Table of Contents

CHAPTER 1
YELLOW FEVER DISEASE

PREAMBLE

Yellow fever is an acute viral haemorrhagic disease transmitted by infected mosquitoes. The "yellow" in the name refers to the jaundice that affects some patients. Up to 50% of severely affected persons without treatment will die from yellow fever. The virus is endemic in tropical areas of Africa and Latin America, with a combined population of over 900 million people.
The yellow fever virus is an arbovirus of the flavivirus genus, and the mosquito is the primary vector. It carries the virus from one host to another, primarily between monkeys, from monkeys to humans, and from person to person. Several different species of the Aedes and Haemogogus mosquitoes transmit the virus. The mosquitoes either breed around houses (domestic), in the jungle (wild) or in both habitats (semi-domestic).
The number of yellow fever cases has increased over the past two decades due to declining population immunity to infection, deforestation, urbanization, population movements and climate change. There is no cure for yellow fever. Treatment is symptomatic, aimed at reducing the symptoms for the comfort of the patient. Vaccination is the most important preventive measure against yellow fever. The vaccine is safe, affordable and highly effective, and appears to provide protection for 30–35 years or more. The vaccine provides effective immunity after 10^{th} day for 95% of persons vaccinated.

1.1 MAGNITUDE OF PROBLEM OF YELLOW FEVER ENDEMIC COUNTRIES

Yellow fever, the original viral hemorrhagic fever, was one of the most feared lethal diseases before the development of an effective vaccine. There are an estimated 200 000 cases of yellow fever, causing 30 000 deaths, worldwide each year. Fortunately, the virus has never emerged in Asia. Asia is considered vulnerable for the potential introduction of the virus, due to the presence of a large susceptible human population and presence of the mosquito vector, *Aedes aegypti*. Possible explanations for absence of the disease in Asia include cross-protection afforded due to by hyperendemicity of dengue fever, low competence of local populations of *Aedes aegypti*, and occurrence of Yellow fever in remote areas in people who do not travel by air and are unlikely to spread the infection. Regions of the world outside the Yellow fever endemic zone infested with *Aedes aegypti* and thus receptive to the introduction and spread of the disease include coastal areas of South America, Central America, the Caribbean, the southern USA, South Africa, India, Southeast Asia, Australia (Queensland), Southern China, Taiwan, and the Pacific Islands.

Up to 5000 cases in Africa and 300 in South America are reported annually, but the true incidence is believed to be 10-50 fold higher than the official reports (WEEKLY EPIDEMIOLOGICAL RECORD, NO. 6, 4 FEBRUARY 2005). Between 1990 and 1999, 11297 cases and 2648 deaths were reported in Africa. The largest number of cases was in Nigeria, which suffered a series of epidemics between 1986 and 1994. Epidemics have also occurred in Cameroon (1990), Ghana (1993-1994, 1996), Liberia (1995, 1998), Gabon (1994), Senegal (1995, 1996), Benin (1996), and Kenya (1992). During epidemics in Africa, the incidence of infection may be as high as 20% and the incidence of disease 3%. In South America, Yellow fever occurs principally in the Amazon region and contiguous grasslands. Between 1990 and 1999, 1939 cases and 941 deaths were reported.

In Africa, where the human population is seasonally exposed in and around villages, children without naturally acquired immunity are at highest risk of disease and there is a slight excess of cases in males. In South America, where the virus is transmitted in sparsely populated forested areas, it principally affects men engaged in lumbering or clearing land for agriculture.

Although WHO Member States are required to report YF cases under the International Health Regulations, reported data underestimate the true incidence of the disease. Studies indicate that YF morbidity and mortality are underestimated by a factor of 10-500. Reasons for underreporting include weak surveillance, particularly in rural areas where there is a higher probability of transmission, and generally less capacity and infrastructure for epidemiological surveillance and laboratory confirmation. Since the late 1980s, there has been a re-emergence of YF; more than 80 % of all YF cases reported to WHO were from Africa. Of the 33 “at-risk” countries in Africa, 16 reported at least 1 outbreak from 1980 to 1999. During the period 2000-2004 alone, 16 countries reported 1 or more outbreaks, with a total of 1927 cases and 425 deaths reported. The largest outbreak recorded during this period was in Guinea in 2000- 2001, where 17 out of the 38 districts reported 833 cases and 246 deaths. Two of the outbreaks reported to WHO since 2000 were urban outbreaks in Abidjan, Cote d'ivoire, in 2001 and Touba, Senegal, in 2002. Outbreaks may occur after long intervals of silence, as in the case of the outbreaks in Kenya in 1993 and Guinea in 2000, which occurred after 20 and 50 years of silence, respectively.

In 2004, out of the total number of cases of yellow fever declared in South America, 111 cases (47%) and 52 deaths (80%) were notified by 5 countries (Bolivia, Brazil, Colombia, Peru and Venezuela). The global case-fatality rate in South America was 47% - far higher than in Africa (11%).

Outbreaks of Yellow fever disease in various endemic countries during 2000-2014 (till April, 2014)

(2008 – April, 2014)	(2003 -2007)	(2000 -2002)
• 24 April 2014 Democratic Republic of Congo • 3 December 2013 Sudan - update • 8 October 2013 in Cameroon • 14 June 2013 in the Democratic Republic of Congo • 31 May 2013 in Ethiopia • 14 February 2013 in Chad • 12 December 2012 in the Republic of Congo • 6 December 2012 in Sudan - update • 22 November 2012 in Sudan - update • 13 November 2012 in Sudan • 3 February 2012 in Cameroon • **3 February 2012** **Cameroon** • **3 February 2012** **Ghana**	**20 May 2008** **Central African Republic** **25 April 2008** **Liberia** **18 April 2008** **Yellow fever in Liberia** **7 March 2008** **Paraguay - update** **Yellow fever vaccination tops 1.27 million in Paraguay** **28 February 2008** **Paraguay - update** **Mobilization against Yellow Fever in Paraguay Continues** **20 February 2008** **Paraguay** **7 February 2008** **Brazil** **3 November 2008** **Burkina Faso** **30 October 2008** **Central African Republic** **29 September 2008** **Guinea** **8 August 2008** **Côte d'Ivoire** **Jan - 12 February 2007** **in Togo** **19 December 2006** **in Togo** **19 October 2006** **Côte d'Ivoire** **19 December 2005** **Guinea - update** **9 December 2005** **Sudan - update 2** **7 December 2005** **Côte d'Ivoire - Update** **28 November 2005** **Mali - Update 3**	**10 October 2003 - Burkina Faso** **30 September 2003 - Sierra Leone - update** **19 August 2003 - Sierra Leone** **11 June 2003 - Sudan - Update** **27 May 2003 - Sudan** **3 February 2003 – Guinea** **17 January 2003 - Brazil** **29 November 2002** **2002 - Senegal –** **20 November 2002 - Senegal -** **1 November 2002 - Senegal** **25 October 2002 - Senegal** **18 October 2002** **2002 - Senegal** **11 October 2002** **2002 - Senegal** **4 October 2002** **2002 - Senegal** **21 January 2002** **2002 - Senegal** **15 November 2001** **2001 - Imported case of yellow fever in Belgium - Update** **12 November 2001** **2001 - Imported case of yellow fever in Belgium** **25 September 2001** **2001 - Guinea** **25 September 2001** **2001 - Côte dÍvoire - Update 5** **18 September 2001** **2001 - Côte d'Ivoire** **13 September 2001** **2001 - Côte d'Ivoire**

- 1 December 2011 Côte d'Ivoire -
- 25 January 2011 Côte d'Ivoire
- 19 January 2011 Uganda
- 5 October 2010 Senegal
- 19 July 2010 Democratic Republic of the Congo
- 27 May 2010 Cameroon
- 24 February 2010 Cameroon
- 12 January 2010 Guinea
- 8 January 2010 Côte d'Ivoire
- 1 December 2009 Yellow Fever in the Central African Republic
- 1 October 2009 Cameroon
- 6 May 2009

Liberia

- 30 April 2009 Republic of the Congo
- 14 January 2009 Guinea
- 6 January 2009 Sierra Leone

28 November 2005
Sudan - Update

21 November 2005
Sudan

16 November 2005
Mali - update 2

10 November 2005
Mali - update

3 November 2005
Mali

2 November 2005
Guinea

20 October 2005
Senegal

22 September 2005
Burkina Faso and Côte d'Ivoire

31 August 2005
Guinea

7 January 2005
Guinea

6 January 2005
Mali

11 March 2004
Liberia –

4 March 2004
Liberia - update

25 February 2004
Liberia

24 November 2004
Burkina Faso

14 September 2004
Venezuela

1 June 2004
Burkina Faso - update

11 May 2004
Burkina Faso

12 September 2001
2001 - Côte dIvoire

5 September 2001
2001 - Côte d'Ivoire - Update

4 September 2001
2001 - Côte d'Ivoire

23 August 2001
2001 - Liberia

7 June 2001
2001 - Peru

31 May 2001
2001 - Côte d'Ivoire

20 March 2001
2001 - Brazil - Update 2

7 March 2001
2001 - Brazil

28 February 2001
2001 - Brazil

29 December 2000
2000 - Guinea

11 September 2000
2000 - Liberia

24 August 2000
2000 - Liberia

19 May 2000
2000 - Nigeria

25 February 2000
2000 - Imported case of yellow fever in the Netherlands

24 January 2000
2000 - Brazil - Update 2

20 January 2000
2000 - Brazil - Update

14 January 2000
2000 - Brazil

Source: WHO

1.2 PROBLEM OF YELLOW FEVER OUTSIDE THE ENDEMIC COUNTRIES

Travelers may wrongly consider yellow fever an "extinct" disease, and may not obtain accurate information about the risk of infection. In part this is because the indigenous population in Africa and South America is immune and virus transmission occurs in the virtual absence of reported cases. During the rainy season and early dry season all rural areas present a danger. In such areas, the risk of infection during a non-epidemic period approximates 1/1000 per month of exposure, but may increase to 1/15 per month during an epidemic. Immunization for travel is imperative.

Between 1996 and 1999, four fatal cases occurred in unvaccinated travelers from the USA and Europe to Brazil (two cases), Venezuela, and Cote d'ivoire. These unfortunate events were completely avoidable by preventative vaccination. In one case (a US citizen infected in Brazil), the patient had not been immunized because the nearest vaccinating centre was inconveniently located, 25 miles from his home in Tennessee. A geographic analysis of vaccinating centers in the USA showed that they were indeed sparsely distributed in rural regions. By international regulation, yellow fever vaccine can only be distributed by centers· approved by the World Health Organization or by designated national health authorities.

1.3 YELLOW FEVER AND INDIA

Yellow Fever does not occur in India. The conditions for transmission of yellow fever are very conducive in India - presence of mosquito vectors in abundance and susceptible population. Government of India has been following a strict yellow fever vaccination programme to prevent the entry of yellow fever in India. All passengers coming to India or passengers going from India to countries endemic for Yellow

Fever should have a valid International Vaccination Card for Yellow Fever or they will be quarantined for a period of 6 days or till the YF vaccination become valid (whichever is earlier).

Strategy of Government of India for prevention of entry of yellow fever disease into India has been screening of all international passengers for vaccination against yellow fever disease at all points of entry in compliance of the International Health Regulations 1969 & 2005 and Aircraft Health Rules 1954 and Port Health Rules 1955. Over the years, Dte. GHS and MOH have set up 27 YFV Centers across the country. The vaccinations in these centers have increased and the demand for YFV has increased from 90,000 to nearly 180,000 in 2014.

Process has already been initiated to increase the yellow fever vaccination centers in the country.

INDIA's RESERVATIONS AND UNDERSTANDINGS TO IHR 2005

Proposed Reservation to IHR 2005:-

1*. The Government of India reserves the right to consider the whole territory of a country as infected with yellow fever whenever yellow fever has been notified under Article 6 and other relevant articles in this regard of IHR (2005). The Government of India reserves the right to continue to regard an area as infected with yellow fever until there is definite evidence that yellow-fever infection has been completely eradicated from that area.*

2. Yellow Fever disease will be treated as disease of Public health significance and all health measures being applied presently like disinsection of conveyance, vaccination requirements and quarantine of passengers and crew (as may be required) (as per Article 7, P.2(b), 42 and relevant annexures) will be continued as has been stipulated under Annex-II of IHR-1969

1.4 CAUSATIVE AGENT OF YELLOW FEVER

The disease is caused by the yellow fever virus, which belongs to the flavivirus group.

1.5 TRANSMISSION OF YELLOW FEVER

There are two modes of transmission of the yellow fever virus, the sylvatic or forest cycle and the urban cycle. Transmission begins when vector mosquitoes (*Aedes africanus* in Africa, and several species of the genus Haemagogus in South America) feed on non-human primates infected with the virus. The infected mosquitoes then feed on humans travelling through the forest. The greatest risk of an epidemic occurs when viraemic humans return to urban areas and are fed on by the domestic vector mosquito *Aedes aegypti*, which then transmits the virus to other humans.

1.6 DISEASE PRESENTATION

Despite intense study, relatively little is known about the disease beyond purely

descriptive accounts. In part, this is due to the occurrence of the disease in remote areas without access to sophisticated medical care. Although the human disease can be modeled quite precisely in nonhuman primates, virtually no research on its pathogenesis has been conducted in the past 20 years.

The clinical disease varies from non-specific, abortive illness to fatal hemorrhagic fever. The incubation period after the bite of an infected mosquito is 3-6 days. Disease onset is typically abrupt, with fever, chills, malaise, headache, lower back pain, generalized myalgia, nausea, and dizziness. On physical examination the patient is febrile and appears acutely ill, with congestion of the conjunctivae and face and a relative bradycardia with respect to the height of fever (Faget's sign). Virus is present in blood and the patient may thus serve as a source of infection for mosquitoes. The average fever is 39°C and lasts 3·3 days. Young children may experience febrile convulsions. Laboratory abnormalities include leukopenia with a relative neutropenia. Between 48 and 72 h after onset and before the appearance of jaundice, serum transaminase levels may rise. This so-called "period of infection" lasts several days and may be followed by a "period of remission", with the disappearance of fever and symptoms lasting up to 24 h. During the period of remission, virus is cleared by antibodies and the cellular immune response. The blood may contain non-infectious immune complexes detectable by immunoassays or PCR. Patients with abortive infections may recover at this stage, without further signs.

In approximately 15- 25% of people affected, the illness reappears in a more severe form (the so-called IrpeHod of intoxication") with fever, vomiting, epigastric pain, jaundice, renal failure, and a hemorrhagic diathesis. Hemorrhagic manifestations include petechiae, ecchymoses, epistaxis, and oozing of blood from the gums and at needle puncture sites. In many cases there is major bleeding, coffee-grounds haematemesis, melaena, or metrorrhagia. laboratory abnormalities include thrombocytopenia, prolonged clotting and prothrombin times, reduced fibrinogen and factors II, V, VII, VIII, IX, and X, and the presence of fibrin split products. These abnormalities suggest a multifactorial bleeding disorder caused by reduced synthesis of clotting factors and consumption coagulopathy. Platelet dysfunction, demonstrated by collagen and ADP stimulated aggregation, has been demonstrated in the monkey model. Myocardial injury is manifest by ST-T wave abnormalities on the electrocardiogram, and occasionally by acute cardiac enlargement.

20-50% of patients with hepatorenal disease die, typically 7-10 days after onset. Events preceding death include hypotension-an increasingly difficult symptom to manage with fluids and vasopressors. Patients also experience agitated delirium, stupor, coma, Cheyne-Stokes respirations, metabolic acidosis, hyperkalaemia, hypoglycaemia, and hypothermia. The cerebrospinal fluid is under increased pressure, with raised albumin but no increase in white blood cells, which is consistent with cerebral oedema. Pathological changes include microscopic perivascular haemorrhages and oedema. True yellow fever viral encephalitis due to viral infection of brain tissue (as opposed to encephalopathy) is very rare.

CHAPTER 2
YELLOW FEVER VACCINE

Yellow Fever Vaccine is an attenuated, live-virus preparation of the 17D strain of yellow fever virus grown in leucosis-free chick embryos. A single dose confers immunity in basically 100% of recipients. Protective immunity is achieved only after 10 days of yellow fever vaccination and persists for 30-35 years in persons residing in yellow fever endemic countries and hence as per present WHO provisions it has been agreed upon by Govt. of India that single dose of yellow fever vaccination in such persons single dose confers lifelong immunity and hence there is no need for re-vaccination in persons residing in yellow fever endemic countries. However, in persons from non-endemic countries and re-immunization is currently recommended after 10 years. This vaccine is given as a single injection given subcutaneously. Yellow fever Vaccination Certificate becomes valid only after 10 days of vaccination.

2.1 Vaccine summary

Type of vaccine	Live viral
Number of doses	One dose of 0.5 ml subcutaneously
Route of Administration	Sub-cutaneous
Schedule	Can be given at nine months of age
Booster	Require a booster every 10 years (for persons from non-endemic countries)
Contraindications	Egg allergy; immune deficiency from medication or disease; symptomatic **HIV** infection; hypersensitivity to previous dose; pregnancy
Adverse reactions	
Special precautions	Hypersensitivity to egg; rarely, encephalitis in the very young; hepatic failure. Rare reports of death from massive organ failure. Do not give before six months of age; avoid during pregnancy
Storage temperature	+2 to +8 degrees centigrade

Source: WHO

2.2 SIDE EFFECTS

Severe or serious adverse reactions to 17D vaccine are extremely rare. Post-vaccinal encephalitis (due to invasion of the brain by the vaccine virus) has long been recognized as a rare complication related to use of the vaccine in very young infants. 18 of the 21 reported encephalitis cases were in children, of whom 16 were under 7 months. Virus recovered from the brain of the single reported fatal case contained two aminoacid changes in the E gene and exhibited increased neurovirulence in animals. It is unknown whether the other cases were due to mutations in the vaccine virus. Anaphylactic reactions to yellow fever vaccine occur at a frequency of approximately 1/58000 and may be due to sensitivity to gelatin used to stabilize the vaccine.

1. **Mild Side Effects of Vaccination**
   - Yellow fever vaccine has been associated with fever and with aches, soreness, redness or swelling where the shot was given. These problems occur in up to 1 person out of 4. They usually begin soon after the shot, and can last up to a week.
   - Most people will get a slight sore arm

- 2-10% may feel tired, headache, muscle aches, fever for 24 hours starting 3-9 days after the vaccine
- 1% need to curtail regular activities

2. More Serious Side Effects of Vaccination

- The risk of a vaccine causing serious harm, or death, is extremely low.
- Severe allergic reaction to a vaccine component (about 1 person in 58,000).
- Severe nervous system reaction (about 1 person in 1,25,000).
- Life-threatening severe illness with organ failure (about 1 person in 2,50,000). More than half the people who suffer this side effect die. These last two problems have never been reported after a booster dose.
- 1 in 130,000 will get immediate hypersensitivity – rash, itching faint or asthma – this is why you need to wait 30 minutes in the clinic
- 0.09-2.5 per million will get inflammation of multiple organs e.g. lungs, kidney, liver, spleen, skin, blood stream
- 1 in 8 million will get encephalitis (Inflammation of the brain)

2.3 MANUFACTURERS, PURCHASE AND SUPPLY OF YF VACCINE:

WHO recommends the immunization of children through routine, preventive and reactive campaigns depending upon the risk level. Four manufacturers offer WHO prequalified YFV:

Manufacturers YFV

Manufacturer	WHO prequel.	Presentation	Shelf Life	WHO Prequal. Status
Bio-Manguinhos (Brazil)	2001	5 ds	24 months	Suspended
	2007	10 ds	24 months	
	2001	50 ds	24 months	
Institute Pasteur de Dakar (Senegal)	2001	5 ds	36 months	Active
	2001	10 ds	36 months	
	2001	20 ds	36 months	
FSUE Chumakov (Russia)	2009	2 ds	24 months	On Temporary Hold
	2009	5 ds	24 months	
	2009	10 ds	24 months	
Sanofi Pasteur (France)	1987	10 ds	36 months	Active

Source: WHO.

In India vaccine is produced and supplied by Central Research Institute, Kasauli. However, in the recent years, there has been a shortfall of yellow fever vaccine in the above 27 centers because of short supply of the vaccine.

CRI, Kasauli: address and contact details are:
Treatment Centre,
Central Research Institute, Kasauli, HP
Phone-01792-272538,01792-273209

The yellow fever vaccine is being imported through WHO (which takes nearly 8 to 9 months for supply). The vaccines which are procured from above mentioned manufactures should have a valid WHO prequalification certification. However, marketing in India also requires approval of DCGI.

2.4 YELLOW FEVER VACCINE PROCUREMENT

The Yellow Fever vaccine is produced in the country by CRI, Kasauli and supplied to various recognized YF vaccination centers by MOHFW. In case of emergency or breakdown of vaccine production/supply, vaccine procurement is done by CRI, Kasauli through WHO and then supplied to various vaccination centers as above. Vaccination requirement is estimated on yearly consumption basis. The Yellow Fever Vaccination centers /Hospitals place the demand and CRI Kasauli procures the Yellow Fever Vaccine as per their need. The Yellow Fever Center/ Hospital make the payment for the vaccine to C.R.I. (Kasauli) after receiving the vaccine from their allocated budget.

DEMAND ESTIMATION

It is suggested that each YF vaccination center while placing the demand should ensure that it has sufficient reserve stock as buffer to meet the demand for six months (which should ideally include 10% wastage amount). Demand should indicate no. and quantity of multi dose vial (10, 5 or 2 ml) required based on the consumption pattern during previous years. The proportion of vials should be based on the consumption pattern during the past few years. The 10 dose vials should break up 50%, 5 dose vial 15%, 2 dose vial 15% and 1 dose vial 20% of the total demand of doses.

VIAL OF YELLOW FEVER VACCINES

Yellow fever vaccines are available in multi dose or single dose vials as given below:

Multi dose (10, 5 & 2 doses vial)
Single dose (1 dose vial)

Presently, the vaccination fee is charged as Rs. 300 per vaccination dose to the passenger. This includes syringes, sterilization, administering, transport and cold chain maintenance cost.

2.5 PRECAUTIONS TO BE TAKEN DURING ADMINISTRATION OF YF (Yellow Fever) VACCINES

Besides keeping a watch for anaphylactic reactions, sensitivity for egg proteins or to any other immunization or drug is invariably confirmed from all passengers. All asceptic precautions are taken. Any unused vaccine that is not used within one to two hours of reconstitution must be discarded.

2.6 AUDITING OF YF VACCINES:

A monthly report is generated at each YF vaccination center giving details of the number of vaccines used and the balance in stock. A complete register is maintained at each centre with all details of the passenger immunized including his passport and contact details. Medical officer posted at vaccination centre supervises the total process of YF vaccination. As each vaccination costs Rs. 300/- a receipt is issued.

CHAPTER 3

YELLOW FEVER VACCINATION CENTERS

3.1 CAPACITY OF GOVERNMENT INSTITUTIONS IN GIVING YELLOW FEVER VACCINATIONS:-

There are 27 vaccination centers **(List enclosed as Annexure-1)**. All these vaccination centers are approved by DGHS and the Ministry of Health and Family Welfare and are based in government institutions either of Centre or State. These centres are spread over the states of TN, West Bengal, Gujarat, UP, Kerala, Maharashtra, Karnataka, HP, AP, Goa and Delhi. These centers follow all measures abiding international health regulations and the rules of the country.

3.2 EXPANSION OF YELLOW FEVER VACCINATION IN OTHER SETTINGS

3.2.1 Expansion of YFV to all existing APHOs/PHOs: - As mentioned above, the YFV services are, presently being provided in 27 government institutions. To expand the YFV, on the first hand all APHOs and PHOs be designated as YFV centres. This include the following existing APHOs/PHOs:

APHO Chennai
PHO Tuticorin
APHO Amritsar
JNPT, Sheva, Mumbai

3.2.2(a). STATES/UTs which are not having any YF Vaccination Centres:

a. Rajasthan
b. J & K
c. Bihar
d. Assam
e. A & N islands
f. Arunachal Pradesh
g. Chattisgarh
h. Haryana
i. Jharkhand
j. Madhya Pradesh
k. Manipur
l. Meghalaya
m. Mizoram
n. Nagaland
o. Orissa
p. Sikkim
q. Tripura
r. Uttaranchal
s. Chandigarh
t. Dadar and Nagar Haveli
u. Daman and Diu
v. Lakshadeep
w. Pondicherry

Travelers who need YF vaccinations from the 3.2.2 areas have to travel to nearby designated vaccination.

3.3 Identification of New YF vaccination centers: MOHFW is exploring possibilities of new/additional vaccination centers for designating as per the WHO norms as authorized YF vaccination centers. Feasibilities of opening YF vaccinations in these areas are have been taken up with DHS of state by the DGHS, MOHFW.

A. **Medical Colleges/ Central Government Institutions**: Vaccination centres can be located in the government settings (central or medical colleges/ institutions).
B. **State Government Institutions**: In areas where there are no Central Government or Medical colleges, State Government Institutions may be designated as YFV centers.

Govt. Institutes/hospitals recommended by the states are first inspected for required manpower and logistics. Then the manpower identified to be deployed at the yellow fever vaccination center is given 2 days orientation training on SOPs and maintenance of records, before final approval is given for designating the yellow fever vaccination center by the director general of health services, MOHFW, GOI.

CHAPTER – 4

PREREQUISITES FOR ESTABLISHING A YELLOW FEVER VACCINATION CENTRE

India is highly vulnerable to the yellow fever introduction in view of highly susceptible population and abundance of mosquito vector- *Aedes aegypti*. The dense population also will contribute to the high morbidity and mortality (case fatality rates being as high as 50 percent in areas where Yellow fever is nonexistent) in case yellow fever is introduced. In view of these facts a strict quality control of YF vaccination process has to be maintained and if introduced in other settings the following aspects will need to be taken care of:

1. **DESIGNATED YELLOW FEVER VACCINATION CENTERS**: For the purpose of yellow fever vaccination, only a vaccination center authorized by the Ministry of Health & FW, Government of India is recognized center. These are designated by Directorate General of Health services and notified to WHO.
2. **COLD CHAIN ISSUES**: Yellow Fever vaccine has to be maintained at a temperature of +2 to +8 degrees centigrade having an effective cold chain mechanism. The maintenance of cold chain can be a problem leading to loss of viability of vaccines. In government settings, an Ice Lined refrigerator is a common practice originating from the large scale immunizations being done in government. For newer facilities similar cold chain mechanism would be required.
3. **DEMAND AND SUPPLY OF YFV**: Presently, each vial of vaccine consists of 10/5/2 doses. As mentioned above, YFV are imported presently from WHO recognized manufacturer and thus each institution will be given a demand for vaccines at least 6 months in advance to facilitate procurement and supply. Each institution will have to give the consumption report on three monthly bases to the CRI Kasauli/DGHS.
4. **INJECTION SAFETY PRACTICES**: Each institution will follow the Injection Safety Practices guidelines as indicated in the chapter on Safe Injection Practices.
5. **TRAINED MANPOWER FOR ADMINISTRATION OF VACCINE:** The manpower at each institution will be trained by the APHO/PHO for administration of YFV. A standard initial training of 2 days has to be undertaken by the personnel of the institutions giving YFV.
6. **APPROPRIATE TRAINING OF MEDICAL AND PARAMEDICAL STAFF IN EMERGENCY MANAGEMENT OF CASES REPORTING ACUTE REACTIONS FOLLOWING IMMUNIZATION:** needs to be arranged in tertiary care hospital for 1 to 2 days. The training should include hands on training on use of laryngeal mask which is a must for treating cases of anaphylactic shock and manifesting in dyspnoea (shortness of breath) due to laryngeal edema (swelling of vocal cords).
7. **AUTHORIZED INTERNATIONAL YFV CARDS – DIFFICULTY IN MAINTAINING UNIFORMITY OF THE YF CARDS OF PASSENGERS COMING TO INDIA: As such, at all recognized YFV centers, the International YF Vaccination Cards printed as per WHO format in IHR (2005) document of WHO, procured from authorized agents is to be used.** In case YF vaccination cards are printed on different stationary it may be difficult to recognize by the immigration officials.
8. **AUTHORIZED SIGNATORY ON YF CARDS:** Medical Officer & Official appointed by Center/State govt. only will be allowed to sign the YF cards. If the supervising clinician is of the opinion that the vaccination or prophylaxis is

contraindicated on medical grounds, the supervising clinician shall provide the person with reasons, (written in English) underlying that opinion, which the competent authorities on arrival should take into account. The supervising clinician and competent authorities shall inform such persons of any risk associated with non-vaccination and with the non-use of prophylaxis.

4.1 SPACE & INFRASTRUCTURE FOR VACCINATION CENTER -

An ideal yellow fever vaccination center should have sufficient space for Registration, Space for waiting area/room, Injection (vaccination) Room, Observation Room and Facilities for public use. *(These specifications are mentioned on the basis of the space provisions at YF vaccination center at APHO, Delhi and not recommended by MOHFW as ideal requirement)*

4.1.1 The Space for waiting area/room

The APHO Delhi is providing yellow fever vaccination on Tuesday & Thursday between 2-4 pm. The APHO Delhi is providing vaccination to 60-80 people per vaccination day.
The Waiting room in APHO Delhi is having following dimension

SPACE	CHAIR
36 ft x 18 ft (length x breath)	25

4.1.2 Injection (vaccination) Room:

The Vaccination room in APHO Delhi is having following dimension

	SPACE	CHAIR
VACCINATION ROOM	18 ft x 19 ft (length x breath)	15

4.1.2a. Equipments & Infrastructure of Vaccination room:-

1) One ml Disposable / A.D. Syringe & Needle
2) 05 ml Disposable syringe & needle
3) Glove
4) Cotton/water Swab
5) Hub cutter
6) Needle destroy
7) Waste disposable bag/bucket
8) Stool (two)
9) Almirah (one)
10) Chair (fifteen- Five for Staff & Ten for Vaccinee)
11) Table (one)
12) Tray,

13) Scissor
14) One bed
15) One Couch
16) Stretcher
17) Moveable screen
18) Two Fridge of 400 liters & 165 liters capacity.

4.1.2b Space for vaccine storage:-

Vaccine Storage:-

The vaccine is to be stored and transported at the temperature of 2 to 8°C. in the place inaccessible to children. The diluents of the vaccine are to be stored at 2-8°C.

Vaccine Storage Space:-

A freezer compartment with size of 12”x21”x19” of 400 liters capacity refrigerator can stores up to 2000 vaccine dose.

4.1.3 Observation Room (In case of anaphylactic shock/adverse reactions)

Observation room should have-

1) Four Bed
2) Thermometer
3) BP instrument
4) Stethoscope

4.1.3 a Emergency Medicine Kit (in Observation Room for any time):-

1) Plastic/disposable syringes
2) Injections
   - Adrenaline
   - Anti- histamine
   - Hydrocortisone
   - Terbutaline
   - Dextrose (25%)
3) IV Canulas (20G and 22G)
4) Cotton gauze
5) IV Infusion set
6) Oral drugs: Paracetamol Antihistamines
7) Mouth gags and tongue depressor
8) Oxygen cylinder
9) AMBU bag
10) Face mask (adult/pediatric)
11) IV Fluids
    - Normal saline
    - N/5 in 5% Dextrose
    - Ringer lactate

4.1.3 a Basic Facilities (Optional):-

Facility for drinking water,
Wash room,
TV

4.2 **Manpower**: (Only for vaccine days and time)

1Doctor
1Nurse
1Clerk/ person for registration
1Helper for vaccination

4.3 THE NECESSARY INFORMATION FOR YELLOW FEVER VACCINE BENEFICIARIES (To be displayed at YF centre for passenger – see Annexure2)

The contraindications to Yellow fever vaccination need to be displayed at all the POEs so as to improve the awareness of the traveler receiving the vaccine. It should also include the likely side effects following vaccination which the passenger should report to the clinician. All passengers should be advised of signs and symptoms of allergic reactions (e.g, urticaria, angioedema, rash, dyspnoea, bronchospasm, and pharyngeal edema, - wheezing and throat tightness), vaccinated persons should be advised to seek immediate medical attention if any symptoms of allergic reactions develop following vaccination.

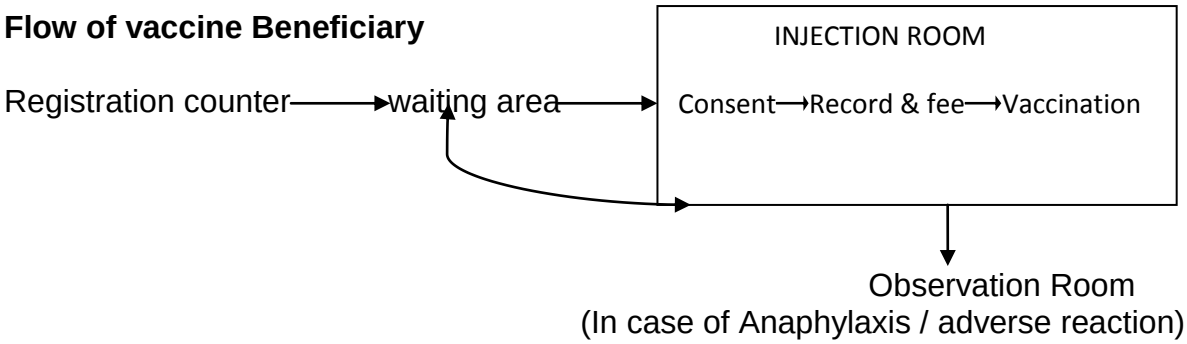
Documentation of provision of information on contraindications of Yellow Fever needs to be maintained at Yellow Fever Vaccination Centres. Preferably a Proforma needs to be developed which lists all the contraindications and the passenger should sign it (it could be in register made for the purpose of informing the traveler of side effects and contraindication of YF vaccine) and declare that he is not suffering from any disease, before being administer the Yellow fever vaccine documentation of informed consent should be taken by all the vaccinees.

CHAPTER 5
VACCINATION PROCEDURE

5.1 All the necessary information regarding the procedure of vaccination and the side effects / Adverse effects related to the Yellow Fever Vaccination should be displayed & informed to all the vaccinee.

The vaccine beneficiary move in following direction

Flow of vaccine Beneficiary



5.2 The procedure for Yellow Fever Vaccination:

1. The vaccination services are to be provided on the first come first served basis.
2. The registration / token distribution system may be followed to maintain the first come first served system.
3. At time of registration, the Travel Document (passport) is to be checked and all the vaccinees are instructed to read the necessary information regarding Yellow Fever Vaccination displayed in the registration / waiting area. (Travel documents may be withheld for half an hour and may be given to passengers after ensuring no reaction). For this, additional facility in terms of waiting room, additional beds may be created at the POEs.
4. The vaccinees are informed to bring/keep the Travel Document (passport) and the vaccination fee Rs.300/- with them at the vaccination time.
5. All the vaccinees are instructed to wait in the waiting area and the vaccinees are called for vaccination in batches of 10 persons in vaccination room.
6. All the vaccinees are informed and allowed to read about the side effects / adverse reactions and other related information about Yellow Fever Vaccination.
7. Administration of live viral vaccines should be deferred in cases on immunosuppressive and immunomodulatory therapies and medical waiver may be considered with advice on protection from mosquito bites.
8. The informed consent is to be taken from all the vaccinees (it could be in register made for the purpose of informing the traveler of side effects and contraindication of YF vaccine).
9. The entries are filled up in the vaccination register from Travel Document (passport) & subsequently the fee for the vaccination are collected and the receipt for the same is given to vaccinee.
10. The vaccinees are directed to complete the entries related to vaccine in WHO Yellow Fever Vaccination card and directed for vaccine inoculation.
11. A Test dose may be given intradermally to selected cases who are suffering from diseases or in egg sensitive persons where caution is advised (CDC Morbidity and Mortality Weekly Report (MMWR: Yellow Fever Vaccine,

Recommendations of Advisory Committee on Immunization Practices (ACIP): Recommendations and Reports July 30, 2010/59 (RR07); 1-27)).

a. Sensitivity testing: Intradermal test: Inject a dose of 0.02 mL of a 1:100 dilution of the vaccine in physiologic saline. Positive and negative control skin tests should be performed concurrently. A wheal 5 mm or larger than the negative control with surrounding erythema is considered a positive reaction. (http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=424f6e3d-14fd-4f77-acd5-b88eb18b2eaa) If vaccination is considered essential, despite a positive skin test, then desensitization can be considered. A full dose of vaccine may be given after negative test dose (to be read after 30 minutes).

12. The doctor/nurse start vaccination procedure as follows:

a. Checks the Vial Viability Marker (**see the Annexure-3 for VVM**)
b. The required amount of diluents mixed in the vial with 5ml disposable plastic syringe.
c. All the bio-medical waste are segregated and collected/disposed in the respective bags at the time of procedure only **as per biomedical waste rules**.
d. The water swab is used to clean the inoculation area.
e. The vaccination dose i.e. 0.5ml for everybody is inoculated to the vaccinee with 1ml disposable/AD plastic syringe.
f. After inoculation the vacinees are asked to wait for 30 minutes and inform then & there any side effects / adverse reactions to doctor on duty.

5.3 Management of AEFI (Adverse Event Following Yellow Fever Vaccination):

As most vaccinees from the Yellow Fever Vaccination Centres travel out of the country after taking the vaccine thereby making it difficult for monitoring the concurrence of AEFI (As these might occur at the destination area of the traveller). Hence in such cases the National AEFI Guidelines needs to be followed:

a. First Information Report (FIR) form to all clinics for reporting any serious AEFI (These are to be notified to aefiindia@gmail.com

b. Develop a stamp /sticker to be glued / printed on all Yellow fever vaccine cards urging the vaccinee/family of vaccine to contact the clinic in case of any serious event /hospitalisation within 30 days of vaccination (Contact no. Of Yellow Fever Vaccination Centres) and send information to aefiindia@gmail.com .

c. It is the responsibility of APHO/PHO in assisting EPI Officers / AEFI Staff in investigating the AEFI after Yellow Fever vaccine. They shall assist in filling out the PIR and DIR forms in case an AEFI is reported after travel to a foreign country by a vaccinee/family of a vaccinee.

The FIR, PIR & Dir Forms are placed at Annexure-IV.

CHAPTER 6
RECORD MAINTENANCE

The following records are to be maintained

1. **Registration record** - record vaccinee's name & travel document details (passport No.).

2. **Consent form/register-**The informed consent is recorded from every vaccinee before vaccination.-

   Consent-

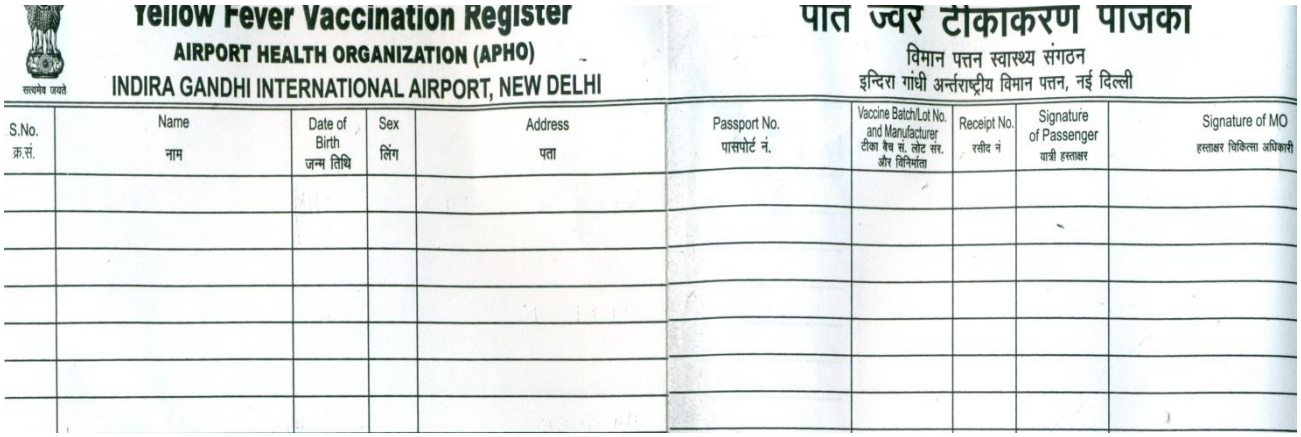
   I hereby, am giving my full, free & voluntary consent for yellow fever vaccination. The procedure, risk, complication, contraindication & other related information to the vaccination has been provided to read and explained to me by the Doctor on duty in the language I understand.

   Signature of the passenger.

3. **Yellow fever vaccination register-**

   The following entries are to be completed in the register –

   Sl. No., Name, Date of Birth, Sex, Passport No., Address, Vaccine Batch No., Receipt No., Signature of passenger, Signature of Medical Officer



Yellow Fever Vaccination Register

AIRPORT HEALTH ORGANIZATION (APHO)

INDIRA GANDHI INTERNATIONAL AIRPORT, NEW DELHI

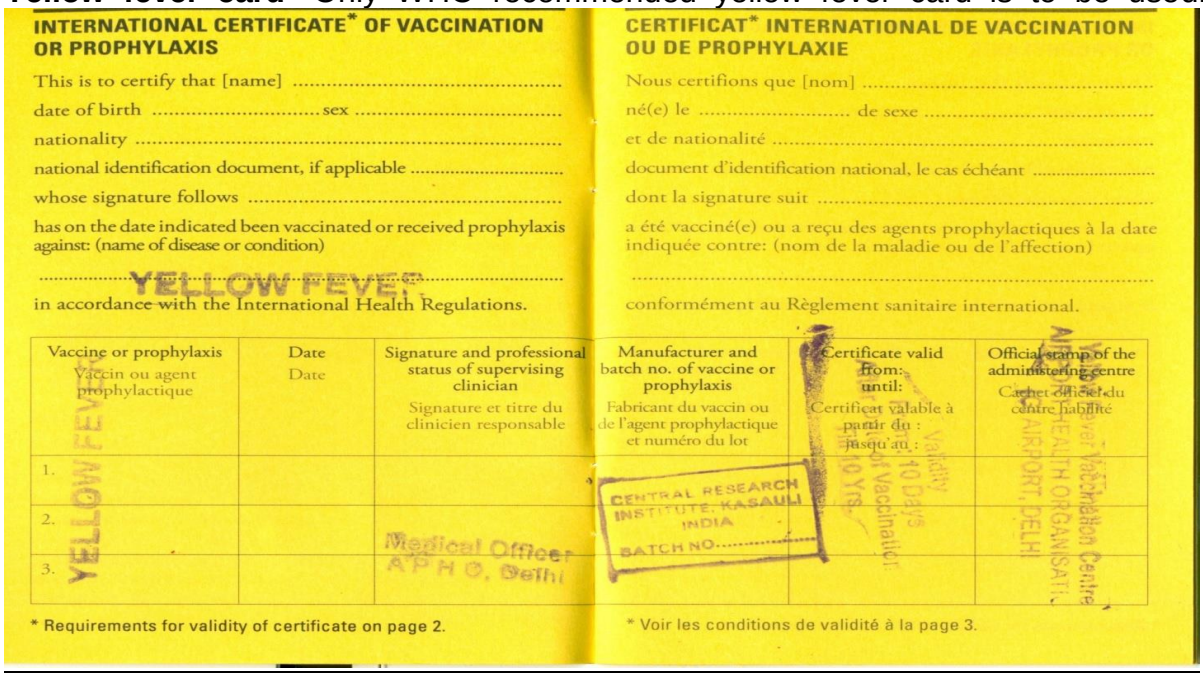
पात ज्वर टीकाकरण पाजका

विमान पत्तन स्वास्थ्य संगठन

इन्दिरा गांधी अर्न्तराष्ट्रीय विमान पत्तन, नई दिल्ली

S.No. क्र.सं.	Name नाम	Date of Birth जन्म तिथि	Sex लिंग	Address पता	Passport No. पासपोर्ट नं.	Vaccine Batch/Lot No. and Manufacturer टीका बैच सं. लोट संख. और विनिर्माता	Receipt No. रसीद नं	Signature of Passenger यात्री हस्ताक्षर	Signature of MO हस्ताक्षर चिकित्सा अधिकारी

4. **Yellow fever card-** Only WHO recommended yellow fever card is to be used.



INTERNATIONAL CERTIFICATE* OF VACCINATION OR PROPHYLAXIS

This is to certify that [name] .....

date of birth ..... sex .....

nationality .....

national identification document, if applicable .....

whose signature follows .....

has on the date indicated been vaccinated or received prophylaxis against: (name of disease or condition)

..... YELLOW FEVER .....

in accordance with the International Health Regulations.

CERTIFICAT* INTERNATIONAL DE VACCINATION OU DE PROPHYLAXIE

Nous certifions que [nom] .....

né(e) le ..... de sexe .....

et de nationalité .....

document d'identification national, le cas échéant .....

dont la signature suit .....

a été vacciné(e) ou a reçu des agents prophylactiques à la date indiquée contre: (nom de la maladie ou de l'affection)

.....

conformément au Règlement sanitaire international.

Vaccine or prophylaxis Vaccin ou agent prophylactique	Date Date	Signature and professional status of supervising clinician Signature et titre du clinicien responsable	Manufacturer and batch no. of vaccine or prophylaxis Fabricant du vaccin ou de l'agent prophylactique et numéro du lot	Certificate valid from: until: Certificat valable à partir du : jusqu'au :	Official stamp of the administering centre Cachet officiel du centre habilité
1.			CENTRAL RESEARCH INSTITUTE, KASAULI INDIA BATCH NO.....	Validity 10 Days Yellow Fever Vaccination 10 Yrs.	AIRPORT HEALTH ORGANISATION Yellow Fever Vaccination Centre INDIRA GANDHI INTERNATIONAL AIRPORT, DELHI
2.		Medical Officer APHO, Delhi			
3.					

YELLOW FEVER

* Requirements for validity of certificate on page 2.

* Voir les conditions de validité à la page 3.

CHAPTER 7
GUIDELINES FOR SAFE INJECTION PRACTICES

1. Use sterile injection equipment

- Use Auto-diasble sterile syringe and needle for each injection and to reconstitute each unit of medication.
- Inspect packaging for breaches in barrier integrity. Discard a needle or syringe if the package has been punctured, torn, or damaged by exposure to moisture

AD Syringes – Instructions for Use

1. Select the correct syringe for the vaccine to be administered

2. Check the packaging. Don't use if the package is damaged, opened or expired.

3. Peel open or tear the package from the plunger side and remove the syringe by holding the plunger. Discard the packaging into a black plastic bag.

4. Remove the needle cover / cap and discard it into the black plastic bag. Do not move the plunger until you are ready to fill the syringe with the vaccine and do not inject air into the vial as this will lock the syringe.

5. Take the appropriate vaccine vial, invert the vial, and insert the needle into the vial through the rubber cap. Insert the needle such that the tip is within the level of the vaccine. If inserted beyond you may draw air bubble, which is very difficult to expel. Do not touch the needle or the rubber cap (septum) of the vial.

6. Pull the plunger back slowly to fill the syringe. The plunger will automatically stop when the necessary dose of the vaccine has been drawn (0.1 or 0.5 ml). Do not draw air into the syringe. In case air should accidentally enter the syringe, follow these steps to remove the air bubbles:

   (a) Remove the needle from the vial. Holding the syringe upright, tap the barrel to bring the bubbles towards the tip of the syringe.

   (b) Pull the plunger back to allow air to come in through the needle until it comes in contact with the air bubble in the syringe barrel.

   (c) Then carefully push the plunger to the dose mark (0.5 or 0.1 ml) thus expelling the air bubble.

7. Clean appropriate injection site, if necessary with a wet swab and administer the vaccine.

8. Push the plunger completely to deliver the dose till it gets locked.

9. Cut the hub of the syringe immediately after use with a hub-cutter that collects the sharps in a hard white translucent plastic container. Do not recap the needle. Then collect the cut syringes in a red plastic bag. The cut/ destroyed syringes, barrels and needles must be disinfected at the designated place and properly disposed off.

Use and Disposal of Syringes
(Preferably Auto-Disable (AD) Syringes should be used)

In practice, at most of the centres, 1 ml disposable plastic syringes are being used for single use, and after use, the syringe is discarded using needle destroyer. The recommended biomedical waste disposal guidelines are to be followed.

Where ever practically feasible, Auto-Disable (AD) syringes are to be used for immunization instead of glass or disposable syringes. In parallel to introducing AD syringes, MoHFW has also developed and disseminated detailed user guidelines that outline steps that should be followed when using an AD syringe and disposing of AD syringes.

Steps / stages for safe disposal:

1. **Procedure for use of Disposable syringes (Plastic):**
   - Injection at the immunisation site using a hub-cutter that cuts plastic hub of syringe and not the metal part of needle
   - The cut needles will get collected in the puncture proof white translucent container of the hub cutter.
   - Segregate and store syringes and unbroken (but discarded) vials in red bag or container. If the Immunisation waste is generated from outreach centres, then handover these to the District Hospitals / CHC / PHC for further disposal.
   - Send the collected materials to the Common Bio-Medical Waste Treatment Facilities. If such facilities do not exist, then go to the next step.
   - Treat the collected material in an autoclave. If it is unable to impart autoclaving, boiling such waste in water for at least 10 minutes / chemical treatment may be imparted. It shall be ensured that these treatments ensure disinfection.
   - Dispose the autoclaved waste as follows: (i) Dispose the needles and broken vials in a pit / tank, (ii) Send the syringes and unbroken vials for recycling or landfill.
   - Wash properly the containers for reuse.
   - Make a proper record of generation, treatment and disposal of waste.

2. **Procedure for use of AD syringes (Plastic):**

- Remove needles from AD Plastic syringe immediately after administering

injection at the immunisation site using a hub-cutter that cuts plastic hub of syringe and not the metal part of needle

- The cut needles will get collected in the puncture proof white translucent container of the hub cutter.

- Segregate and store syringes and unbroken (but discarded) vials in red bag or container. If the Immunisation waste is generated from outreach centres, then handover these to the District Hospitals / CHC / PHC for further disposal.
- Send the collected materials to the Common Bio-Medical Waste Treatment Facilities. If such facilities do not exist, then go to the next step.

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- Dispose the autoclaved waste as follows: (i) Dispose the needles and broken vials in a pit / tank, (ii) Send the syringes and unbroken vials for recycling or landfill.

- Wash properly the containers for reuse.

- Make a proper record of generation, treatment and disposal of waste.

2. Prevent contamination of injection equipment and medication

- Prepare each injection in a clean designated area where blood or body fluid contamination is unlikely. Prepare each injection in a clean designated area where blood or body fluid contamination is unlikely.
- Select pop-open ampoules rather than ampoules that require use of a metal file to open.
- If using an ampoule that requires a metal file to open, protect fingers with a clean barrier (e.g. small gauze pad) when opening the ampoule.
- Inspect for and discard medications with visible contamination or breaches of integrity (e.g. cracks, leaks).
- Follow specific recommendations for use, storage, and handling.
- Discard a syringe and needle that has touched any non sterile surface.

3. Prevent needle stick injuries to the provider

- Anticipate and take measures to prevent sudden patient movement during and after injection.
- Avoid recapping and other hand manipulations of needles. If recapping is necessary, use a single-handed scoop technique.
- Collect used syringes and needles at the point of use in a sharps container that is puncture and leak-proof and that can be sealed before completely full.

4. Prevent access to used needles

- Seal sharps containers for transport to a secure area in preparation for disposal. After closing and sealing sharps containers, do not open, empty, reuse, or sell them.
- Manage sharps waste in an efficient, safe, and environment friendly way

to protect people from voluntary and accidental exposure to used injection equipment.

5**. Other practice issues**

- **Provider's hand hygiene and skin integrity**. Perform hand hygiene (i.e., wash or disinfect hands) prior to preparing injection material and giving injections. The need for hand hygiene between each injection will vary based on the setting and whether there was contact with soil, blood or body fluids. Avoid giving injections if skin integrity is compromised by local infection or other skin condition (e.g., weeping dermatitis, skin lesions, and cuts). Cover any small cuts.
- **Gloves**. Gloves are not needed for injections. Single use gloves may be indicated if excessive bleeding is anticipated.
- **Swabbing of vial tops or ampoules**. Swabbing of vial tops or ampoules with an antiseptic or disinfectant is unnecessary. If swabbing with an antiseptic is selected for use, use a clean, single use swab and maintain product specific recommended contact time. Do not use cotton balls stored wet in a multi-use container.
- **Skin preparation prior to injection**. Wash skin that is visibly soiled or dirty. Swabbing of the clean skin prior to giving an injection is unnecessary. If swabbing with an antiseptic is selected for use, use a clean, single use swab and maintain product specific recommended contact time. Do not use cotton balls stored wet in a multi- use container.

ANNEX. 1

List of Yellow Fever Vaccination Centres

S. No.	Name of the Yellow Fever Vaccination Centre	Address of Vaccination Centre	Officer Incharge	Days and Timings of Yellow Fever Vaccine	Contact Details (i.e. Phone/Fax/Mobile/ Email)
1	Airport Health Organization, Delhi	Airport Health Officer Airport Health Organization IGI Airport, Opp. Radisson Hotel Near New Toll Barrier, Mahipal Pur New Delhi-110037	APHO	Monday, Tuesday, Thursday & Friday 2:00 PM – 4:00 PM. (Registration 12.00 Noon to 1.00 PM on the day of Vaccination)	011-25655081(O) 011-25655079(F) 011-25652129 (YF Hosp.) aphopalam@gmail.com
2	Port Health Organization, Chennai	Port Health Organization Rajaji Salai, Chennai-600001	Dr. Maheswari Dy. Port Health Officer	Every Monday & Wednesday 10.00 AM to 2.00 PM (Registration upto 10.30 AM only)	044-25225858 (O) 09003080850 (M) quarantinechennai@yahoo.com
3	Porth Health Organization, Kerala	Port Health Officer Port Health Organisation Willingdon Island Cochin-682009, Kerala	Dr. K.A. Shyamini	Wednesday & Friday in every week excluding Holidays 10:00 AM - 01:00 PM	0484-2666060 / 0484-2666024 (O) 09495932702 (M) phocochin@yahoo.com drshyamini@gmail.com
4	Port Health Organization, Visakhapatnam	Port Health Officer Port Health Organization Port Area, Visakhapatnam-35 Andhra Pradesh	Dr. A. Biswas CMO(SAG)	Every Tuesday & Thursday	0891-2562681 (O) 0891-2562681 (F) 08333040943 (M) phovizagport@yahoo.com

S. No.	Name of the Yellow Fever Vaccination Centre	Address of Vaccination Centre	Officer Incharge	Days and Timings of Yellow Fever Vaccine	Contact Details (i.e. Phone/Fax/Mobile/ Email)
5	Port Health Organization, Gujarat	Port Health Officer Port Health Organization Kandla, P.O. Kandla Port-370210 (Kachchh), Gujarat	Dr. S. Senthil Nathan PHO	On every working Thursday from 10.00 AM to 01.00 PM	02836-270189 / 270220 / 270312 (O) 02836-270189 (F) 09428506206 (M) phokandla@gmail.com
6	Port Health Organization, Kolkata	Port Health Officer Port Health Organization Marine House, Kolkata-700022	Dr. M.K. Bag, PHO	Monday, Wednesday, Friday (to report by 12.30 PM)	033-22230904/0414 (O) 033-22230435 (F) 09433184524 (M) phokolkata@redifmail.com
7	Airport Health Organization, Kolkata	Airport Health Organization, NSCBI Airport, Kolkata-700052	Dr. Prakash Chandra Mandal, APHO	Tuesday & Thursday11.00 AM to 4.00PM	033-25119044(O)033-25119370(F)09831047763 / 08902497324 (M)aphokolkata@yahoo.co.in
8	Airport Health Organization, Mumbai	Airport Health Officer Incharge Airport Health Organization C.S.I. Airport, Next to Ambassador Sky Chef, Sahar Mumbai-400099	Airport Health Officer	Monday to Friday 10.00 AM to 4.00 PM	022-28392302(O) 022-28322353(O) 022-28392429(F) mumbaiapho@gmail.com
9	Port Health Organization, Goa	Port Health Officer Port Health Organisation Marmagoa Harbour, Goa-403803	Dr. A.K. Mandal Port Health Officer	Every Thursday 9.00 AM to 12 Noon	0832-2520292/1886 (O) 0832-2520292 09503130983 (M) phogoa@gmail.com

S. No.	Name of the Yellow Fever Vaccination Centre	Address of Vaccination Centre	Officer Incharge	Days and Timings of Yellow Fever Vaccine	Contact Details (i.e. Phone/Fax/Mobile/ Email)
10	Port Health Organization, Mumbai	Seamens Medical Examination Organisation & Yellow Fever Vaccination Centre, Nav Bhavan Building, Ground Floor Ramjibhai Kamani Marg, Ballard Estate, Mumbai-400001	Dr. P.D. Parmar, Port Health Officer, Mumbai	Monday to Friday 10.30 AM to 12.30 PM	022-22612256 (O) - YFV Centre 022-22020027 (Head Office) 022-22020814 (F) phomumbai@mtnl.net.in
11	General Hospital, Gujarat	General Hospital, Oppt. S.T. Depot, Sector No. 12, Gandhinagar, Gujarat	Dr. B.B. Patel, Medical Superintendent	Every Monday 09.00 AM to 01.00 PM	079-23221931/32/13 (O) 079-23222733 (F) cdmo.health.gandhinagar@gmail.com
12	Bhavsinhji General Hospital, Gujarat	Bhavsinhji General Hospital, Near Railway Station, Porbandar, Gujarat	Chief District Medical Officer cum Civil Surgeon	Thursday 09:00 AM - 12:00 Noon	0286-2242910(O) 0286-2242910(F) aha.health.porbandar@gmail.com cs-por@gujarat.gov.in
13	Armed Force Clinic	Armed Force Clinic, Dalhousie Road, New Delhi-110011	Mr. Rajeev Mehra, Lt. Col, OIC Medical Stores	Wednesday, Friday 09:00 AM - 05:00 PM	011-23019405(O) 011-23792356(F)
14	Ahmedabad Municipal Corporation, Ahmedabad	Yellow Fever Vaccination Center, Sardar Patel Bhavan, Ahmedabad Municipal Corporation Head Office, Ground Floor, Danapith, Ahmedabad-1	Dr. A.N. Chaudhari (MBBS)I/c Yellow Fever Vaccination	Every Tuesday & Thursday12:00 Noon to 5:00 PM(Lunch Hr: 2.00 to 2.30 PM)	079-25391811 Ext. 698 (O) 09879446691 (M)

S. No.	Name of the Yellow Fever Vaccination Centre	Address of Vaccination Centre	Officer Incharge	Days and Timings of Yellow Fever Vaccine	Contact Details (i.e. Phone/Fax/Mobile/ Email)
15	Municipal Corporation of Delhi, Delhi	Municipal Corporation of Delhi Public Health Department 19th Floor, Dr. S.P. Mukerjee Civic Centre, J.L. Nehru Marg, Minto Road, New Delhi-02	MHO	Monday & Friday 10:00 AM – 12:00	011-23226913(O) 011-23226920(F)
16	Urban Health Centre, Goa	Urban Health Centre, Behind National Theatre Panaji, Goa	Dr. Mangala Tamba Health Officer	Every Month 2nd & 4th Wednesday 9.00 AM to 1.00 PM	0832-2426495 uhcpanaji@gmail.com
17	Public Health Institute, Bangaluru	Joint Director (Labs), Public Health Institute, Sheshadri Road, Opp. To S.J. Polytechnic, Bengalure-560001	Chemical Examiner	Every Wednesday 10.30 AM to 1.30 PM*	080-22210248 / 22213824 (O) 080-22277389 (F) jdphilabs@gmail.com
	*: If there is Government Holiday, next day will be the vaccination Day.				
18	Dr. RML Hospital, New Delhi	Yellow Fever Vaccination Centre, Room No. 2, Old College of Nursing, RML Hospital, New Delhi-110001	Dr. Smita Roy, Chief Medical Officer Dr. P.K. Das Chief Medical Officer (SAG)	Wednesday – 10 AM - 11.30 AM Saturday 9.30 AM – 11.00 AM	011-23404668 011-23404417 drsmitaroy@gmail.com

S. No.	Name of the Yellow Fever Vaccination Centre	Address of Vaccination Centre	Officer Incharge	Days and Timings of Yellow Fever Vaccine	Contact Details (i.e. Phone/Fax/Mobile/ Email)
19	All India Institute Of Hygiene & Public Health, Kolkata	Department of Microbiology All India Institute Of Hygiene & Public Health Bidhannagar Campus 27 & 27B J.C. Block, Sector III Salt Lake-700098 (Near Tank No.14) Kolkata	-	Friday 11:00 AM- 01:00 PM (Reporting Time 10.00 AM)	033-23359556(O) 033-22418717(F)
20	Central Research Institute, Himachal Pradesh	Treatment Centre,Central Research InstituteKasauli, Himachal Pradesh-173204	Dr. Santosh KuttyCMO(SAG)	Every Monday & Thursday between 1.30 PM to 4.30 PM	01792-273209 (O)01792-272016 (F)09418001959 (M)
21	International Inoculation Centre, New Delhi	International Inoculation Centre, Near St. Thomas School, Mandir Marg, New Delhi-110001	Dr. S. Srivastava, CMO I/C, NDMC	Wednesday & Friday 2:00 PM - 4:00 PM	011-23362284 drshakuntalandmc@gmail.com
22	Base Hospital, Delhi	Commandant, Base Hospital, Delhi Cantt., Delhi-10	Col. Amita Chaturvedi	Daily	011-23337177 Ext. 37008 (O) 011-25681531 (F)
23	King Institute of Preventive Medicine and Research, Chennai	King Institute of Preventive Medicine and Research, Guindy, Chennai-600032	Dr. Sasikala Rajkumar, Deputy Director	Friday 10.00 AM to 01.00 PM	044-22501520 / 22500592 (O) 044-22501263 (F) kipmguindy@yahoo.com ivcatking@gmail.com
24	Balrampur Hospital, Lucknow	Balrampur Hospital, Gola Ganj, Lucknow (U.P.)	Dr. Vishnu Lal, Sr. Consultant	Every Wednesday 10.00 AM to 1.00 PM	09335281326 (M) directorbhl2012@gmail.com

S. No.	Name of the Yellow Fever Vaccination Centre	Address of Vaccination Centre	Officer Incharge	Days and Timings of Yellow Fever Vaccine	Contact Details (i.e. Phone/Fax/Mobile/ Email)
25	Institute of Preventive Medicine, Hyderabad	Institute of Preventive Medicine, Public Health Labs and Food (Health) Admn., Narayanaguda, Hyderabad-29		Tuesday and Friday 09:00 AM – 02:00 PM	040-27557728(O) 040-27567894(F)
26	Guru Gobind Singh Govt. Hospital, Gujarat	Guru Gobind Singh Govt. Hospital Pandit Nehru Marg Jamnagar-361008, Gujarat	Dr. P.M. Gosai, RMO	Monday & Thursday 3.30 PM to 6.00 PM	0288-2550240 (O) 0288-2679592 (F) npcdcsjamnagar@gmail.com
27	Station Health Organisation (Navy), Mumbai	Station Health Organisation (Navy), Old Navy Nagar, Colaba, Mumbai-400005		Daily only for serving persons 08:00 AM – 02:30 PM	022-22152080 (O) 022-22152080(F)

ANNEX. 2

INFORMATION FOR YELLOW FEVER VACCINE BENEFICIARIES

1. **All the vaccine beneficiary have to read the following carefully and comply strictly and honestly**.
   - **All vaccine beneficiaries will have to wait approximately for 30 minutes after receiving the vaccination and**
   - **Please inform immediately to the doctor on duty in case of any uneasiness, side effect, reaction or any other adverse reaction to the beneficiary or staff nurse (in any emergency)**

2. **Who should not get yellow fever vaccine?**
   - Anyone with allergy to eggs, chicken proteins, or gelatin,
   - who had a severe allergic reaction to a previous dose of Yellow fever vaccine (Tell your doctor if you have any severe allergies)
   - You are pregnant, or could be pregnant now or in the next two weeks
   - Children younger than 12 months of age (as per existing norms of Govt. of India),
   - If you have HIV/AIDS
   - If your immune system is weakened as a result of cancer or other medical conditions, a transplant, or radiation or drug treatment (such as steroids or cortisone, cancer chemotherapy, or other drugs that affect immune cell function).
   - Persons who have an acute/moderate illness (with or without a fever) should postpone receiving this vaccine until they are well.
   - Those who have a thymus disorder, such as myasthenia gravis, DiGeorge syndrome, or thymoma or Thymus removed.
   - If you have any major liver or kidney disease

3. **Other Advisory**

   - Nursing mothers should avoid or postpone travel to an area where there is risk of yellow fever
   - Adults 60 years of age and older might be at increased risk for severe problems following vaccination.

 # Exemption or contraindication to yellow fever Vaccination does not provide any immunity from quarantine (isolation)

4. **Mild Side Effects of Vaccination**

   - Yellow fever vaccine has been associated with fever and with aches, soreness, redness or swelling where the shot was given. These problems occur in up to 1 person out of 4. They usually begin soon after the shot, and can last up to a week.
   - Most people will get a slight sore arm
   - 2-10% may feel tired, headache, muscle aches, fever for 24 hours starting 3-9 days after the vaccine
   - 1% need to curtail regular activities

5. **More Serious Side Effects of Vaccination**
   - The risk of a vaccine causing serious harm, or death, is extremely low.
   - Severe allergic reaction to a vaccine component (about 1 person in 58,000).
   - Severe nervous system reaction (about 1 person in 125,000).
   - Life-threatening severe illness with organ failure (about 1 person in 2,50,000). More than half the people who suffer this side effect die. These last two problems have never been reported after a booster dose.
   - 1 in 1,30,000 will get immediate hypersensitivity – rash, itching faint or asthma – this is why you need to wait 30 minutes in the clinic
   - 0.09-2.5 per million will get inflammation of multiple organs e.g. lungs, kidney, liver, spleen, skin, blood stream
   - 1 in 8 million will get encephalitis (Inflammation of the brain)
   -
6. **What if there is a severe reaction?**

   a. **What should I look for?**
      - Look for any unusual condition, such as a high fever, behaviour changes, or flu-like symptoms
      - Signs of an allergic reaction can include difficulty in breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart-beat, or dizziness within a few minutes to a few hours after the shot.

   b. **What should I do?**
      - Call a doctor, or get the person to a doctor right away.
      - Tell the doctor what happened, the date and time it happened, and when the vaccination was given.

ANNEX. 3 VIAL VIABLITY MARKER (VVM)

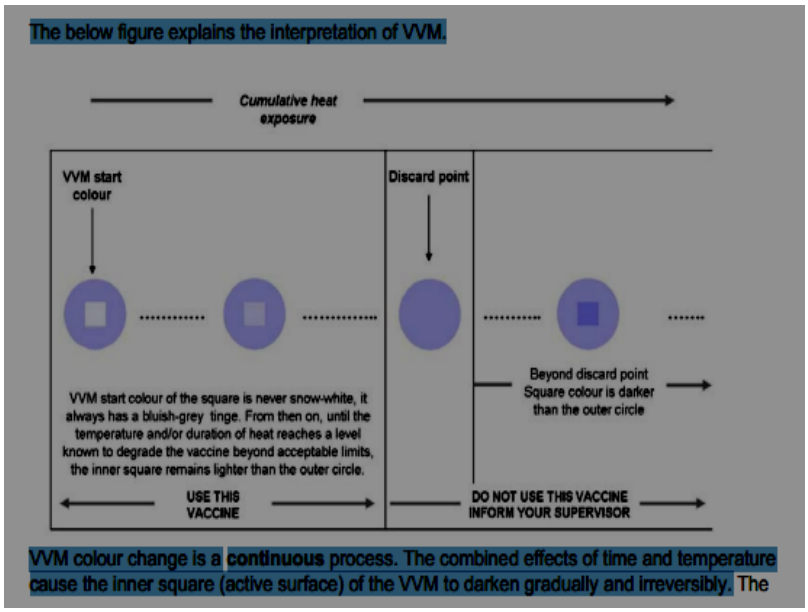
A vaccine vial monitor (VVM) is a label containing a heat sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time. The combined effects of time and temperature cause the inner square of the VVM to darken, gradually and irreversibly. A direct relationship exists between the rate of colour change and temperature:-

ƒ The lower the temperature, the slower the colour change.

ƒ The higher the temperature, the faster the colour change.

The VVM is a circle with a small square inside it. It can be printed on a product label, attached to the cap of a vaccine vial or tube, or attached to the neck of an ampoule.

The inner square of the VVM is made of heat sensitive material that is light at the starting point and becomes darker with exposure to heat. At the starting point, the inner square is a lighter colour than the outer circle. From then on, until the temperature and/or duration of heat reaches a level known to degrade the vaccine beyond acceptable limits, the inner square remains lighter than the outer circle.



At the discard point, the inner square is the same colour as the outer circle. This reflects that the vial has been exposed to an unacceptable level of heat and the vaccine degraded beyond acceptable limits. The inner square will continue to darken with heat exposure until it is much darker than the outer circle. Whenever the inner square matches or is darker than the outer circle, the vial must be discarded.

VVMs are located either on the label or on the top of the cap or on the neck of the ampoule depending on the type of vaccine (liquid or freeze-dried). VVM for liquid type vaccines are placed on custom labels to allow reference to VVM readings even though those vials have been opened and intended to be used in subsequent sessions according to multi-dose vial policy (MDVP). VVM for freeze dried vaccines are placed either on top of the cap (vials) or on the neck of the ampoule so it is

discarded by the time of reconstitution. Since freeze-dried vaccines must be discarded within six hours or at the end of the session whichever comes first, VVM can only be referred until the time of reconstitution.

The point to focus on is the colour of the inner square relative to the colour of the outer circle:

ƒRule 1: If the inner square is lighter than the outer circle, the vaccine may be used.

ƒRule 2: If the inner square is the same colour as, or darker than, the outer circle, the vaccine must not be used.

There are four different types of VVMs designed for different types of vaccines depending on their heat stability. Reaction rates are specific to four different models of VVM, relating to four groups of vaccines according to their heat stability at two specific temperature points.

ANNEX. 4 FIR, PIR & Dir Forms

Annex 1
FIR : Page 1/2

Section A **FIRST INFORMATION REPORT (FIR)**

(To be completed by the person reporting the AEFI and sent to MO - Immediately)

(Only for Serious Adverse Events Following Immunization)

Serious AEFI category (Encircle): **Death / Hospitalized / Cluster* / Disability**

State	**District**
Block/ Ward	**Village/ Urban Area**
Address of the site:	
Reported by (Name) :	Today's Date:
Posted at: Designation:	Time of preparing this form: AM / PM
Contact phone number (with STD Code) :	Time sent to MO: AM / PM

Patient Name																									

Age (in months) / Date of Birth	Sex	Male	Female

Father/Mother Name																									

Complete Address of the Case with landmarks *(Street name, house number, village, block, Tehsil, PIN No., Telephone No. etc.)*

P	**I**	**N**	-							**P**	**H**	**O**	**N**	**E**	-										

Date of Vaccination	*D*	*D*	*M*	*M*	*Y*	*Y*	*Y*	*Y*	Time of Vaccination	*H*	*H*	*M*	*M*	*(*	*AM*	*PM*	*)*								

Name of recent Vaccine(s) given:

Date of first symptom	*D*	*D*	*M*	*M*	*Y*	*Y*	*Y*	*Y*	Time of first symptom	*H*	*H*	*M*	*M*	*(*	*AM*	*PM*	*)*								

Current status **(encircle)**	**Death / Still Hospitalized / Recovered & Discharged / Left Against Medical Advice (LAMA)**

Date of Death	D	D	M	M	Y	Y	Y	Y	Time of Death	H	H	M	M	(	AM	PM	)

Additional Information:

* use separate form for each case in a cluster

Section B: **FIRST INVESTIGATION REPORT (FIR)**

(To be reported by MO to District HQ within 24 hours of AEFI case notification)

(Only for Serious Adverse Events Following Immunization)

AEFI Case ID (To be assigned by DIO): **IND (AEFI) /** *State Code* / *District Code* / *Year* / *Serial No.*

Reporting Medical Officer (Dr.) Name : Date of filling FIR by MO :

Posted at: Designation: Mobile No. Fax No.:

Land Line (with STD Code) : Case Informed By :

If MO disagrees with information in Section A, please record details (with justification) here	

Patient Name																				

Date of Birth	D	D	M	M	Y	Y	Y	Y		Age (in months)				Sex	Male	Female

Date of Notification	D	D	M	M	Y	Y	Y	Y	Date of Investigation	D	D	M	M	Y	Y	Y	Y
Date of Vaccination	D	D	M	M	Y	Y	Y	Y	Time of Vaccination	H	H	M	M	(	AM	PM	)
Date of Onset	D	D	M	M	Y	Y	Y	Y	Time of Onset	H	H	M	M	(	AM	PM	)

Hospitalization No/ Yes Date	D	D	M	M	Y	Y	Y	Y	Time of Hospitalization	H	H	M	M	(	AM	PM	)

Name and Address of hospital:

Outcome **(encircle)**	**Death / Still Hospitalized / Recovered & Discharged / Left Against Medical Advice (LAMA)**

If died, Date of Death	*D*	*D*	*M*	*M*	*Y*	*Y*	*Y*	*Y*	Time of Death	*H*	*H*	*M*	*M*	*(*	*AM*	*PM*	*)*

Post mortem done? (*encircle*)	Yes**/ No / Planned on (date) _____	If Yes, Date_____ Time_____

** Attach report (if available) with FIR

Details of vaccine, diluents & Vitamin-A given to the patient

(*In the doses administered column write the dose received by beneficiary like 1st, 2nd, 3rd, booster and any other)

Vaccine/Vit-A/ Diluent	*Dose Administered	Name of Manufacturer (in BLOCK Letters)	Batch No.	Manufacturing Date	Expiry Date
BCG					
BCG Diluent					
DPT					
OPV					
Measles					
Measles Diluent					
Hep-B					
DT					
TT					
Vit-A					
Others					

Place of Vaccination: Govt. Health Facility /Outreach / Private Health Facility/ Other ____
Session: SIA / Routine/ Other ___

Total number of beneficiaries immunized at session site: Pregnant women _____ Children _____

Number of other beneficiaries who received vaccine from the SAME VIAL:
_____

Signature of Reporting Medical officer …… **Email id**……

Section C: **The following information is to be completed by DIO & forwarded to GoI and State within 24 hours of receiving the above information.**

Proposed date of District AEFI committee review meeting for this case	D	D	M	
Proposed date of preliminary investigation	D	D	M	

Notes/comments:

DIO/ District Nodal Person ***(Officer forwarding this report)***

Name …….
Date.....Designation……..…

Mobile No……. Landline (with STD code)…….…… Fax No. ……

Email id……. Complete Office address (with Pin code)……

……
……

……
……Signature/ Seal

To be sent to : State Immunization Officer & Assistant commissioner (UIP), Immunization division of Govt. of India, MOHFW, Nirman Bhawan, New Delhi – 110108. (Fax No. – 011 23062728 / e mail: aefiindia@gmail.com

Section A — PRELIMINARY INVESTIGATION REPORT (PIR)

(To be reported to State & GoI within 7 days of submitting FIR)

(Only for Serious Adverse Events Following Immunization - Death / Hospitalized / Cluster / Disability)

DIO/RCHO/District Nodal Officer to complete all details in BLOCK letters only

State	**District**	**Case ID IND (AEFI) /**	*State Code / District Code / Year / Serial No.*
Block/ Ward		**Village/ Urban Area**	

Place of Vaccination *(encircle)* : Govt. Health Facility/ Private Health Facility / Other Specify _____
Vaccination in (encircle) : SIA / Routine
Type of site (encircle) Outreach / SC / PHC / CHC / BPHC / Dist Hospital State Hospital / Medical Collage / Other specify ____

Site Address:

Name of Reporting Officer :	Date of filling PIR :
Designation :	Posted at :
Land Line (with STD Code) :	Mobile No.: Fax No.:

Patient Name*

* Use separate form for each case in a cluster

Date of Birth (D D M M Y Y Y Y) Age (in months) Sex Male Female

Father's Name

Mother's Name

Complete Residential Address of the Case with landmarks *(Street name, house number, village, block, Tehsil, Pin No., etc.)*

P I N - P H O N E -

Details of vaccine, diluents & Vitamin-A given to the patient at this session site on the day of the event

Vaccine/Vit-A/Diluent	* Dose Administered	Name of Manufacturer (in BLOCK Letters)	Batch No.	Manufacturing Date	Expiry Date
BCG					
BCG Diluent					
DPT					
OPV					
Measles					
Measles Diluent					
Hep-B					
DT					
TT					
Vit-A					
Others					

(*In the doses administered column write the dose received by beneficiary like 1st, 2nd, 3rd, booster and any other

Date of First Information		Date of Preliminary Investigation	
Date of Vaccination		Time of Vaccination	
Date of first symptom		Time of first symptom	
Date of Hospitalization		Time of Hospitalization	

Outcome (encircle) **Death / Still Hospitalized / Discharged / Left Against Medical Advice (LAMA) / Not Hospitalized**

Date of Death Time of Death

Post mortem done? *(encircle)* *Yes / No / Planned on (date)* _____ If Yes**, Date _____ Time _____
** Attach report (if available) with FIR

95

Name **Case Id Number** **IND (AEFI) /** *State Code / District Code / Year / Serial No.*

Section B Relevant Information of the patient prior to immunization :

	If 'Yes', specify
Past H/o similar event	Yes / No
Reaction after previous vaccination	Yes / No
H/o allergy	Yes / No
Pre-existing illness / disorder	Yes / No
H/o hospitalization in last 30 days with cause	Yes / No
Recent H/o trauma with date, time, site and mode	Yes / No
For adult women • Currently Pregnant? • Currently Breastfeeding	 Yes / No Yes / No
Family History of any disease or allergy	Yes / No
• Natal history • Delivery	• Full term / pre mature / post dated • Normal / Caesarian / Assisted birth / any complication (specify)
Was the patient on any concurrent medication for any illness (if Yes : name the drug, indication & Doses)	Yes / No / Unknown

Section C Details of first examination* of serious AEFI case

***Instructions – Attach copies of ALL available documents and then complete additional information NOT AVAILABLE** in existing documents (case sheet, discharge summary, case notes, post mortem reports etc). i.e.

- If Patient has taken medical care - Attach copies of all available documents (including case sheet, discharge summary, laboratory reports and post mortem reports - if available) and complete only additional unavailable information below
- If patient has not taken medical care – Complete this form fully
- **If the investigator has disagreement with the findings in any of the document(s) mentioned above, the same may be expressed here with justification**

Source of information (*encircle all that apply*) : **Examination by the investigator/ Documents/ Verbal autopsy/ Other** _____

If from verbal autopsy, please mention the source (encircle)	Name of the person who first examined the child:_____ Other sources (specify)

Signs and Symptoms in Chronological order:

The clinical details below are filled up by_____	Designation :
Date and time of onset of 1st symptoms	Date and time of examination :

Findings on initial examination that are NOT documented in the available documents or if the investigator disagrees with the information documented please record details (with justification) here

Consciousness	Alert / drowsy / Unconscious other (specify)_____ Describe:
Vitals	Pulse Temperature Respiratory rate BP
Skin	Rash / cyanosis / petechiae / pallor / jaundice / others (specify)_____ Describe:
Eyes	Vision: Normal / Impaired Pupil : Normal / Constricted / Dilated / Reacting to light
Hearing Speech	Normal / Impaired (Describe) Normal / Abnormal (Describe)

Name **Case Id Number** **IND (AEFI) /** State Code / District Code / Year / Serial No.

Neck	Neck Stiffness:	Present / Absent
Chest	Auscultation	Normal / Crepts / Rhonchi
	Heart sounds	Normal / Murmur
	(Describe)	
Respiratory	Normal / Cough / Shortness of breath / others (specify) _____ Describe :	
GI	Pain abdomen / Vomiting / diarrhea / dysentery / others (specify) _____ Describe :	
Abdomen	Normal / Distended / Tender	
	Liver : Not palpable / Palpable (If palpable specify size)	
	Spleen : Not palpable / Palpable (If palpable specify size)	
	(Describe)	
Limbs	Tone	
	• Upper Limbs	Normal / Increased / Decreased
	• Lower Limbs	Normal / Increased / Decreased
	Reflexes	
	• Biceps	Normal / Increased / Decreased / Absent
	• Triceps	Normal / Increased / Decreased / Absent
	• Supinator	Normal / Increased / Decreased / Absent
	Plantar	Extensor / Flexor

Any other abnormal signs.

Treatment provided:

Provisional diagnosis:

Add additional pages if needed

Name **Case Id Number** **IND (AEFI) /** State Code / District Code / Year / Serial No.

Section D Details of immunization provided at the site on the day AEFI reported

Number of beneficiaries immunized at session site. Attach record if available.	BCG	Hep-B1	OPV Birth	Hep B Birth	DPT-1	DPT-2	DPT-3	DPT-B1	DPT-B2	OPV-1	OPV-2
	OPV-3	OPV-B	Hep-B2	Hep-B3	Measles	DT	TT-1	TT-2	TT-B	Vit-A	Others

a)	Number of beneficiaries immunized from the implicated vaccine vial/ampoule	
b)	When was the patient immunized? *(encircle below)*	
	• Within the first vaccinations of the RI session / Within the last vaccinations of the RI session / Unknow	
	• Within the first few doses of the vial administered / Wthin the last doses of the vial administered / Unknow	
c)	Number of OTHER beneficiaries immunized with the implicated vaccine vial in the same session	
d)	Number of OTHER beneficiaries immunized with the implicated vaccine having the same batch number in the PHC/ CHC / district hospital/ other location specify _____	
e)	Is this case a part of a cluster?	Yes / No
	• If yes, How many other cases have been detected in the cluster?	
	• Did all the cases receive vaccine from the same vial?	Yes / No
	• If No, Number of vials implicated	

Section E Immunization practices at the location(s) where implicated vaccine was used

(fill up this section by asking & or observing practice)

Any other abnormal signs.

• Temp of ILR (°C)		
• Temp of deep freezer (°C)		
• Correct procedure of storing vaccines, diluents and syringes followed?	Yes	No
• Any other item (other than RI vaccines and diluents) in the ILR or freezer?	Yes	No
• Partially used reconstituted vaccines in the ILR?	Yes	No
• Unusable vaccines (expired, no label, VVM stage 3 & 4, frozen) in the ILR?	Yes	No
• Unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in the store?	Yes	No
Specific key findings/additional observations and comments:		

Vaccine Transportation:

• Type of vaccine carrier used		
• Vaccine carrier sent to the RI site on the same day of vaccination?	Yes	No
• Vaccination carrier returned from the RI site on the same day vaccination?	Yes	No
• Conditioned ice-pack used?	Yes	No

Specific key findings/additional observations and comments:

Syringes and Needles Used:

• Are AD syringes used fro immunization?	Yes	No

If No, specify the type of syringes used: Glass/ Disposable/ Recycled disposable/ other speciy_____

Specific key findings/additional observations and comments:

98

Name **Case Id Number** **IND (AEFI) /** State Code / District Code / Year / Serial No.

Reconstitution: (complete only if applicable, write NA if not applicable)

• Reconstitution procedure (encircle)			
Same reconstitution syringe used fro multiple vials of same vaccine?	Yes	No	NA
Same reconstitution syringe used for reconstituting different vaccines?	Yes	No	NA
Separate reconstitution syringe for each vaccine vial?	Yes	No	NA
Separate reconstitution syringe for each vaccination?	Yes	No	NA
• Are the vaccines and diluents from the same manufacturer?	Yes	No	NA

Specific key findings/additional observations and comments:

Injection technique: (Observe another session in the same locality – same or different place)

• Correct dose and route?	Yes	No
• Time of reconstitution mentioned on vial (in case of BCG, Measles, JE)?	Yes	No
• Non-touch technique followed?	Yes	No
• Contraindication screened prior to vaccination?	Yes	No
• How may AEFI reported from the PHC that distributed the vaccine in last 30 days?		
• Training on RI received by the vaccinator : (Specify the last training including date)	Yes	No

Specific key findings/additional observations and comments:

Private practitioner : (complete only if applicable, write NA for not applicable)

• Source of vaccine (encircle)	Government Supply	Procured from manufacturer	Pharmacy (Chemist)	Others

Address of source from where vaccine was obtained for this patient

Status of cold chain at private clinic (encircle)	Satisfactory***/ Unsatisfactory/ Not observed (specify why_____)
Status of cold chain at procurement (encircle)	Satisfactory***/ Unsatisfactory/ Not observed (specify why_____)

***If it complies with ALL criteria in section E "Last vaccine storage point"

Additional observations and comments:

Section F Community Investigation (Please visit locality and interview parents/others)

Any similar events reported recently in the locality? Yes / No
If Yes, Describe:

If Yes, How many events / Episodes?

Of those effected, How many are

- Vaccinated:_____
- Not Vaccinated:_____
- Unkown:_____

Name **Case Id Number** IND (AEFI) / State Code / District Code / Year / Serial No.

Section G District AEFI Committee Review & Investigation Report

a) District AEFI committee review held?				Yes			No	
If Yes, then date of review by district AEFI committee	D	D	M	M	Y	Y		
b) Any implicated samples sent for testing following District AEFI committee review?				Yes			No	

Details of Vaccine/ Diluent samples sent to CDL Kasauli

Vaccine/Diluent Name	Used Vial/Amp. Quantity	Batch no, Lot no, date of expiry	Date Sent	Unused Vial/Amp. Quantity	Batch no, Lot no, date of expiry	Date Sent

Details of Syringe/ Needle samples sent to CDL Kolkata

Type of Syringes	Quantity	Batch no, Lot no, date of expiry	Date Sent	Type of Needles	Batch no, Lot no, date of expiry	Date Sent

c) Any biological product (CSF, Blood, Urine, etc) sent for testing? If yes, specify details of the lab; attach copy of report if available Note: for AEFI resulting within 28 days following JE vaccine, send sample of CSF, Serum to nearest NIV lab in Pune or Gorakhpur	Yes	No
d) Was local drug inspector involved in collecting additional samples?	Yes	No

e) Other investigation, specify the findings and attach report.

Section H Preliminary Assessment (working hypothesis of AEFI committee)

Probable underlying cause of the adverse event:

Type of Adverse Event suspected based on preliminary findings (encircle)	Programme Error	Vaccine Reaction*	Coincidental	Injection Reaction	Unknown

Specific reasons for suspecting the above:

Corrective actions/recommendations:

*If an event is suspected to be related to vaccine(s)/ diluent(s), immediate efforts should be initiated by DIO/ District Cold chain Office to collate the information related to - Number of blocks supplied with the suspected batch and Number of beneficiaries vaccinated with the suspected batch.

Name **Case Id Number** IND (AEFI) / State Code / District Code / Year / Serial No.

Attached copies of reports / documents etc with this PIR:

1.
2.
3.
4.
5.
6.

District AEFI Committee that conducted the preliminary investigation

Name	Designation	Phone #	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			

Section I **DIO/District Nodal Person (Office forwarding this report)**

Name ..... Designation.....Date of submission to state/ national level.....

Mobile No .....Landline (with STD code) ..... Fax No. .....

Email id ..... Complete Office address (with pin code).....

.....

..... Signature/ seal..... Date.....

Please ensure that this PIR form (All 7 pages) reach:
State Immunization Officer & Assistant commissioner (UIP), Immunization division of Govt. of India,
MOHFW, Nirman Bhawan, New Delhi - 110108
Fax No. - 011 23062728 or Email : aefindia@gmail.com

Important Laboratory Addresses:

Send Vaccines and Diluents to	Send Vaccines and Diluents to	Send Vaccines and Diluents to	
CDL Kasauli	CDL Kolkata	NIV Gorakhpur	NIV Pune
Director. Central Drugs Laboratory Central Research Institute Kasauli – 173204. Himachal Pradesh.	Director Central Drugs Laboratory Ministry of Health & Family Welfare Govt. of India 3, KYD Street Kolkata-700016	Director Officer In-Charge National Institute of Virology Gorakhpur Unit. BRD Medical College Campus Gorakhpur – 273013.	Director National Institute of Virology 20/ A, Dr. Ambedkar Road. Post Box No. 11, Pune - 411001 Maharashtra
Email : nclkasauli@bsnl.in	Email : cdlkol@gmail.com	Email : cdlkol@gmail.com	Email : nivicl@pn3.vsnl.net.in
Phone : 0179-2272046 0179-2272060 Fax : 0179-2272049 0179-2272016	Phone : 033-22299021 033-22870513 Fax : 033-222 99380 033-222 99541	Phone : 0551-2506696 Fax : 0551-2506698	Phone : 020-26127301 020-26006290 Fax : 020-26122669 020-26126399

For State level use only
Note: *If an event is suspected to be related to vaccine(s)/ diluent(s), then immediate efforts should be initiated by State Immunization Officer and State Cold chain Officer to collate the information related to the districts supplied with the suspected batch and number of beneficiaries vaccinated with the suspected batch. The consolidated data needs to be sent to the govt. of India as early as possible

Section A

DETAILED INVESTIGATION REPORT (DIR)

(To be reported by district AEFI committee to State & within 90 days of filling FIR)

(Only for Serious Adverse Events Following Immunization - Death / Hospitalized / Cluster / Disability)

DIO to fill page 1 to 4 ans SEPIO to fill page 4 & 5 to complete all details in BLOCK letters only

State	**District**	**Case ID IND (AEFI) /**	*State Code / District Code / Year / Serial No.*
Block/ Ward		**Village/ Urban Area**	
Place of Vaccination (encircle) : Govt. Health Facility/ Private Health Facility / Other Specify _____ **Vaccination in** (encircle) : SIA / Routine **Type of site** (encircle) Outreach / SC / PHC / CHC / BPHC / Dist Hospital State Hospital / Medical Collage / Other specify ____			
Site Address:			
Name of Reporting Officer :		Date of filling DIR :	
Designation :		Posted at :	
Land Line (with STD Code) :		Mobile No.:	Fax No.:
Patient Name*			

* Use separate form for each case in a cluster

Date of Birth	D D M M Y Y Y Y	Age (in months)		Sex	Male	Female
Father's Name						
Mother's Name						

Complete Residential Address of the Case with landmarks *(Street name, house number, village, block, Tehsil, Pin No., etc.)*

P I N - P H O N E -

Date of Vaccination	D D M M Y Y Y Y	Time of Vaccination	H H M M AM PM
Date of Onset	D D M M Y Y Y Y	Time of Onset	H H M M AM PM
Date of Hospitalization	D D M M Y Y Y Y	Time of Hospitalization	H H M M AM PM
Outcome (encircle)	**Death / Still Hospitalized / Discharged / Left Against Medical Advice (LAMA) / Not Hospitalized**		
Date of Death	D D M M Y Y Y Y	Time of Death	H H M M AM PM
Date of Post Mortem	D D M M Y Y Y Y	Time of Post Mortem	H H M M AM PM

Documents attached with this DIR: (Please retain the original and enclose ONLY COPIES)

Sl. No.	Documents	Date of submission/ completion	Attached with this document? (encircle)	Remarks (if any) and in case response is "No" then give reason
1.	First Information Report (FIR)		Yes / No	
2.	Preliminary Investigation Report (PIR)		Yes / No	
3.	Post Mortem Report done? (*in case of death*)		Yes / No	
4.	Result of any Pathology/Microbiology (Blood, CSF and Urine) Test done?		Yes / No	
5.	Doctor's prescription/treatment record for this AEFI		Yes / No	
6.	Doctor's prescription/treatment record for other illness		Yes / No	
7.	Report of Laboratory test of vaccine/ diluent (if sent for testing)		Yes / No	

Patient Name **Case Id Number** IND (AEFI) / State Code / District Code / Year / Serial No.

8.	Report of Laboratory result of syringes/other drugs		Yes / No	
9.	Report of Laboratory test of vaccine/ diluent (if sent for testing)		Yes / No	If yes, specify & attach report

Refer to FIR & PIR for writing the following case summary. Remember to include the following points, add additional sheet as necessary :

1. Detailed history of signs and symptoms and signs in chronological order
2. Additional relevant information prior to immunization:
3. Status of immunization on the day of AEFI reported (Completed doses before the event):
4. Vaccines administered on the day of the event:
5. Examination findings on first examination of serious AEFI case:
6. Any other abnormal signs (if any observed during initial examination). Add additional pages if needed:
7. Progress of the patient's condition, treatment provided and diagnosis:
8. Details of Community investigation if conducted:

CASE SUMMARY

Please add additional sheets to complete...

Please add additional sheets to complete...

Patient Name **Case Id Number** **IND (AEFI) /** *State Code / District Code / Year / Serial No.*

DIO's report on District Assessment (working hypothesis of AEFI committee)

Probable underlying cause of the adverse event:

Type of Adverse Event Suspected based on preliminary findings (encircle)	Programme Error	Vaccine Reaction*	Coincidental	Injection Reaction	Unknown

Specific reasons for suspecting the above:

Corrective actions/recommendations:

Details of District AEFI Committee members who conducted the preliminary investigation

Name	Designation	Phone #
1.		
2.		
3.		
4.		
5.		
6.		
7.		

*If an event is suspected to be related to vaccine(s)/ diluent(s), then immediate efforts should be initiated by DIO/ District Cold chain Officer to collate the information related to - number of blocks supplied with the suspected batch and Number of beneficiaries vaccinated with the suspected batch and the consolidated data needs to be reported in the following table:

Name of Vaccine/Diluent	Batch of suspected vaccine/diluent	Total number of blocks supplied with suspected vaccine/diluent in the district	Total number of beneficiaries vaccinated with suspected batch in the district	
			Children	Adults/ Preg women

DIO/District Nodal Person (Office forwarding this report)

Name ..... Designation.....Date of submission to state/ national level.....

Mobile No .....Landline (with STD code) ..... Fax No. .....

Email id ..... Complete Office address (with pin code).....

.....

..... Signature/ seal..... Date.....

Patient Name **Case Id Number** IND (AEFI) / State Code / Distnct Code / Year / Serial No

Section B

To be completed at State Level (Office of State Immunization Officer)

Date of receipt of this DIR at State								

State/UT Causality Assessment Report

Note : State vaccine safety (AEFI) committee to complete causality assessment exercise and forward the report to GoI within 90 days of filling FIR.

Preparation for causality assessment check list for state EPI officer:

Sl. No.	List of document copies sent to the Govt of India	Availability (encircle)	Remarks (if any) / (if no why)
1.	First Information Report (FIR)	Yes / No	
2.	Preliminary Investigation Report (PIR)	Yes / No	
3.	Is the case summary completed in the DIR?	Yes / No	
4.	Report of Post Mortem Report done? (in case of death)	Yes / No	
5.	Report of any Pathology/Microbiology (Blood, CSF, Urine) Test done?	Yes / No	
6.	Copies of Doctor's prescription/treatment record	Yes / No	
7.	Copy of Laboratory Request Form (L.R.F.)	Yes / No	
8.	Copy of Laboratory result of vaccine (if sent of testing)	Yes / No	
9.	Copy of Laboratory result of syringes/ other drugs (if sent of testing)	Yes / No	
10.	Any other document relevant to case	Yes / No	If Yes, specify & attach report

Conclusion of State vaccine safety and AEFI committee

Probable underlying cause of the adverse event:

Type of Adverse Event Suspected based on preliminary findings (encircle)	Programme Error	Vaccine Reaction*	Coincidental	Injection Reaction	Unknown

***Causality: Very likely/Certain/ Probable/Possible/ Unlikely/Unrelated/Unclassifiable

(*** Refer to the relevant section on the Operational Guidelines on AEFI Surveillance - 2010 MoHFW - Government of India)

Specific reasons for suspecting the above:

Corrective actions/recommendations:

Patient Name **Case Id Number** **IND (AEFI) /** State Code / District Code / Year / Serial No.

Details of District AEFI Committee members who conducted the causality assessment

Name	Designation	Phone #
1.		
2.		
3.		
4.		
5.		
6.		
7.		

Date of review of the case	D D M M Y Y Y Y	Date of submission of report to GoI	D D M M Y Y Y Y

*If an event is suspected to be related to vaccine(s)/ diluent(s), then immediate efforts should be initiated by DIO/ District Cold chain Officer to collate the information related to - number of blocks supplied with the suspected batch and Number of beneficiaries vaccinated with the suspected batch and the consolidated data needs to be reported in the following table:

Name of Vaccine/Diluent	Batch of suspected vaccine/diluent	Total number of blocks supplied with suspected vaccine/diluent in the district	Total number of beneficiaries vaccinated with suspected batch in the district	
			Children	Adults/ Preg women

State Nodal Person (Officer forwarding this report)

Name ..... Designation.....Date of submission to state/ national level.....

Mobile No .....Landline (with STD code) ..... Fax No. .....

Email id ..... Complete Office address (with pin code).....

.....

..... Signature/ seal..... Date.....

Please ensure that this DIR form reaches:

Assistant Commissioner Immunization Division,
Immunization division of Govt. of India, MOHFW, Nirman Bhawan, New Delhi - 110108
Fax No. - 011 23062728 or Email : aefindia@gmail.com

Section B **For use at National Level (Office of Assistant Commissioner - Immunization Division)**

Date of receipt of DIR from District	D	D	M	M	Y	Y	Y	Y
Date of receipt of DIR from State (with Causality assessment report)	D	D	M	M	Y	Y	Y	Y

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