dear All,

You may be aware that preparations are underway for conducting COVID19 vaccinations in states and districts, starting with certain priority groups. In connection with this, steps need to be taken to strengthen Adverse Events Following Immunization (AEFI) surveillance following COVID19 vaccinations to maintain confidence in safety of vaccines. MoHFW has identified initiatives which are essential to further strengthen the existing AEFI Surveillance System of India so that timely & complete AEFI reporting for COVID19 vaccination is possible. These initiatives are enclosed with this letter.

I request that these initiatives are implemented at the earliest so that required changes take place well before the COVID19 vaccine is introduced in the district/state. For any additional information or support in implementing the above interventions, State/UT may contact the Senior Zonal AEFI Consultant of your state or your local Surveillance Medical Officer, WHO-NPSP or the AEFI Secretariat, MoHFW.

With kind regards,

Yours sincerely,

(Dr. Manohar Agnani)

Additional Chief Secretary/Principal Secretary/Secretary (Health), all states/UTs

Copy to:

1. Mission Director (NHM), all states/UTs
2. Chair, National AEFI Committee
3. Chairpersons of State AEFI Committees
4. Dr Jaiprakash, Secretary-cum-Scientific Advisor (I/C), Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Govt. of India, Sector-23, Raj Nagar, Ghaziabad-201 002.
5. State Immunization Officer, all states/UTs
6. Dr Pankaj Bhatnagar, Acting Team Lead, WHO-NPSP
7. Dr Vineet Goyal, AEFI Focal Person, WHO-NPSP
8. Team Lead – AEFI, ITSU

Annexure**Initiatives to Strengthen AEFI Surveillance System for COVID19 Vaccination**

1. **Include medical specialists in addition to paediatricians in state and district AEFI committees** - The COVID19 vaccinations will be given to adults, many of whom may have co-morbidities. Events due to pre-existing comorbidities (strokes, heart attacks, etc.) may be reported as AEFIs following COVID19 vaccinations. Membership of State AEFI Committees should be revised to include neurologists, cardiologists, respiratory medicine specialists who can recognise such events and differentiate them from events related to vaccines/ vaccinations. Similarly, directions may be issued to districts to include medical specialists (neurologists, cardiologists) in the district AEFI committees.
2. **State AEFI Technical Collaborating Centres** - Each state must choose a medical college to function as state AEFI technical collaborating centre. The clinical specialists of the medical college (neurologists, cardiologists, respiratory medicine specialists in addition to paediatricians) and experts from the Department of Community Medicine will assist the state/state AEFI committee in conducting rapid causality assessments, case investigations in districts, laboratory tests in certain cases to find the cause of AEFIs, etc. These specialists (neurologists, cardiologists, respiratory medicine specialists, etc.) may be invited to attend AEFI committee meetings.
3. **Training of specialists of state AEFI committees and state AEFI technical collaborating centres for investigation and causality assessments** - The new committee members/ specialists should be oriented on the immunization programme, COVID19 vaccinations, AEFI surveillance and conduction of causality assessments for AEFI cases when they attend the AEFI committee meetings.
4. **More frequent meetings of state and district AEFI committees** - While state and district AEFI committees are required to meet once a quarter, in view of the need to clear the backlog of existing cases for investigations and causality assessments and to familiarise new members on AEFI surveillance processes and their roles and also to monitor the preparations for managing AEFI surveillance following COVID19 vaccinations, it is recommended that the AEFI committees meet at least once a month and share meeting minutes with the Immunization Division/AEFI Secretariat. The state AEFI committees should track whether district AEFI committee meetings are being held every quarter or more frequently, if required.
5. **Hiring of state AEFI consultants** - As COVID19 vaccinations are scaled up, there will be an increase in AEFI reporting due increased sensitization. All these cases need to be investigated, followed up for completion of documents

by the districts and causality assessed at the state level as soon as possible to elicit safety issues at the earliest for action. The following states were requested to ask for funds to hire state AEFI consultants in their PIP: Uttar Pradesh, Madhya Pradesh, Rajasthan, Bihar, Chhattisgarh, Jharkhand, Maharashtra, Gujarat, West Bengal, Andhra Pradesh, Telangana, Karnataka, Tamil Nadu and Odisha. While a few states have hired the consultant, others are requested to complete the process as soon as possible.

6. Expanding reporting network of AEFI surveillance for adult vaccinations – District Immunization Officers may be directed to

- a. Prepare a list of government and private hospitals and health care facilities, medical colleges, health care facilities of other ministries like railways, defense, ESIC, etc. in the districts and contact the head of the institutions to identify a Nodal Officer (AEFI reporting).
- b. Ensure that the Nodal Officer (AEFI reporting) conducts one-hour sensitization meetings with all doctors in the institutions to record vaccination history in OPDs, casualty/emergency consultations and in-patient admissions (focusing on medical, neurology, cardiology, respiratory medicine, obstetrics and gynaecology, in addition to paediatrics). Doctors should be able to report identified AEFIs immediately to the DIO and share clinical records of the case.
- c. Ensure that an AEFI register is available for medical officers to record minor, serious and severe AEFI details. The registers should be reviewed preferably daily by the Nodal Officer (AEFI reporting) or at least once a week. Any unreported serious/severe AEFIs should be reported to the DIO immediately. Each Nodal Officer (AEFI reporting) should have blank CRFs with them.
- d. Share the list of all such institutions with contact details of Nodal Officers (AEFI reporting) and dates of orientation of doctors to the state immunization officer for records.

7. Operational PHC AEFI registers – DIOs should ensure that AEFI registers are available at all planning units/cold chain points/ PHCs/CHCs/district hospitals and medical colleges and ANMs, medical officers and other staff are recording details of minor, serious and severe AEFIs in the register. These registers need to be reviewed weekly by the Nodal Officer (AEFI reporting) or medical officer in charge of the PHC/CHC. All forms and formats for reporting of AEFI cases are available at all health institutions.

8. Adverse Drug Reaction Monitoring Centres (AMCs) – Around 300 medical colleges and tertiary care hospitals across the country have Adverse Drug Reaction Monitoring Centres which report vaccine adverse events along with other adverse drug reactions. DIOs should contact such AMCs and request them to report serious and severe AEFIs directly. The current list of AMCs is available at https://ipc.gov.in/images/LIST_OF_311_AMC_UNDER_PvPI.pdf

9. Ensure involvement of drug inspectors in investigations in the districts-

The drug inspector of the district should be a member of the district AEFI committee and may be involved in AEFI investigations, whenever required.

10. Availability of injection adrenaline in Anaphylaxis and AEFI management kits and training of vaccinators on use of Anaphylaxis kits-

The districts should ensure that there is enough stock of injection Adrenaline for the coming months for use in Anaphylaxis kits and AEFI management kits. It is important to note that Adrenaline has short expiry date. It is also important that all vaccinators (including temporary hires for routine immunization and for COVID19 vaccinations) should be trained on use of the Anaphylaxis kits.

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भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

डॉ. मनोहर अगनानी, भा.प्र.से.
अपर सचिव

DR. MANOHAR AGNANI , IAS
Additional Secretary

D.O. No. Z-16025/05/2012 Imm p/f
Dated the 22nd December 2020

This is in reference to the letter No T.13020/08/2018-NHM dated 18th November 2020 regarding initiatives to strengthen AEFI surveillance for COVID 19 vaccination, following action points has been recommended by National AEFI committee in a meeting held on 15th December 2020:

- **Inclusion of Obstetrics/Gynaecologist in the State/District AEFI committee.**
- **Contents of the AEFI Kit are revised,** which are annexed at Annexure I.
- **Training on use of Anaphylaxis kits for alternate vaccinators:** While it is expected that all vaccinators involved in UIP vaccinations are trained in use of Anaphylaxis kits, and therefore it is requested that all additional/alternate vaccinators including those from the private sector may be trained to identify suspected anaphylaxis and use contents of the Anaphylaxis kit.

For any additional information or support in implementing the above interventions you are kindly requested to contact Senior Zonal AEFI Consultant of your State/UT or local Surveillance Medical Officer (SMO) WHO-NPSP or the AEFI Secretariat.

Yours sincerely,

Encl: as above

(Dr. Manohar Agnani)

To,
Additional Chief Secretary/Secretary/Principal Secretary (Health) – All States/UTs

Copy to:

1. Mission Director (NHM)- All States/UTs
2. Chair, National AEFI Committee
3. Chairpersons of State AEFI Committees
4. Dr Jai Prakash, Secretary-cum-Scientific Advisor (I/C), Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Govt. of India, Sector-23, Raj Nagar, Ghaziabad-201 002.
5. State Immunization Officer - All States/UTs
6. Dr Pankaj Bhatnagar, Acting Team Lead, WHO-NPSP
7. Dr Vineet Goyal, AEFI Focal Person, WHO-NPSP
8. Team Lead – AEFI, ITSU
9. Senior AEFI Zonal Consultants, MoH&FW, ITSU
10. PPS to AS&MD (NHM), MoH&FW
11. PPS to Joint Secretary (RCH), MoH&FW
12. PS to Advisor (RCH), MoH&FW
13. PS to Additional Commissioner (UIP), MoH&FW
14. PS to Joint Commissioner (Immunization), MoH&FW


(Dr. Manohar Agnani)

Annexure I**REVISED LIST OF CONTENTS OF AEFI MANAGEMENT KIT**

The revised list of contents of the AEFI management kit for use at AEFI Management Centres is as follows:

1. Inj. Adrenaline (1:1000 dilution) - three ampoules
2. Tuberculin/insulin syringes - three
3. 24G/25G one inch needles - three
4. Cotton swab - three
5. Inj. Hydrocortisone – one
6. Ringer lactate/Normal saline – two units
7. 5% dextrose – two units
8. IV drip set – two units
9. Scalp vein sets or IV cannula – two
10. Disposable syringes – 5 ml with 24/25G IM needles – three sets
11. Adhesive tape – one