सत्यमेव जयते

Ministry of Health & Family Welfare
Government of India

OPERATIONAL GUIDELINES INITIAL MANAGEMENT OF ANAPHYLAXIS USING INJECTION ADRENALINE BY ANMs

2018

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

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

15th February 2018

MESSAGE

The Government of India's Universal Immunization Program (UIP) envisages to protect all eligible beneficiaries from vaccine preventable diseases (VPD) by administering life-saving vaccines. India has the largest cohort of eligible beneficiaries in the world i.e. 26 million children and 29 million pregnant women which are to be vaccinated every year through 9 million immunization sessions being conducted by trained health workers across the country.

Many vaccines such as rotavirus vaccine and pneumococcal vaccine, which were earlier available at a cost in the private sector are now available free of cost in the UIP programme. We have expanded the basket of vaccines and simultaneously intensified efforts to increase the immunization coverage. With an increase in administered vaccine doses to the community, we need to have sufficient preparedness to manage adverse reactions if any. Serious Adverse Events Following Immunization (AEFI) are rare but if they happen then there is a need to manage it quickly not only to prevent mortality and morbidity in the individual recipient but also to ensure there is no disruption by maintaining confidence in vaccines and the UIP. In our constant efforts to provide safe and effective vaccines, the Govt. of India has taken a series of steps to strengthen the process of reporting and management of AEFIs.

One of the rare expected adverse reaction following immunization is anaphylaxis, which though not preventable can be managed if suspected early, diagnosed correctly and managed in time. In this regard, the Government of India, in consultation with experts has approved the use of a single, age-appropriate dose of adrenaline, which is the drug of choice for treating anaphylaxis, to be administered by ANM in the field and immediate transfer of the patient to the nearest health facility for further management. This decision is intended to reduce the likely resultant morbidity and mortality and help in faster recovery of vaccine recipients developing anaphylaxis following vaccination.

It is my pleasure to thank all the experts who have contributed to the development of the operational guidelines to help the vaccinator (ANMs/HW) gain requisite technical knowledge and expertise to administer the life-saving drug adrenaline in case of anaphylaxis reaction. I hope that this step will further lead to confidence building among the community for vaccination and would result in achieving full immunization coverage of >90% by 2018.

(Manoj Jhalani)

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Foreword

India is committed towards saving lives by reducing morbidity and mortality caused by vaccine preventable diseases. Since 2011, several initiatives have been taken to strengthen Universal Immunization Program. Since 2012, five new vaccines (pentavalent vaccine, inactivated polio vaccine, rotavirus vaccine, bivalent OPV and Japanese Encephalitis vaccine for adults) have been introduced in the Universal Immunization Programme (UIP). Mission Indradhanush was launched to improve full immunization coverage (FIC) in select districts in 2015. This has resulted in an increase in FIC from 65 to 71 percent. In order to consolidate the gains of Mission Indradhanush and accelerate progress in FIC to 90 percent by end 2018, the Government of India has launched an ambitious Intensified Mission Indradhanush in October 2017. After eradication of polio from the South East Asian Region including India, the Government has set sights to eliminate measles and control rubella by introducing measles-rubella vaccine across the country in phases through campaigns.

Anaphylaxis is a known but rare adverse event following immunization, which may also occur due to any trigger such as medications (e.g. antibiotics), insect bites, foods, colouring agents, etc. Most vaccines in India are given by ANMs in outreach sessions. Anaphylaxis usually occurs immediately after vaccination. Immediate management with adrenaline (the drug of choice for treating anaphylaxis) will reduce mortality and result in faster recovery from anaphylaxis. Though a rare adverse event, the Government is committed to reduce morbidity and mortality due to anaphylaxis by allowing ANMs to administer a single dose of adrenaline to suspected anaphylaxis cases.

I am extremely happy to present the operational guidelines for initial management of anaphylaxis in the field by ANMs. These guidelines are a culmination of multiple discussions by paediatricians, public health experts, drug regulators and administrators who were part of the expert group and committee formed to review and discuss the safety of injection adrenaline for use in field settings.

I urge all states/UTs to prepare the health systems and their front line health workers like ANMs and all concerned health care providers using these guidelines so that they are equipped well to handle anaphylaxis following vaccinations when they occur.

I convey my best wishes to all the ANMs working under most difficult conditions to provide health care almost at doorsteps of every citizen of the country.

(Vandana Gurnani)

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Preface

India's Universal Immunization Program (UIP) aims to fully immunize 26 million children and 29 millionpregnant women, the largest cohort of eligible beneficiaries in the world through 9 million immunization sessions held in the country each year by ANMs.

Hypersensitivity to one or more components of vaccines may manifest as anaphylaxis which is a known serious Adverse Events Following Immunization (AEFI). Such events are rare (one in a million doses administered) but with approximately 500 million doses administered each year, around 500 anaphylaxis reactions are expected to occur. In the absence of immediate emergency management, these reactions can be potentially fatal. Given the reality of field conditions, the ANM is the only person who can provide the required intervention immediately.

The MoHFW requested the Health Technologies Assessment wing of National Health Systems Resource Centre (NHRSC), New Delhi to submit a report assessing the feasibility of use of various drugs (injection adrenaline, injection pheniramine and injection hydrocortisone) by health workers in the field and assess market availability of suitable products. An expert group was set up to study the report submitted by the NHSRC. The expert group identified injection adrenaline as the drug of choice for treating anaphylaxis safely. It also reviewed existing literature to study the safety issues related to use of adrenaline by ANMs. It recommended the use of a single intra-muscular, age-appropriate dose of injection adrenaline in a case of suspected anaphylaxis. The suspected case should be immediately transported to the nearest health facility for further management under a medical practitioner.

These recommendations were presented to another independent expert committee which reiterated that injection adrenaline was the drug of choice for immediate management of anaphylaxis in field. It also noted that one age-appropriate dose of adrenaline given intramuscularly is safe, even in cases which are not anaphylaxis. However, it underlined the need for proper training to be imparted to ANMs for recognition of anaphylaxis cases and use of age appropriate doses of adrenaline.

These guidelines describe steps to be taken by an ANM to identify a case of anaphylaxis, safely administer a single dose of adrenaline and also referral to a health facility. The guidelines include training plans, required logistics and job aids for ANMs.

It is hoped that these guidelines will help to build the capacity of ANMs to safely administer adrenaline to reduce morbidity and complications due to anaphylaxis. The overall aim is to sustain public trust in the safety of the vaccines.

(Dr.PradeepHaldar)

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From Program Officer's Desk

Recent years have seen the expansion of Universal Immunization Program not only in terms of introduction of newer vaccines but also in terms of newer strategies for increasing the reach of immunization services, improving the quality of services and strengthening the Routine Immunization. Introducing a new vaccine involves not only looking at the capacity for production of vaccines to cater to a large birth cohort, assess cold chain capacity and augment it for storing the new vaccines, improve monitoring and reporting of vaccine coverage but also to strengthen AEFI surveillance systems. There was apprehension of occurrence of serious/severe AEFIs in higher numbers due to better coverage as well as introduction of new vaccines, especially when a large scale campaign like MR campaign is undertaken covering wide age group of children in phased manner.

Anaphylaxis though rare but is an expected adverse event which may occur in higher numbers with increase in administration of vaccine doses especially in situations such as catch up campaigns such as Measles-rubella. It is difficult to prevent since it is impossible to know before-hand which child may have anaphylaxis. An expert group and an expert committee examined the issue of managing anaphylaxis in field situation and after reviewing the existing literature, safety aspects and effectiveness of various strategies and options recommended that administration of a single, age- appropriate dose of adrenaline intramuscularly in suspect anaphylaxis cases in the field can prove lifesaving.

However, the challenge was that adrenaline, the drug of choice to manage anaphylaxis can be administered only under prescription of a medical officer at present and as almost 70% of the immunization sessions are in outreach at village level, therefore Medical Officer may not be available in case of need. Expert group and expert committee recommended that ANMs may be allowed to administer a single age appropriate dose of adrenaline, intramuscularly to a child in which anaphylaxis is suspected. The experts also recommended that after administering the single dose of adrenaline, the patient should be transported to the nearest health facility having a medical officer. The recommendations of the expert committee were accepted by the Ministry and have been conveyed to the states and UTs already. However, ANMs should receive a formal, well documented training for using adrenaline, therefore this operational guidelines has been readied. This operational guidelines includes training guidance with plans and job aids, etc.

It is expected that programme managers at all levels train all health workers before they are handed over the Anaphylaxis kits containing Inj. Adrenaline for use in the field. The trainings need to be well documented and records kept by name. It is also important to ensure that medical officers are aware of the decision to allow health workers to use adrenaline in the field. Medical officers should also be involved in certification of expiry dates of contents of the anaphylaxis kits especially of adrenaline vials as these have short expiry dates.

I would like to thank all those who have been involved in this process especially the esteemed members of the expert group and the expert committee as well as the AEFI Secretariat, ITSU.

(Dr. M. K. Aggarwal)

ABBREVIATIONS

AEFI:	Adverse Events Following Immunization
ANM:	Auxiliary Nursing Midwife
CHC:	Community Health Centre
CRF:	Case Reporting Form
DIO:	District Immunization Officer
DTwP:	Diphtheria Tetanus and whole cell Pertussis
FIC:	Full Immunization Coverage
HPV:	Human Papilloma Virus
HW:	Health Worker
IM:	Intramuscular
IV:	Intravenous
JE:	Japanese Encephalitis
MMR:	Measles Mumps and Rubella
MR:	Measles and Rubella
MO:	Medical Officer
MoHFW:	Ministry of Health and Family Welfare
PHC:	Primary Health Center
SC:	Subcutaneous
SEPIO:	State Extended programme of Immunization Officer
TT:	Tetanus Toxoid

1. BACKGROUND AND RATIONALE

Anaphylaxis is an acute, serious, life threatening generalized or systemic hypersensitivity allergic reaction which may cause death. It may occur due to hypersensitivity to any allergen. Patients who have had an anaphylactic reaction have a strong likelihood of having another one. A history of concomitant diseases (asthma, cardiovascular disease, mastocytosis, allergic rhinitis and eczema), food allergy (e.g. milk, peanut, egg), drug allergy and insect bites are precipitating factors for anaphylaxis. The true global rate of occurrence of anaphylaxis from all triggers in the general population is unknown because of under recognition by patients and caregivers and under diagnosis by health care professionals.

Globally, lifetime prevalence of anaphylaxis has been estimated to be 0.05-2%. Studies have estimated the range of incidence of anaphylaxis (all causes) to be 10-30 cases per 100,000 population, with approximately one case of anaphylaxis in 400 to 2000 patients admitted in emergency in a year. In India, anaphylaxis cases have been reported following drugs, food stuff and insect bites.

Anaphylaxis is a rare, but known adverse event following immunization (AEFI) and it can occur following any vaccine. Anaphylaxis following immunization may be caused by any of the following ingredients: ovalbumin, neomycin, streptomycin, polymyxin, gelatin, yeast, latex and aluminum salts, etc. Estimated rate of anaphylaxis cases is around one per million administered doses of vaccine. Table 1 shows global rate of anaphylaxis following different vaccines.

Table : Rates of anaphylaxis per 1,000,000 doses of vaccine administered

Vaccine	Expected cases of anaphylaxis/10^6 doses
DTWP[b]	1.3
Hepatitis B[a]	1.1
HPV[a]	1.7
Influenza (live-attenuated)[a]	2
Measles/MMR/MR[b]	1-3.5
Tt[a]	1-6

a = 2012 WHO Vaccine Information Sheet b = 2014 WHO Vaccine Information Sheet

Anaphylaxis is to be managed as a medical emergency. It should be suspected and recognized early so that it can be managed immediately by trained staff and the patient is transferred to the nearest health facility. In India, most vaccinations are administered in outreach settings. More than 500 million doses are administered in routine sessions alone every year. Around 517[1] cases of anaphylaxis as AEFIs are expected to take place annually. Globally, adrenaline is the treatment of choice for management of anaphylaxis. An expert group constituted by Ministry of Health & Family Welfare (MoHFW) reviewed scientific literature and asserted that immediately administering a single dose of adrenaline by the health worker (ANM) is safe. It further recommended that the case should be then immediately transported to the nearest health facility for further management. This was reemphasized by another expert committee which studied the findings and recommendations of the expert group.

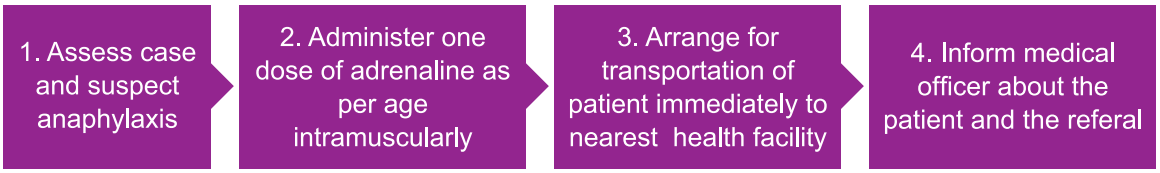
[1]Calculated on the basis of doses of DTwP & Pentavalent, Measles Containing Vaccine, TT and Hepatitis B reported in HMIS in 2014.

2. ROLE OF ANM/VACCINATOR

ANMs are in continuous contact with the community and are responsible for delivery of multiple health services, including immunization, antenatal care, reproductive and child health. They are trained on safe injection practices and also can administer injectable vaccines (infants, children and adults), intramuscular magnesium sulphate to pregnant women and gentamycin for possible serious bacterial infection or sepsis in young infants. In order to initiate the process of timely management of anaphylaxis cases by ANMs, they need to be trained for:

1) Early recognition of a case of anaphylaxis
2) Immediate administration of a single age-appropriate dose of injection adrenaline intramuscularly
3) Arranging immediate transportation of patient to the nearest health facility/ center (well equipped to manage anaphylaxis)
4) Providing details of the patient to medical officer for follow up and proper documentation in records and reports

Figure 1: Steps for Initial Management of Anaphylaxis



3. Steps to be taken by an ANM

3.1 Assess case and suspect anaphylaxis

A case of anaphylaxis is suspected if the following criteria are met:

Early onset and rapid progression of ≥ ONE sign/s and symptom/s of any two of the following three systems –

- respiratory,
- cardiovascular and
- dermatological/mucosal

Usually respiratory, dermatological and cardiovascular systems are involved in anaphylaxis. The signs and symptoms under each of the three systems are listed in Table 2.

Table 2: Signs and symptoms of Anaphylaxis*

System	Signs and Symptoms
Respiratory	• Swelling in tongue, lip, throat, uvula or larynx • Difficulty in breathing • Stridor (Harsh vibrating sounds during breathing) • Wheezing (breath with whistling or rattling sound in the chest) • Cyanosis (bluish discoloration of arms and legs, tongue, ears, lips etc.) (Figure 2.1) • Grunting (noisy breathing)
Cardiovascular	• Decreased level /loss of consciousness (fainting, dizziness) • Low blood pressure (measured hypotension) • Tachycardia (increased heart rate, palpitation)
Dermatological or mucosal	• Generalized urticaria (raised red skin lesion, rash with itching) (Figure 2.2) • Generalized erythema (redness of skin) • Local or generalized angioedema- itchy/ painful swelling of subcutaneous tissues such as upper eyelids, lips, tongue, face etc. (Figure 2.3) • Generalized pruritus (itching) with skin rash

*Modified from The Brighton Collaboration Anaphylaxis Working Group; Anaphylaxis: Case Definition and Guidelines for data collection, analysis, and presentation of immunization safety data; Vaccine; Vol. 25, (2007); 5675-5684

In most cases of anaphylaxis, skin and mucous membrane are affected. In addition to the signs and symptoms given in Table 2, following features may also be observed: anxiety, diarrhea, abdominal cramps, nausea, vomiting and sneezing or rhinorrhea.

Figure 2.1: Cyanosis

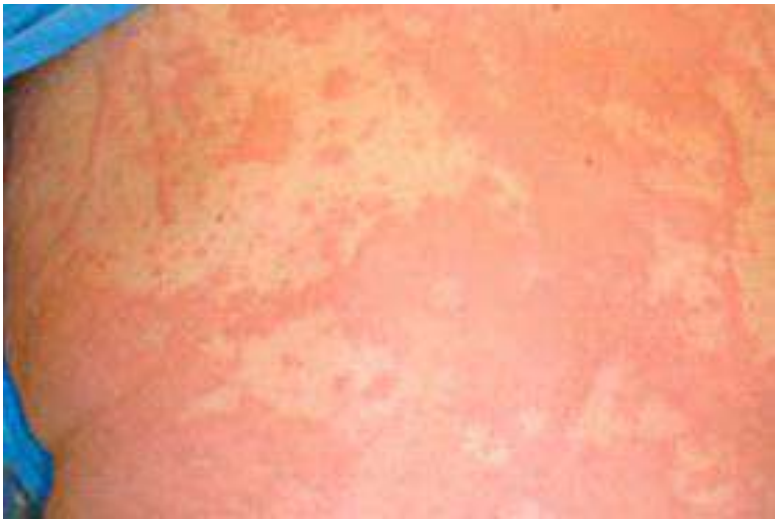


Figure 2.2: Urticaria

Figure 2.3: Angioedema

3.2 Initial management of suspected anaphylaxis case

Following vaccination, a case of anaphylaxis can be suspected if there is early onset of symptoms (within minutes to 6 hours) with rapid progression. In such a case,

- The ANM should reassure the patient, parents and relatives.
- The suspected case should never be left alone.
- If the patient is conscious, he/she should be kept in a supine position with lower limbs raised higher than head level.
- If the patient is unconscious, he/she should be kept in left lateral position.
- As per the age of patient, ANM must administer one dose of injection adrenaline by deep intramuscular route.
- ANM should seek help to immediately arrange for an ambulance/vehicle to transport the patient to the nearest health facility (PHC/CHC/District Hospital/Civil Hospital).

Steps for administration of injection adrenaline by ANM

- Take one ampoule of adrenaline (1:1000 dilution) solution from Anaphylaxis Kit (Box No.1) and check name, dilution and expiry date on label of vial (not from kit label). Remember that adrenaline ampoules are also labelled as epinephrine. Epinephrine is another name for adrenaline.
- Take a 1 ml tuberculin syringe or a 40 unit insulin syringe and a 24/25 G one inch long needle
- Using the "age specific dosing chart" available in the anaphylaxis kit, load the syringe with the appropriate dose of adrenaline. [Table 3]
- Use swab to clean the middle 1/3rd of anterolateral aspect of the thigh of the opposite limb to that in which vaccine was given.
- Give deep intramuscular injection at 90 degree angle to skin in middle 1/3rd of anterolateral aspect of thigh.

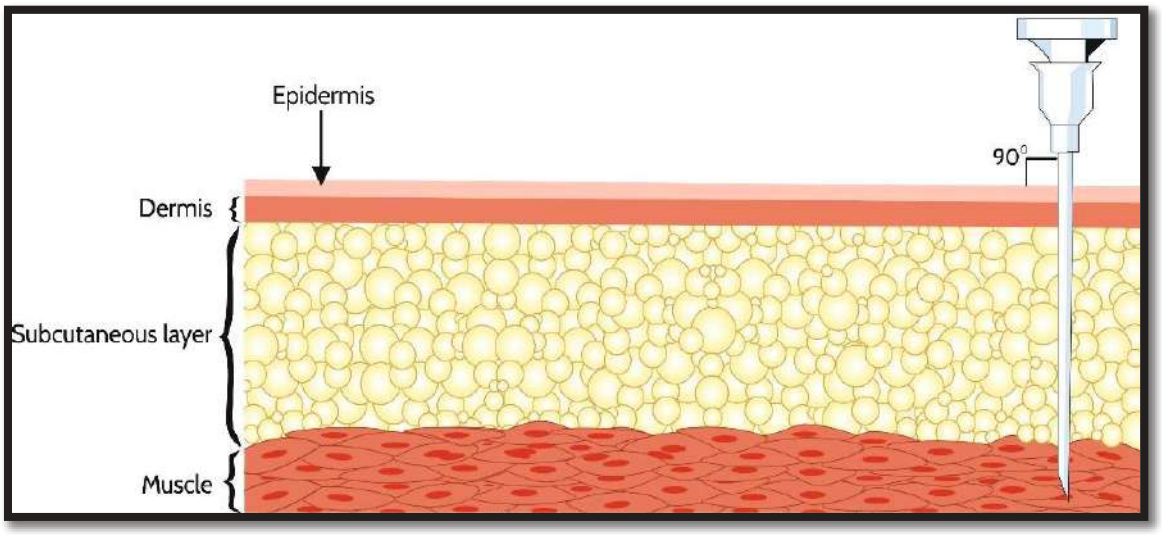


Figure 3. Administration of intramuscular injection

Table 3: Chart listing age-specific dose of adrenaline (1:1000) to be administered intramuscularly using tuberculin / insulin syringes for one-time management of anaphylaxis by health worker

Age group	Dose in mL (tuberculin syringe)#	Equivalent volume in insulin syringe#
0-1 year	0.05	2
1-6 years	0.1	4
6-12 years	0.2	8
12-18 years	0.3	12
Adults	0.5	20

#Based on type of syringe available (tuberculin 1mL/insulin), choose relevant volume of adrenaline for administration

3.2.1 Anaphylaxis kit for ANM

In order to ensure availability of adrenaline and the required syringes and needles for administration at the session site, an anaphylaxis kit should be available with the ANM at every session. The contents of the anaphylaxis kit is listed in Box No. 1 and shown in Figure no. 4.

Box No.1 Anaphylaxis kit for ANM

Anaphylaxis Kit – Each kit should contain the following items:

- Annexure 1 of these guidelines translated into local language taped to inside of the box lid – 1 no.
- 1 mL ampoule of adrenaline (1:1000) – 3 nos.
- 1 mL tuberculin syringes / 40 unit insulin syringes without fixed needles – 3 nos.
- 24/25 G needles of 1 inch length – 3 nos.
- Swabs – 3 nos.
- Up to date contact information of Medical Officer(s) of PHC/CHC and local ambulance services.
- Format for quarterly certification of anaphylaxis kit by Medical Officer of PHC

Store the contents in a plastic air tight container away from light. **Ensure the contents of Anaphylaxis kits are verified every three months. Adrenaline has a short expiry date.**

Figure 4: Anaphylaxis Kit

The anaphylaxis kit may have either tuberculin syringe or insulin syringe (without fixed needles).

Usually insulin syringes are more easily available as compared to tuberculin syringes. The needle to be used should be of 24G or 25G with length of one inch for IM administration.

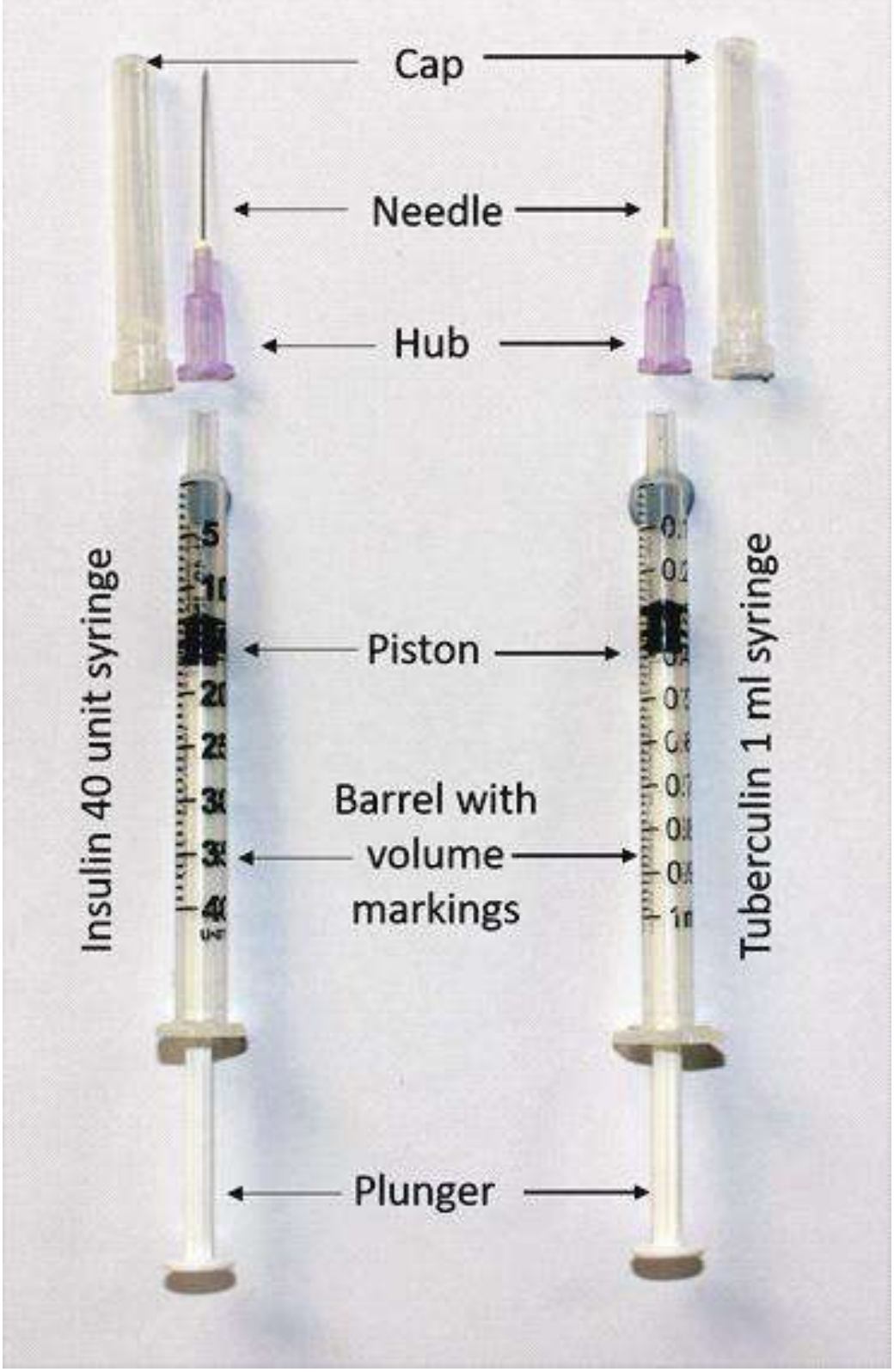


Figure 5: Parts of tuberculin and insulin syringes with separate 24/25G needles of one inch length

Based on the availability of tuberculin or insulin syringe and considering the age of the patient, the appropriate dose of adrenaline should be loaded in the syringe. A comparison of the markings on tuberculin (in mL) and insulin (in units) syringes for corresponding volumes is shown in Figure 6 below.

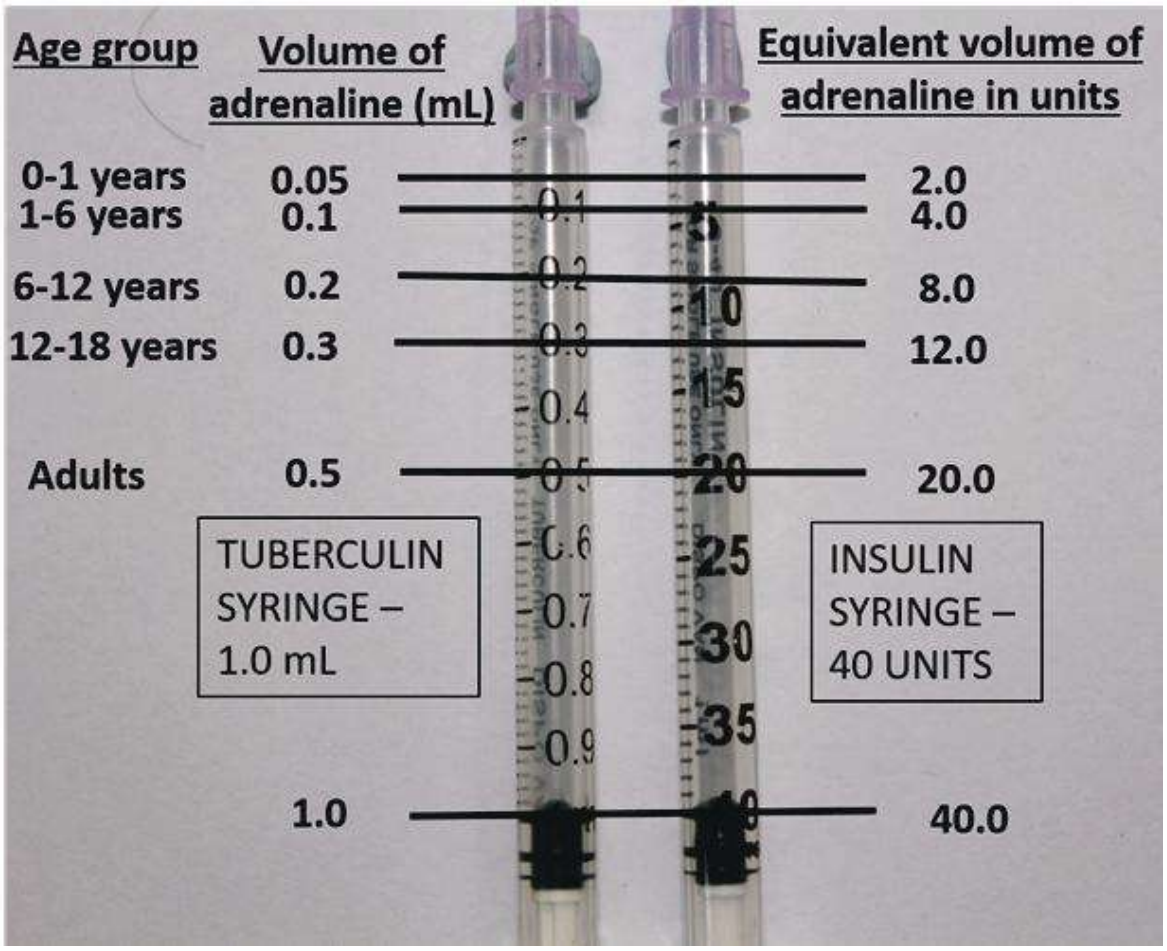


Figure 6: Markings of age appropriate dosage of adrenaline in mL (tuberculin syringes) and equivalent volume in units when using insulin syringes

ANM should administer only one dose of adrenaline and refer the patient to health facility well equipped to manage anaphylaxis. The following details of the patient should be conveyed to the medical officer of the health facility well equipped to manage anaphylaxis: Name, age, date, time, site, route and dose of adrenaline administered. The same should be available as a record with the ANM after transferring the patient.

3.2.2 About injection adrenaline

Epinephrine and adrenaline are synonyms. Adrenaline ampoules may also be labeled as epinephrine. The ampoules may be plain or amber coloured. These should not be exposed to temperature above 25 degree Celsius.

Key features of adrenaline are as follows:

- Adrenaline is a naturally occurring catecholamine.
- Dosage: 0.01ml/Kg body weight (refer to age appropriate dosing chart)
- Route of administration: Intramuscular
- Site of injection: middle 1/3rd of anterolateral aspect of thigh in children and deltoid region of arm in case of adults.
- Preparation: injection adrenaline is available in 1 mg/ml preparation.
- Storage: Store in airtight containers, protected from light.
- Expiry: 12 to 18 months from manufacturing

Figure 7: Ampoule of adrenaline may be plain or amber coloured

3.3 Transporting suspected anaphylaxis case to the nearest health facility

As soon as the ANM suspects anaphylaxis, she should administer injection adrenaline intramuscular and call for the ambulance. The ANM should ensure that the patient is transferred to the ambulance / vehicle without delay and refer the case to nearest health facility well equipped to manage anaphylaxis for further management.

- The ANM should keep contact details of an alternate vehicle owner/driver always. If an ambulance is not available or it is delayed, the ANM should contact the owner/driver of the alternate vehicle to transport the case to nearest health facility equipped to manage anaphylaxis. The untied sub centre funds may be used to reimburse cost of transportation.

3.4 Informing the medical officer and documentation

- As the child is being transferred, the ANM will inform the Medical officer about the case with necessary details (name, age, date, time, site, route and dose of adrenaline administered) for further management at the health facility well equipped to manage anaphylaxis and for follow up.
- The anaphylaxis reaction (suspected or confirmed) should be recorded in the immunization card in block letters and further vaccinations should be given only as per prescription of a medical officer in hospital settings with availability of adrenaline and other resuscitation equipment.
- The case details should also be recorded in the AEFI register and reported as a serious/severe AEFI case by the MO in the CRF to the DIO.

Flow Chart: Initial management of Anaphylaxis by ANM

After immunization let the parents or guardians wait for 30 minutes. Suspect* Anaphylaxis in a case with following symptoms and signs.	
Step 1: Assess Case	**Early onset (within few minutes to 6 hours) & rapid progression of ≥ 1 signs & symptoms of any of the two systems (Respiratory, cardiovascular and dermatological / mucosal)** **Respiratory:** • Swelling of tongue, lip, throat, uvula, larynx • Difficulty in breathing • Stridor (harsh vibrating sounds during breathing) • Wheezing (breathing with whistling or rattling sound in the chest) • Cyanosis ((bluish discoloration of arms and legs, tongue, ears, lips etc.) • Grunting (noisy breathing) **Cardiovascular:** • Decreased level /loss of consciousness (fainting, dizziness) • Low blood pressure (measured hypotension) • Tachycardia (increased heart rate, palpitation) **Dermatological or mucosal:** • Generalized urticaria (raised red skin lesion, rash with itching) • Generalized erythema (redness of skin) • Local or generalized Angioedema- itchy/ painful swelling of subcutaneous tissues such as upper eyelids, lips, tongue, face etc. • Generalized pruritus (itching) with skin rash **Other signs/symptoms:** anxiety, diarrhea, abdominal cramps, nausea, vomiting and sneezing or rhinorrhea.

Management of anaphylaxis	
Step 2: Administer one dose of adrenaline deep IM	• Reassure patient, parents/ relatives • Immediately administer one dose of injection Adrenaline by deep IM route • Seek help to immediately arrange for ambulance to transport the patient to the nearest health facility (PHC/CHC/District Hospital/Civil Hospital) • Do not leave the patient alone • If patient is conscious, he/she should be kept in supine position with lower limbs raised higher than head • If patient is unconscious, he/she should be kept in left lateral position

Refer to higher center	
Step 3: Refer immediately	• Call for ambulance • Inform MO about the case before arriving at the health facility for timely management

Step 4: Document suspected anaphylaxis	Document suspected anaphylaxis on immunization card in block letters against vaccines administered

*ANM may administer a single dose of adrenaline injection at the first sign or symptom suggestive of allergy or anaphylaxis

4. ROLE OF MEDICAL OFFICER

The medical officer of the PHC should frequently sensitize ANMs about anaphylaxis as an AEFI and the steps to be taken to manage it in the field. S/he should ensure that the adrenaline in supply for use should be of 1:1000 dilution and be within expiry date. As soon as the ANM informs him/her of the anaphylaxis case, s/he should be prepared to manage the case at least for initial 24 hours.

- Health facility must prepare to receive and manage the patient with anaphylaxis before the ambulance arrives
- Assess airway, breathing and circulation of the patient and manage as an emergency. If required administer subsequent doses of Adrenaline.
- Report the case as a serious AEFI as per national AEFI guidelines 2015.
- Patient should be kept under observation for at least 12-24 hours and if needed, referred to higher facility for further management

4.1 Quarterly certification of anaphylaxis kits by Medical Officer

- Medical officer will ensure availability of anaphylaxis kit with all ANMs at session sites / sub centres during field visits.
- He will examine and certify contents of the anaphylaxis kit during March, June, September and December i.e. at least once a quarter
- He will ensure injection adrenaline and other logistics do not have expiry dates within the next three months of date of examination/certification.
- If the expiry date of any logistics is within three months of visit, this will be replaced during the next visit of the ANM to the PHC and signed by the Medical Officer in the following format which will be part of the kit:

FORMAT FOR QUARTERLY CERTIFICATION OF ANAPHYLAXIS KITS BY MEDICAL OFFICER PHC

Name of ANM:		Subcentre:		Name, contact number of MO:	
Date of checking	**Contents**	**Expiry dates**	**Signature of MO**	**Action required (replace ampoule/ syringe)**	**Action taken, signature of MO, date**
	1 mL ampoule adrenaline (1:1000) – 3 nos.				
	1 mL/40 unit syringes – 3 nos.				
	24/25 G one inch needle- 3 nos.				
	1 mL ampoule adrenaline (1:1000) – 3 nos.				
	1 mL/40 unit syringes – 3 nos.				
	24/25 G one inch needle- 3 nos.				
	1 mL ampoule adrenaline (1:1000) – 3 nos.				
	1 mL/40 unit syringes – 3 nos.				
	24/25 G one inch needle- 3 nos.				
	1 mL ampoule adrenaline (1:1000) – 3 nos.				
	1 mL/40 unit syringes – 3 nos.				
	24/25 G one inch needle- 3 nos.				

4.2 Differences between Anaphylaxis kit and AEFI kit

The anaphylaxis kit is specifically for use by ANMs at the session site for initial management of anaphylaxis. AEFI kits are available at health facility well equipped to manage anaphylaxis (PHCs, CHCs, etc.) for use by medical officer for managing serious AEFIs.

Anaphylaxis kit	AEFI kit
At immunization session site	At health facility well equipped to manage anaphylaxis (PHC/CHC, etc.)
For use by ANM	For use by medical officer
Contains adrenaline, tuberculin/insulin syringes, 24/25 G one inch needles, swabs, guidelines/job aid with dose calculation	In addition to contents of the Anaphylaxis kit, contains intubation and resuscitation equipment, hydrocortisone (injection and tablet), ringer lactate, normal saline, 5 % dextrose, IV drip set, scalp vein sets.

Box 2: Contents of the AEFI Management Kit at health facility

1. Clearly labeled adrenaline ampoules (1:1000)-3 ampoules
2. Hydrocortisone vials (100mg)-1vial
3. IV fluids (Ringer lactate/ Normal Saline): 1unit in plastic bottle
4. IV fluids (5% Dextrose):1 unit in plastic bottle
5. IV drip set
6. Disposable syringes (tuberculin) of 1 ml with 50 gradations and 24/25G needle of one inch length- 3 sets
7. Disposable syringes (5ml) and 25/26G IM needle- 3 sets
8. Cotton wool + adhesive tape:1 each
9. Sphygmomanometer (adult and child cuff)
10. Stethoscope
11. Swabs
12. Tourniquet
13. Flashlight and extra batteries
14. AEFI reporting forms (CRF)
15. Label showing: Date of inspection, expiry date of Inj. Adrenaline and shortest expiry date of any of the components
16. Drug dosage tables of Inj Adrenaline and Hydrocortisone
17. In hospital settings, oxygen support and airway intubation facility should be available.

5. OPERATIONALIZATION OF USE OF ADRENALINE BY ANMS/HEALTH WORKERS IN FIELD

5.1 State Level

- Issue a notification/letter for operationalization of guidelines with instructions for indenting of anaphylaxis kits containing adrenaline, syringes and needles.
- Ensure all ANMs are trained to identify early symptoms of anaphylaxis and the steps for initial/ immediate management of anaphylaxis in field setting within six months of issue of notification/letter.
- Cascading training will be followed in which DIOs/district training teams will be trained at state level and further trainings of ANMs will be conducted at district/block level along with medical officers of PHCs.
- A session-wise list of all ANMs and MO PHCs trained on use of adrenaline for managing anaphylaxis will be maintained as record and photocopies shared with the SEPIO.
- Training sessions should be monitored for quality.
- Regular immunization session monitoring should include training status of ANM on use of adrenaline in suspected anaphylaxis case, availability of anaphylaxis kit with ANM at session site and availability of adrenaline within expiry date in the kit by checking certification by medical officer.
- State should ensure availability of adrenaline, appropriate syringes and needles with all ANMs and health facilities.
- If ambulance is not available, the ANMs may be authorized to hire a vehicle in an emergency to transport the patient to nearest PHC/CHC. She should be reimbursed for the same subsequently.
- The state should arrange for translation and printing of Annexure 1, pre-training and post-training test formats (without answers) and Annexure 3 (without responses) into the local language and supply to the districts for use during trainings of ANMs (one per ANM and facilitator).

5.2 District Level

- Ensure all ANMs are trained on use of adrenaline for initial management of suspected anaphylaxis. Records of training should be maintained with names of participants.
- If required, the district will print/photocopy the translated Annexure 1, pre-training and post-training test formats (without answers) and Annexure 3 (without responses) for use during trainings of ANMs (one per ANM and facilitator).
- Estimate, procure and make available required quantity of the injection adrenaline, appropriate tuberculin/insulin syringes and needles at district level as part of anaphylaxis kit.
- Regularly monitor availability of anaphylaxis kit with ANMs and certification of kit by MO.
- Report any anaphylaxis case following vaccination as a serious/severe AEFI by filling CRF.

5.3 Estimation of Logistics

Estimation of adrenaline, syringes and needles supply requirements

- Each ANM will be provided one anaphylaxis kit containing 3 adrenaline ampoules, three 1ml syringes (tuberculin) or 40 Units insulin syringes (without fixed needles), three 24/25G needles (1 inch).
- MO PHC should ensure that adequate buffer stock of adrenaline injection (10% of the requirement for total number of ANMs under the PHC) is available at PHC.
- At the district, buffer stock of adrenaline ampoules equivalent to 20% of annual requirement of the district should be maintained.

5.4 Training of health workers

ANMs/health workers should be trained to recognize anaphylaxis and its initial management by using adrenaline in field setting. It is desirable that medical officers should also be present in the training so that s/he is aware of the process and her/his role.

- Trainers: DIO/District training team
- Other opportunities to be used for training in use of adrenaline:
  - Regular monthly meeting of ANM at block level
  - New vaccine introduction trainings
  - Regular ANM training on immunization
  - Training for campaigns (MR or JE) or Supplementary Immunization Activities

- Allocate 120 minutes for a training session on suspecting and recognition of anaphylaxis and use of adrenaline injection in management of anaphylaxis.
- Translate Annexure 1 (Guidelines for initial management of anaphylaxis using injection adrenaline), pre-training and post-training test formats (without answers) and Annexure 3 (without responses) in local language and prepare copies for distributing as handouts/job aids.
- Refer to Annexure 2 for training agenda.
- Ensure monitoring of training.

Annexure 1 (to be translated into local language)

Guidelines for Initial Management of Anaphylaxis using Injection Adrenaline

Remember: Giving one dose of adrenaline to any suspected case of anaphylaxis intramuscularly is completely safe even if it actually turns out NOT to be a case of anaphylaxis later.

A. Suspecting a case of anaphylaxis

A case of anaphylaxis is suspected* if there is early onset (within few minutes to 6 hours of vaccination) and rapid progression of signs and symptoms with involvement of at least one sign/symptom from at least two of the three systems given below:

System	Sign and Symptom
Respiratory	• Swelling in tongue, lip, throat, uvula or larynx • Difficulty in breathing • Stridor (Harsh vibrating sounds during breathing) • Wheezing (breath with whistling or rattling sound in the chest) • Cyanosis (bluish discoloration of arms and legs, tongue, ears, lips etc.) • Grunting (noisy breathing)
Cardiovascular	• Decreased level /loss of consciousness (fainting, dizziness) • Low blood pressure (measured hypotension) • Tachycardia (increased heart rate, palpitation)
Dermatological or mucosal	• Generalized urticaria (raised red skin lesion, rash with itching) • Generalized erythema (redness of skin) • Local or generalized Angioedema- itchy/ painful swelling of subcutaneous tissues such as upper eyelids, lips, tongue, face etc. • Generalized pruritus (itching) with skin rash
Others	• Anxiety, diarrhea, abdominal cramps, nausea, vomiting and sneezing or rhinorrhea.

*Many of the initial signs and symptoms are similar in both mild allergic reactions and severe allergic reactions / anaphylaxis. ANM may administer a single dose of adrenaline injection at the first sign or symptom suggestive of allergy or anaphylaxis.

CYANOSIS

URTICARIA

ANGIOEDEMA

B. Steps to manage a case of suspected anaphylaxis:

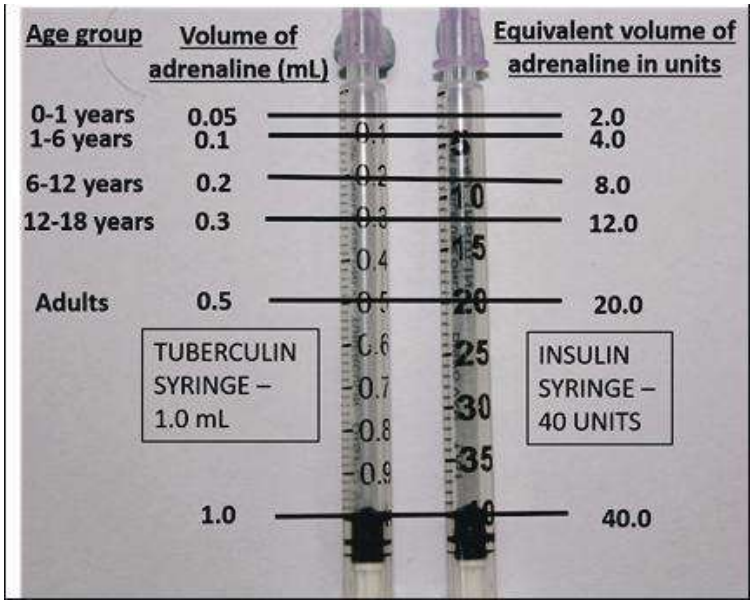
1. Do not panic; reassure patient/parents and care givers.
2. Conscious patient should be kept in a supine position with lower limbs raised higher than head. The unconscious patient should be kept in left lateral position.
3. Immediately administer one dose of injection adrenaline by deep intramuscular route.

C. Steps for administration of injection Adrenaline by ANM

1. From the anaphylaxis kit, take one ampoule of adrenaline (1:1000) and check name, dilution and expiry date on label.
2. Take a 1 ml tuberculin / 40 unit insulin syringe and a 24G/25G one inch long needle and use the chart given below to choose and load the required dose of adrenaline as per age and type of syringe supplied.

Age group	Dose in mL (tuberculin syringe)#	Equivalent volume in insulin syringe#
0-1 year	0.05	2
1-6 years	0.1	4
6-12 years	0.2	8
12-18 years	0.3	12
Adults	0.5	20

Based on type of syringe available (tuberculin/insulin), choose relevant volume of adrenaline for administration



1. Use swab to clean the middle 1/3rd of anterolateral aspect of the thigh of the opposite limb to that in which vaccine was given.
2. Give deep intramuscular injection at 90 degree angle to skin in middle 1/3rd of anterolateral aspect of thigh.

D. Transportation, informing MO and documentation

1. Immediately arrange for an ambulance to transport the patient to the nearest health facility well equipped to manage anaphylaxis / health facility (PHC/CHC/District Hospital/Civil Hospital).
2. As the patient is being transported to health facility, inform medical officer about the case with necessary details (name, age, date, time, site, route and dose of adrenaline administered) for further management at the health facility well equipped to manage anaphylaxis and for follow up.
3. Record the anaphylaxis reaction in the immunization card in block letters
4. The case details should also be recorded in the AEFI register at the PHC

Annexure 2

Training plan

Objectives: At the end of the training session, the ANM will be able to:

- List the early signs and symptoms of anaphylaxis in a vaccine recipient
- Enumerate steps to manage anaphylaxis and refer the patient to higher centre
- Describe the process of administering one age-appropriate dose of adrenaline injection
- Understand the importance of anaphylaxis kit and ensure its availability in sessions

Preparation

- State will issue a letter to DIOs to conduct trainings in districts with instructions and timelines.
- The state will translate Annexure 1, pre-training and post-training test formats (without answers) and Annexure 3 (without responses) in local language, print and supply to the districts for use during trainings of ANMs (one per ANM and facilitator).
- DIO will prepare training calendar in consultation with medical officer of PHC/planning unit and share with the state.
- The required copies of operational guidelines should reach districts at least 15 days before first training session. Prepare anaphylaxis kits – one per participant and trainer – at least one week before the training.
- One day before the training, prepare the classroom, arrange the seating so that ANMs can see and communicate with each other and with facilitator. Ensure availability of adequate training materials.

Training Supplies (For 1 batch of 30 ANMs)

Equipment

- Black board with chalk/white board or flip chart with marker pens, duster
- Laptop with projector and screen and speakers for showing film on anaphylaxis

Materials needed by facilitator

- Anaphylaxis kit
- Operational guidelines
- Annexure 1
- Annexure 3 (Pre-training, case studies and post-training tests) with answers
- Film on anaphylaxis
- Attendance sheet

Materials for participants (One per participant)

- Anaphylaxis kit
- Handout (Annexure 1)
- Pre-training test format
- Post-training test format
- Case studies

Training Agenda

Topic	Description	Time
Introduction, session objectives	Provide information about purpose of training and its objectives	5 min.
Pre-training test	Each participant answers the pre-training test using format.	5 min.
Vaccines benefits, risks and AEFIs	Start with asking participants about benefits of vaccines. Ask some of them to describe their experiences (the event, vaccine involved, actions and outcome) with AEFIs. Ask participants to describe/list minor, serious and severe AEFIs, which ones to notify and the reporting procedure.	10 min.
Recognizing anaphylaxis	Participants loudly read out Point A (Suspecting a case of anaphylaxis, table and photographs) of Annexure 1 (Guidelines for Initial Management of Anaphylaxis using Injection Adrenaline). Discuss involvement of three systems (cardiovascular, respiratory and skin manifestations) and other symptoms. Ask participants to read the three case studies (Annexure 3) one by one and answer Question 1 for each case study. Explain signs and symptoms of different systems and stress on early onset and rapid progression of signs and symptoms.	25 min.
Managing a suspected case of anaphylaxis	Participants read the three steps in Point B in Annexure 1 and answer Question 2 in each Case study 1A, 1B and 1C.	5 min.
Demonstration of Anaphylaxis kit and practise loading adrenaline	Participants read steps in Point C of Annexure 1and study the table and photograph of syringes. ANMs take out contents of Anaphylaxis kit and arrange them on table. They answer Question 3 for each of the three case studies using the table in Annexure 1. They also practise loading the appropriate amount of adrenaline in the syringe supplied in the Anaphylaxis kit. They answer Question 4 of Case Study 1 and discuss. **Stress that even if adrenaline (single, age appropriate dose, intramuscularly) is given in a non-anaphylaxis case, it will not harm the patient.**	25 min.
Case Referral	Participants read steps in Point D. They then read Case Study 2, answer questions with discussions on solutions.	10 min.
Film	Show film on anaphylaxis	10 min.
Post training test	Each participant answers the post training test in given format	10 min.
Recap	Clear doubts, discuss answers of pre and post training tests, summarize the session.	15 min.

Annexure 3

Pre-training test for ANMs

Q 1. Serious AEFIs which should be immediately notified to the Medical Officer are any adverse event following vaccination resulting:

a. Death
b. Hospitalization
c. Disability
d. Cluster
e. Parental/community concern
f. All of the above

Q2. Severe AEFIs are

a. Another term for serious AEFIs
b. Minor AEFIs with a higher degree of severity but not hospitalised
c. Serious AEFIs which have not been hospitalized due to some reason
d. Both b and c
e. None of the above

Q3. The following AEFIs should be entered in the PHC AEFI register:

a. Minor
b. Severe
c. Serious
d. All of the above

Q4. Which vaccine can cause allergic reaction/anaphylaxis?

a. Pentavalent
b. OPV
c. Measles
d. Any vaccine

Q5. For how long the vaccinee should be observed following immunization?

a. 30 minutes
b. 60 minutes
c. 10 minutes
d. No need to observe

Case Studies

Case Study 1A:

Nisha, a two month old female child received A, B and C vaccines at the sub center at around 11 am in the morning. Prior to vaccination child was breast fed at 10:00 am and had no complaints. Within 30 minutes of vaccination, child developed fast and labored breathing, increased drooling from mouth, redness and swelling of lips and started getting drowsy and was not accepting breast feed. Parents rushed the child to the ANM.

Case Study 1B:

Chintu, a seven year old boy received D vaccine at around 10 am during a campaign in the school. After 30 minutes of vaccination, he developed rashes over face and upper body, swelling and redness of eyes and lips and seemed to have difficulty in breathing with sharp whistling sound from the chest. He loses consciousness within 5 minutes of onset of symptoms. The ANM is informed by the teachers.

Case Study 1C:

Khushi, a 2 years old girl was vaccinated with a booster dose of a vaccine at the sub centre. Khushi's mother remained at the sub centre for about 30 minutes and she was playful without any complaints. After 30 minutes of vaccination, on the way home, Khushi vomited once and started crying pointing to her stomach. Soon she started having difficulty in breathing and mother noticed rashes on her body. Her mother rushed back to the sub centre in panic.

In each of the case studies (1A, 1B and 1C) ask the participants the following:

1. What are the signs / symptoms in each case which point towards suspected anaphylaxis?
2. What are the steps the ANM must take on suspecting anaphylaxis in each case?
3. What is the dose of adrenaline that she must load and administer, if her anaphylaxis kit has an insulin syringe? What is the dose in ml if she has a tuberculin syringe?
4. Should the ANM be worried about over-dosage or side effects after administering the dose of adrenaline? If yes, why? If no, why not?

Case Study 2:

After administering a single IM age appropriate dose of adrenaline, the ANM called the 108/102 ambulance service. The 108/102 ambulance service was taking a long time in arriving. She quickly mobilized a jeep to take the child to the PHC. She informed her MO (PHC) about the incident and that she was on her way to the PHC with the child. At the PHC, the MO examined the child and used the AEFI management kit to maintain airway, breathing and circulation of child. He gave another dose of Adrenaline, i/v fluids and oxygen to the child. Despite some improvement, the MO (PHC) decided to transfer the child to the CHC as a paediatrician and anaesthetist were available at the CHC. The MO informed the CHC and accompanied the child to the CHC. The child was further managed at the CHC and discharged the next day.

1. What are the risks (what can go wrong) in this case study?
2. How can the risks be managed?

Post-training test for ANMs

Q 1. Serious AEFIs which should be immediately notified to the Medical Officer are any adverse event following vaccination resulting:

a. Death
b. Hospitalization
c. Disability
d. Cluster
e. Parental/community concern
f. All of the above

Q2. Severe AEFIs are

a. Another term for serious AEFIs
b. Minor AEFIs with a higher degree of severity but not hospitalized
c. Serious AEFIs which have not been hospitalized due to some reason
d. Both b and c
e. None of the above

Q3. The following AEFIs should be entered in the PHC AEFI register:

a. Minor
b. Severe
c. Serious
d. All of the above

Q4. Which vaccine can cause allergic reaction/anaphylaxis?

a. entavalent
b. OPV
c. Measles
d. Any vaccine

Q5. For how long the vaccine recipient should be observed following immunization?

a. 30 minutes
b. 60 minutes
c. 10 minutes
d. No need to observe

Q6. What will you do in case of redness at injection site which starts spreading rapidly within few minutes following immunization throughout the body?

a. Give symptomatic treatment and refer the child to Medical Officer in charge
b. Refer to Medical Officer in charge
c. Reassure the mother or care giver
d. Leave as such and send home
e. a, b and c

Q 7. What are the main systems involved in Anaphylaxis?

a. Respiratory
b. Cardiovascular
c. Dermatological/mucosal
d. All of the above

Q 8. What are the signs and symptoms in which Anaphylaxis is suspected?

a. Urticaria
b. Cyanosis
c. Wheezing
d. Swelling of lips, eyes, tongue
e. All of the above

Q 9. What is the route of administration of injection Adrenaline by ANM?

a. Intramuscular
b. Subcutaneous
c. Intradermal
d. Intravenous

Q 10. What is the dose of Adrenaline for 3 months old infant?

a. 0.05ml/2 units
b. 0.1ml/4 units
c. 0.2ml/8 units
d. 0.5ml/20 units

Q 11. What is the dse of Adrenaline for 2 years old child?

a. 0.5ml/20 units
b. 0.3ml/12 units
c. 0.1ml/4 units
d. 0.2ml/8 units

Q 12. What should be done after giving Adrenaline injection?

a. Send the patient home
b. Immediately arrange to shift the patient to nearby health facility
c. Inform the Medical Officer about the case
d. Both b and c

Q 13. What will you do if Adrenaline injection is given subcutaneously?

a. Repeat the dose intramuscularly
b. Don't repeat the dose and arrange transportation of the patient to the nearest health facility

Q 14. How many doses of adrenaline injection will an ANM administer in case of suspected anaphylaxis?

a. ANM is not allowed to administer adrenaline
b. One dose only
c. Two doses only
d. As many as needed every 15 minutes

Q 15. Before administering injection adrenaline, what details on the label of the adrenaline ampoule should be checked:

a. Name of the drug
b. Dilution of adrenaline
c. Expiry date
d. All of the above

Answers

Case studies 1A, 1B and 1C

1. What are the signs / symptoms in each case which point towards suspected anaphylaxis?

   1A. Within 30 minutes of vaccination, child developed fast and labored breathing, increased drooling from mouth, redness and swelling of lips and started getting drowsy and was not accepting breast feed.
   1B. After 30 minutes of vaccination, he developed rashes over face and upper body, swelling and redness of eyes and lips, difficulty in breathing with sharp whistling sound from the chest. He loses consciousness within 5 minutes of onset of symptoms.
   1C. After 30 minutes of vaccination, child vomited once, started crying pointing to her stomach. Soon she started having difficulty in breathing with rashes on her body.

2. What are the steps the ANM must take on suspecting anaphylaxis in each case?

   1. Do not panic; reassure patient/parents and care givers.
   2. Conscious patient should be kept in a supine position with lower limbs raised higher than head. The unconscious patient should be kept in left lateral position.
   3. Immediately administer one dose of injection adrenaline by deep intramuscular route.

3. What is the dose of adrenaline that she must load and administer, if her anaphylaxis kit has an insulin syringe? What is the dose in ml if she has a tuberculin syringe?

   1A. 2 months – 0.05 ml (tuberculin syringe); 2 units (insulin syringe)
   1B. 7 years – 0.2 ml (tuberculin syringe); 8 units (insulin syringe)
   1C. 2 years – 0.1 ml (tuberculin syringe); 4 units (insulin syringe)

4. Should the ANM be worried about over-dosage or side effects after administering the dose of adrenaline? If yes, why? If no, why not?

No. There is no documented adverse event following administration of a single age-appropriate dose of intramuscular adrenaline in infants and children. Injection Adrenaline is a lifesaving drug and benefits of its administration outweigh the risks, even in those with greater susceptibility to its adverse consequences e.g., the elderly and individuals with hypertension, known ischaemic heart disease and arteriopathies.

Case study 2

1. What are the risks (what can go wrong) in this case study?
   There may be phone connectivity issues. She may not be able to get through to 102/108 service. The ambulance may be delayed. She may not have the contact details of alternate vehicle owner/driver. He may not be available at that moment. MO may not be contactable. PHC or CHC may be far away from the village. PHC may not have appropriate resuscitation instruments……..

2. How can the risks be managed?
   Discuss solutions with the ANMs regarding the risks listed by them.

Pre-training and post-training test

1f; 2d; 3d; 4d; 5a; 6e; 7d; 8e; 9a; 10a; 11c; 12d; 13b; 14b; 15d

Annexure 4

Frequently Asked Questions

Q 1. What is Anaphylaxis? How does it manifest?

Anaphylaxis is an extreme and severe allergic reaction, that is potentially life threatening. The whole body is affected, often within minutes of exposure to the allergen (substance causing the allergic reaction), but sometimes after hours. Most of the anaphylactic reactions occur within a few minutes to up to 6 hours. It occurs because your immune system overreacts to an allergen, and causes secretion of chemical substances that cause swelling of blood vessels. Common allergens include foods such as peanuts, dairy products, eggs etc. and non-foods such as wasp or bee sting, medications, vaccines, latex etc. The symptoms of an anaphylactic reaction include generalized flushing of the skin, nettle rash (hives) anywhere on the body, swelling of throat and mouth, difficulty in swallowing or speaking, alterations in heart rate, severe asthma, abdominal pain, nausea and vomiting, sudden feeling of weakness (drop in blood pressure), collapse and unconsciousness.

Q 2. Who are the individuals at higher risk of anaphylaxis?

There aren't many known risk factors for anaphylaxis, but a personal history of anaphylaxis, allergies or asthma, and a family history of anaphylaxis increases risk of anaphylaxis. If you've experienced anaphylaxis once, your risk of having this serious reaction increases. Future reactions may be more severe than the first reaction.

Q3. How will you suspect a case of anaphylaxis?

In anaphylaxis, there is sudden onset of symptoms which rapidly worsens in a matter of minutes. The individual may complain of difficulty in breathing and/or giddiness/loss of consciousness, hypotension, skin changes such as generalized rashes, swelling of the lips and tongue (angioedema), hives (urticaria) and flushing. The person may have had a severe allergic reaction or anaphylaxis in the past. However, this may be the first time. Sudden onset and rapid progression of ≥ 1 signs and symptoms of any of the two systems (respiratory, cardiovascular and dermatological/mucosal) should be suspected as a case of anaphylaxis.

Q 4. What are the steps the ANM should take if anaphylaxis is suspected in a patient?

If the patient is conscious, keep him/her in a supine position with lower limbs raised higher than head. If the patient is unconscious, he/she should be kept in left lateral position. Immediately speak to medical officer and arrange for an ambulance. Administer one dose of injection adrenaline by deep intramuscular route.

Q 5. What is the treatment of choice for anaphylaxis?

Injection Adrenaline is the treatment of choice for management of anaphylaxis. Age appropriate dose can easily be calculated and administered by an ANM in session sites.

Q 6. What are the contents of Anaphylaxis kit?

An anaphylaxis kit consists of three ampoules of adrenaline (1:1000 dilution), three 1 ml tuberculin syringes or 40 unit insulin syringes, three 1 inch needles lengths (24G/25G), swabs, a job aid (Annexure 1) and a certification by MO regarding expiry dates of adrenaline ampoules, syringes and needles.

Q 7. How to administer adrenaline injection?

Take one ampoule of adrenaline (1:1000) solution from Anaphylaxis Kit and check name, dilution and expiry date on label of the vial. Then, take a 1 ml tuberculin or 40 unit insulin syringe and 24/25 G 1 inch needle and load with age-appropriate dose of adrenaline. Clean the middle 1/3rd of anterolateral aspect of the thigh with swab. Give deep intramuscular injection at 90 degree angle to skin in middle 1/3rd of anterolateral aspect of thigh.

Q 8. What is dose of adrenaline for infants, 1-6 years, 6-12 years, 12-18 years and adults?

Recommended dose: When using 1mL tuberculin syringe for infants (0.05ml); 1-6 years (0.1ml); 6-12 years (0.2ml); 12-18 years (0.3ml) and adults (0.5ml). Equivalent volume of adrenaline when using a 40 unit insulin syringe for infants (2 Units); 1-6 years (4 Units); 6-12 years (8 Units); 12-18 years (12 Units) and adults (20 Units).

Q 9. I have administered vaccine to an infant and within few minutes the condition of the child deteriorates (difficulty breathing, irritability, drowsiness, unable to feed). I do not know whether these are signs of anaphylaxis. It could be something else. Can I administer injection adrenaline intramuscularly? Will it harm the patient, if it is not a case of anaphylaxis?

If you suspect anaphylaxis, you can safely administer one dose of adrenaline immediately. Transport the case to a health centre/hospital for immediate treatment. On the other hand, adrenaline will be immediately effective in managing anaphylaxis and will save the life of the child.

Q 10. Is adrenaline injection safe enough to be administered in field settings or if administered in higher volume than recommended dose?

There is no documented adverse event following administration of a single age-appropriate dose of intramuscular adrenaline in infants and children. Injection Adrenaline is a lifesaving drug and its administration benefits outweigh the risks, even in those with greater susceptibility to its adverse consequences e.g., the elderly and individuals with hypertension, known ischaemic heart disease and arteriopathies.

Q11. How should adrenaline ampoules be stored?

The quality of adrenaline solution can deteriorate when exposed to light and heat. Keep the adrenaline ampoules in a plastic container at 20°-25°C. Do not refrigerate. Periodically check the expiry date to make sure the ampoules are not expired. Dispose expired ampoules and get them replaced. Before use, check for cloudiness, discoloration or presence of any visible particle. Replace the ampoules, if required.

Q 12. What should you do after administering adrenaline injection?

After administering one dose of IM adrenalin injection, patient should be immediately referred to nearest health facility for further management. Inform medical officer before the patient arrives at the health facility.

Annexure 5

Differential diagnosis and management of AEFIs occurring soon after vaccination

Most AEFIs occurring after vaccination are usually minor AEFIs and are self-limiting – local pain, swelling, low/medium grade fever, abscess, etc. These occur beyond a few hours of vaccination. Some severe /serious AEFIs may occur soon after vaccination (few minutes to few hours). These require immediate attention:

1. Allergic reactions (very rare - <0.01% of all vaccinated individuals)
2. Breath-holding spells
3. Syncopal attacks (rare - 0.01 to 0.1% of vaccinated individuals)
4. Convulsions
5. Toxic Shock Syndrome
6. Anaphylaxis (very rare - <0.01% of all vaccinated individuals)

Common AEFIs and their management

Adverse event	Signs and symptoms, reporting	Treatment	Vaccines Involved
Fever	Fevers below 102°F/ < 39°C (low/medium grade) may be listed in AEFI register as minor AEFI if medical care was sought. High grade fever i.e. 102°F to 104.7°F (39 to 40.4°C) above should be reported as severe AEFI if not hospitalized.	Symptomatic; Paracetamol	Any vaccine
Severe local reaction	Redness and/or swelling around the injection site and one or more of the following: • Swelling beyond the nearest joint • Pain, redness and swelling of more than 3 days duration • Requires hospitalization. Local reactions of lesser intensity occur commonly and are trivial and do not need to be reported. Settles spontaneously within a few days to a week.	Symptomatic; Paracetamol	Any vaccine
Injection site abscess	Fluctuant or draining fluid-filled lesion at the site of injection. Bacterial if evidence of infection (e.g. purulent, inflammatory signs, fever, culture), sterile abscess if not. Reported and investigated as serious, if hospitalized for treatment.	• Incise and drain • Anti-inflammatory (e.g. Syp. Ibuprofen) • Antibiotics if bacterial	Any vaccine
Seizures	Occurrence of generalized convulsions that are not accompanied by focal neurological signs or symptoms. Febrile seizures; if temperature elevated >100.4 °F/ > 38°C (rectal) Afebrile seizures: if temperature normal. Self-limiting.	• Supportive care • Paracetamol and cooling if febrile • Rarely anticonvulsants	All, especially Pertussis containing vaccine (DPT, Penta), Measles

Adverse event	Signs and symptoms, reporting	Treatment	Vaccines Involved
Persistent inconsolable screaming	Inconsolable continuous crying lasting 3 hours or longer accompanied by high-pitched screaming.	• Settles within a day or so • Analgesics may help.	DPT, Penta
Hypotonic Hypo-responsive Episode (HHE) or shock-collapse	Event of sudden onset occurring within 48 (usually less than 12) hours of vaccination and lasting from one minute to several hours, in children younger than 10 years of age. All of the following must be present: • Limpness (hypotonic) • Reduced responsiveness (hyporesponsive) • Pallor or cyanosis	• Episode is transient and self-limiting • Does not require specific treatment • Not a contraindication for further doses of the vaccine.	Mainly DPT, Penta rarely others

Differential diagnosis for anaphylaxis, breath holding spell and convulsion; allergic reactions;

	Breath holding spell	Convulsion	Anaphylaxis
Triggering factor	Triggered by sudden fright/ pain/injury to head; occurs in young children	Illness, fever, medication, or injury	Any drug including vaccine, food, insect bite etc.
Clinical features	Child becomes pale, loses consciousness, develops facial flushing & cyanosis, may become sweaty, or stiffen, have a few body jerks or loose bladder control	Child cries/groans loudly. Tonic phase – body is rigid, with clenched teeth. Lips may turn blue. Clonic phase- Resumes shallow breathing; arms and legs jerk quickly and rhythmically; pupils contract and dilate	Urticaria, swollen eyes, face, generalized rash; Noisy breathing from airways obstruction; Tachycardia; Weak carotids; Loss of consciousness; little response in prone position
Duration	Episodes are brief and lasts less than minute	Generally lasts 1 - 3 minutes. Seizure lasting more than five minutes requires emergency medical help.	With early and appropriate intervention, anaphylaxis can pass within a few hours. If progresses to a serious stage, recovery may take a few days. May cause death within minutes or hours after onset if appropriate steps are not taken
Recovery	Child will regain consciousness, recognises people but may seem sleepy	Child relaxes, may lose control of bowel or bladder. Regains consciousness slowly. May appear drowsy, confused, anxious, or depressed.	Potentially fatal if not recognised and treated appropriately soon after onset. Recovery may take days.

	Mild allergic reactions	Severe allergic reactions / Anaphylaxis
Onset and progression	Fast onset immediately following vaccination, does not progress in severity; not life threatening	Quick onset, progresses quickly in severity
Signs and symptoms	Itching, redness, mucosal involvement (swelling of lips, face, eyes), tingling sensation in mouth, abdominal pain	In addition to dermatological involvement as in mild allergic reactions, the case may progress quickly to involve other systems such as cardiac (persistent dizziness, pale appearance, sudden collapse) or respiratory system (difficulty /noisy breathing, swelling /tightness of throat, difficulty in talking /hoarse voice, wheeze).
Management	Requires symptomatic treatment and refer to medical officer for further management	ANM can safely administer single dose of adrenaline intramuscularly before referring the case immediately to appropriate health facility.
	Many of the initial symptoms and signs are similar in both mild allergic reactions and severe allergic reactions/anaphylaxis. ANM may administer a single dose of adrenaline injection at the first sign or symptom suggestive of allergy or anaphylaxis.	

	Fainting/syncope	Anaphylaxis
Onset	Immediate - At the time or soon after injection	Within few minutes of injection
Skin	Pale, sweaty, cold and clammy	Urticaria, swollen eyes, face; generalized rash.
Respiratory	Normal to deep breaths	Noisy breathing from airways obstruction
Cardiovascular	Bradycardia Strong carotid pulse	Tachycardia Weak carotids
	Transient hypotension	Hypotension
Gastrointestinal	Nausea/Vomiting	Abdominal cramps
Neurological	Transient loss of consciousness, good response once prone	Loss of consciousness, little response once prone

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