



# **Operational Guide Japanese Encephalitis Vaccination in India**

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**Immunization Division  
Department of Family Welfare  
Ministry of Health and Family Welfare  
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## **FOREWORD**

Japanese Encephalitis has been a major health problem in India. Large scale outbreaks have been repeatedly reported from the endemic districts of the country since the early 70s. During the last decade JE cases have been reported from 101 districts in 12 States. During the year 2005 more than 6300 cases have been reported from 10 districts in the country. The case fatality rate is around 30% and 40% of those who survive the JE infection live with permanent neurological disability.

Japanese Encephalitis control has been a priority for the Ministry considering the huge burden of disease and mortality rate in children. Vector control alone has not yielded the desired results. Vaccination with inactivated mouse brain vaccine has been focal due to limited supply. There is enough global evidence of control of Japanese Encephalitis by planned and sustained vaccination.

9.3 million Children were immunized in 11 endemic districts of 4 States in 2006 using live attenuated SA-14-14-2 JE vaccine. The strategy adopted is one time campaign covering at risk children (1-15 years) followed by inclusion of the JE vaccine into the routine immunization programme in the same district to cover the new cohort of 1-2 years. Other 90 endemic districts will be covered in phased manner in next four years.

Training of health workers is essential for the successful implementation of any vaccination campaign. The Ministry has prepared an operational field guide for those who are involved in implementing the programme at the field level. I hope that these guidelines will be a useful tool for the programme managers and health workers at all levels of planning and implementation of the JE vaccination programme.

I take this opportunity to thank our partners PATH, WHO and UNICEF in helping us in plan and implement of JE vaccination programme in India.

*Naresh Dayal*  
(NARESH DAYAL)

Secretary of the Government of India.



सम्पर्क से पहले सोचो, एच आईवी/एडस से बचो

**HIV/AIDS : Prevention is better than cure**

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## Abbreviations

AEFI	Adverse Event Following Immunization
AES	Acute Encephalitis Syndrome
AFP	Acute Flaccid Paralysis
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
AWW	Anganwadi Worker
BMO	Block Medical Officer
BPHC	Block PHC
CDC	Centres for Disease Control
CDL	Central Drug Laboratory
CDIBP	Chengdu Institute of Biological Products, China
CHC	Community Health Centre
CDSCO	Central Drug Standard Control Organization
CHC	Community Health Centre
FW	Family Welfare
CMO/CS	Chief Medical Officer/ Civil Surgeon
DC UIP	Deputy Commissioner Universal Immunization Program
DCG (I)	Drug Controller General of India
DF	Deep freezer
DIO	District Immunization Officer
DIR	Detailed investigation report
DMO	District Malaria Officer
DTF	District Task Force
EPI	Expanded Program on Immunization
HSC	Health Sub Centre
FDA	Food & Drugs Administration
FIR	First information report
GoI	Government of India
ICDS	Integrated Child Development Services Scheme
IEC	Information Education Communication
ILR	Ice Lined Refrigerator
IMA	Indian Medical Association
IAP	Indian Association of Paediatrics
JE	Japanese Encephalitis
JEV	Japanese Encephalitis Virus
MO	Medical officer
MoHFW	Ministry of Health & Family Welfare
NCL	National Control Laboratory
NID	National Immunization Days
NIV	National Institute of Virology
NRA	National Regulatory Authority
NRHM	National Rural Health Mission
NVBDCP	National Vector Borne Disease Control Program
PATH	Program for Appropriate Technologies in Health
PHC	Primary health centre
PHC MO	Primary health centre Medical Officer
PIR	Preliminary investigation report
RIT	Regional Investigation Team
RI	Routine Immunization
SC	Sub centre
SEA	South East Asian Region
SEPIO	State Immunization Officer/State EPI Officer
SNID	Supplementary National Immunization Days
SLEV	St. Louis Encephalitis Virus
SRA	State Regulatory Authority
SOPs	Standard Operating Procedure
WNV	West Nile virus

WHO	World Health Organization
WPR	Western Pacific Region
UHC	Urban Health Centre
UIP	Universal Immunization Program
UNICEF	United Nations children's Fund
UT	Union territory
UP	Uttar Pradesh
VVM	Vaccine Vial Monitor

## 1. BACKGROUND

Japanese encephalitis (JE) is the leading viral cause of Acute Encephalitis Syndrome (AES)<sup>1</sup> in Asia. The disease primarily affects children under the age of 15 years. Seventy percent of those who develop illness either die or survive with a long-term neurological disability. Since the first case of JE was documented in the late 19<sup>th</sup> century, the disease has spread beyond its early domain - traveling as far as Australia by the year 2000. Over the past 60 years, it has been estimated that JE has infected ~10 million children globally, killing 3 million and causing long-term disability in 4 million.

**Figure 1. At risk areas for Japanese encephalitis (source CDC)**



Countries have not been able to generate adequate JE surveillance data because of the difficulty in making a clinical recognition of the disease. Reporting and the lack of sufficient laboratory support has also been a problem. Even in countries with adequate surveillance data, there are only a few interventions that countries can adopt to control the disease. Despite the fact that 68 percent of the babies born in Asia are at risk for JE, there remain major gaps on JE reporting, effecting decision making purposes.

Historically, vector control has been the mainstay of JE control, but it has had a limited impact and requires large resources because the vector breeds in paddy fields. The most promising

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<sup>1</sup> **AES** - The clinical case definition, applied to suspected cases of Acute Encephalitis Syndrome (AES), recommended by the WHO and currently in use for JE surveillance in India is as follows: *Clinically, a case of AES is defined as a person of any age, at any time of year with the acute onset of fever and a change in mental status (including symptoms such as confusion, disorientation, coma, or inability to talk) AND/OR new onset of seizures (excluding simple febrile seizures). Other early clinical findings may include an increase in irritability, somnolence or abnormal behavior greater than that seen with usual febrile illness.-Source WHO*

preventive tool is JE vaccine. It has been available since 1941, but because of small production capacity and its relatively high cost, the vaccine has remained out of reach for most countries. Fortunately in recent times, the development and increasing availability of new vaccines is making the control of JE more of a reality.



## 2. The Epidemiology of Japanese Encephalitis

### 2.1 The JE Virus

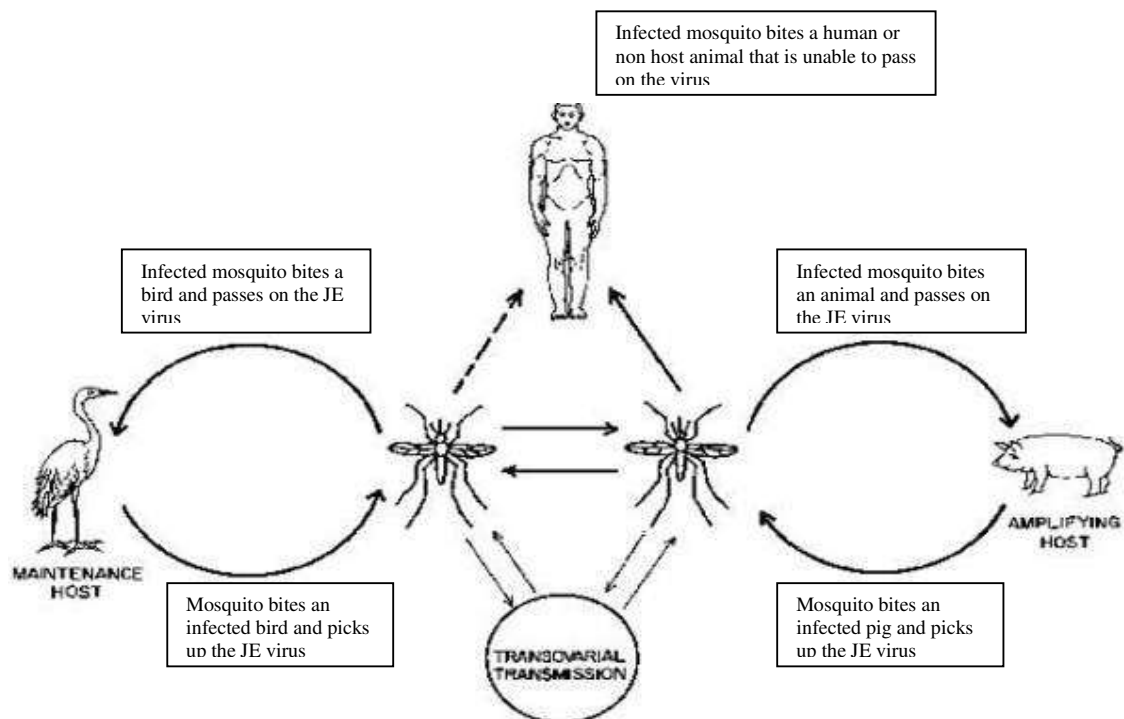
The JE virus (JEV) is a member of the genus Flaviviridae, together with the Yellow Fever virus and Dengue Virus. The JE virus belongs to the same serological group as the West Nile virus (WNV) and the St. Louis Encephalitis Virus (SLEV).

With the help of genome sequencing studies, it has been possible to determine the various genotypes of JEV in circulation in different geographic areas. The two Indian isolates [GP78 and Vellore P20778] show genetic similarity to the Chinese SA14 and Beijing genotypes.

### 2.2. Communicability and transmission

The JE virus is transmitted by the Culex mosquitoes particularly of the Culex vishnui group (Cx. tritaeniorhynchus). Water birds and pigs play a major role as amplifying hosts. Humans get infected following a bite by an infected mosquito. However, as human are dead end hosts, further spread from human to human does not take place (Figure 3).

Figure 3. JE Epidemiology



### **3. Japanese Encephalitis in transmission in India**

The transmission of the JE virus has been widespread in India. The first evidence of presence of the presence of the JE virus dates back to 1952 in the Nagpur subdivision of Maharashtra. JE was clinically diagnosed for the first time in 1955 at Vellore in the North Arcot district of Tamil Nadu. The first major JE epidemic was reported from the Burdwan and Bankura districts of West Bengal in 1973 followed by another outbreak in 1976.

The Directorate of National Vector Borne Disease Control Programme (NVBDCP) began monitoring the incidence of JE in the country since 1978. In subsequent years, cases of JE were reported from 26 States and Union Territories (UTs) occasionally, however, since 1978 repeated outbreaks have been reported only from a few States. (Uttar Pradesh (UP), West Bengal, Assam, Andhra Pradesh, Karnataka, Kerala, Bihar, Tamil Nadu and Haryana. Till 2006, 104 districts were identified as being endemic for JE, but in the recent years, through the steadfast efforts from the Government of India (GoI), through improved surveillance and increased awareness 18 states and 175 districts are endemic for JE. New states like Arunachal Pradesh, Nagaland, Uttarakhand, Manipur, Delhi, Jharkhand and Meghalaya are reporting cases of JE.

In the past, attempts were made in India to vaccinate children against JE with mouse brain derived JE vaccine in high risk blocks of a few states like Tamil Nadu, Andhra Pradesh and U.P.. However the inadequate availability of the mouse brain derived JE vaccine limited the campaigns to small geographical areas. Although, following the sustained JE vaccination in the aforementioned areas, there was some impact in reducing the case load and the incidence of the disease, however, JE outbreaks kept being reported in the subsequent years. The Case Fatality Rate (CFR) due to AES/ JE in India has been around 18 % with wide variations in the states. Annual reported cases due to JE range between 56 and 6727 while deaths due to JE range between 367 and 1684 (Source- NVBDCP- link: <http://nvbdcp.gov.in/je-cd.html>)

The JE transmission in India occurs mostly in the monsoon and post monsoon season. The state wise JE transmission in India is given in table 1

Table 1 shows the *transmission season for the 18 states undertaken/ to be undertaken in the JE campaigns* – Source NVBDCP

Table 1.	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Assam							Peak					
Manipur							Peak					
Nagaland							Peak					
Meghalaya												
Arunachal Pradesh							Peak					
West Bengal									Peak	Peak		
Delhi												
U.P									Peak	Peak		
Uttarakhand									Peak	Peak		
Bihar									Peak	Peak		
Jharkhand												
Haryana									Peak	Peak		
Maharashtra									Peak			
Goa									Peak			
Tamil Nadu							1 <sup>st</sup> Peak				2 <sup>nd</sup> Peak	
Kerala									Peak			
Karnataka									Peak			
Andhra Pradesh									Peak			

## 4. Control of Japanese Encephalitis

The consensus statement from all the global JE meetings over the years (1995, 1998 and 2002) has been that human vaccination is the only effective long term control measure against JE. All at-risk population should receive a safe and efficacious vaccine as part of their national immunization program,

### **Surveillance for cases of encephalitis**

Sentinel site hospitals have been identified for disease surveillance and case management across India. The list of sentinel sites and Apex laboratories are enclosed in Appendices– K & I,

### **There are 3 strategies for prevention and control of JE**

#### **1. Integrated Vector Control**

- **Personal protection:** Insecticide Treated Bed Nets/Curtains.
- **Larval Control –**
- Chemical larvicides/ Biolarvicides/ Larvivorous fish

In certain situations where the breeding of the vector is restricted to irrigation channels with vegetation or small pits, larval control maybe feasible, however, majority of the situations, the aquatic stages of the vector are usually encountered in paddy fields which are quite extensive. Hence, the larval control in these situations is both labour and cost intensive.

- **Environmental management** – keep environment clean, stagnation should be avoided and low lying areas should be filled up with mud to reduce the vector population.

#### **2. Pig Control**

- Segregation of pigs is not feasible. However, improved habitation of the pigs needs to be encouraged.
- Improved habitation recommended to be done through Screened shelters

#### **3. Vaccination:**

- Vaccination is the most cost effective and the best means of preventing and controlling JE. In India currently, the live attenuated SA 14-14-2 manufactured by Chengdu Institute of Biological Products (CDIBP), China is being used. *(For details of product and administration refer to Appendix A).*

## 5. JE vaccination in India – Strategy

Following the massive outbreak of JE in 2005 in the districts of Eastern UP and the adjoining districts of Bihar, the GoI made the decision to introduce and expand JE vaccination to the 15 JE endemic States (113 districts) of the country in a phased manner. The following factors were considered for the decision making

- Regular reports of outbreaks of Japanese encephalitis from certain districts in the country including the massive outbreak in Eastern UP and Bihar in 2005.
- The high mortality and morbidity associated with the disease.
- Experience of other countries controlling the disease following vaccination.
- Availability of a safe, affordable, efficacious and cost-effective vaccine.

### **The criteria used to identify JE endemic districts were:**

- Case load of JE- Total number of cases reported (AES/ suspected JE/ lab confirmed JE).
- Incidence of JE
- Evidence of recent transmission of the disease
- Serological evidence from JE studies.
- Epidemiological link to known areas of transmission

### 5.1 Strategy

Based on the recommendations of the Bi-Regional Consultation on JE (WHO SEA/WPR and PATH, Thailand, March-April 2005), GoI decided on the following strategy for the introduction of the JE vaccine in the endemic districts in India:<sup>2</sup>

- A one time mass campaign targeting all children in the age group of 1-15 years in the districts.
- Six months following the campaigns integration of the JE vaccine into UIP to cover the new cohort (children attaining more than 1 year of age) in the districts covered previously under the JE vaccination campaign. These children would be administered the JE vaccine at 16-24 months of age along with the DPT booster dose,

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<sup>2</sup>.(WHO Position Paper on JE Vaccines - Japanese Encephalitis Vaccines-WEEKLY EPIDEMIOLOGICAL RECORD, NO. 34/35, 25 AUGUST 2006 Page 331- 240

## **5.2 Coverage area**

Though JE is primarily a disease that affects children living in rural areas, there have also been reports of cases from urban areas. Therefore, a decision was made to vaccinate all target children in both rural and urban areas of the operational districts to have the maximum impact of the program.

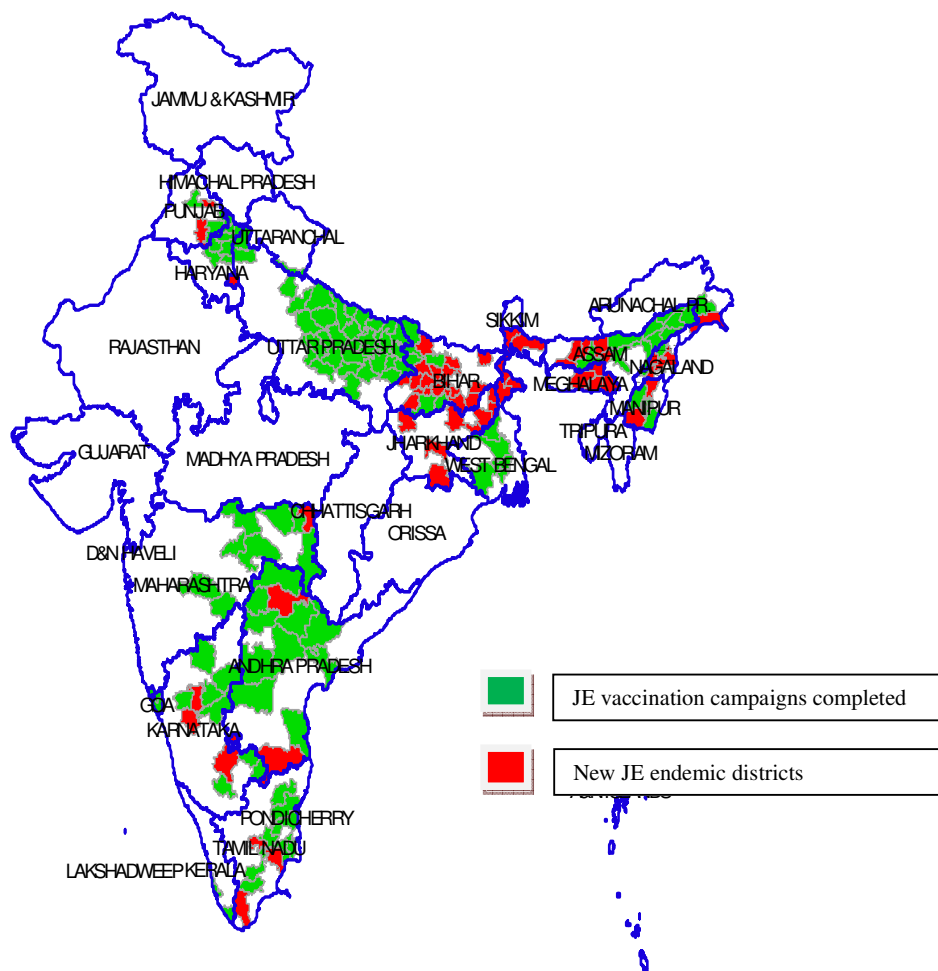
## **5.3 Phased Implementation Plan:**

Based on the available vaccination supply, a 5 year plan was developed wherein the JE vaccination campaigns were to be conducted in 113 districts of 15 states using live attenuated SA 14-14-2 JE vaccine.

## **5.4 JE vaccination**

Since 2006 – 2011, the first phase of the five year plan of JE vaccination campaigns was completed. 78 million children were immunized in 113 districts of 15 states (*for details of JE vaccination campaign coverage from 2006- 11 refer to Appendix K*). Since 2006, the surveillance has improved and currently there are 77 Sentinel site for AES/ JE surveillance across India (for list of Sentinel Sites and Apex Laboratories refer to Appendixes I & J), After completion of the campaigns in 2010-11, 62 new districts and 4 new states(Punjab, Delhi, Meghalaya and Jharkhand) reported JE transmission. .Hence, the GoI made the decision to expand the campaigns and cover these 62 additional districts in 2012-13 and 2013-14. The map below shows areas where JE vaccination campaigns have been completed and new areas in red where JE vaccination campaigns are planned.

**Map 1: Areas where JE Vaccination campaigns have been completed from 2006 – 2011 and new areas in red where JE vaccination campaigns are planned 2012-2014.**



## 6. Macroplanning, Coordination and Timelines for Activities

The highest level of political, administrative ownership, commitment and support needs to be sustained for successfully implementing JE vaccination campaigns. The Central Government, the State Governments, and international and national development partners need to work together and complement each other's strengths. The JE vaccination campaigns are a one-time activity and therefore coverage must be near 100% in the target age-group to impact on disease transmission.

### **Activities at the District before the campaigns:**

- The plan specifying date of the campaign in each village should be made available to the DTF well ahead of the program.
- The District Immunization and Vector Borne departments should work in coordination for each activity and both should be involved in the preparatory activities and the monitoring and supervision of the campaigns.
- Participating departments of the districts should intimate identified functionaries at the village level of the date of the campaign for that village and assign specific responsibilities at least one week prior to the program.
- District Task Force (DTF existing) meetings should be held during the JE campaign - to review the activity and make further plans for the introduction of the JE vaccine in the routine immunization program.
- A media crisis plan should be developed and one person should be identified at the State and the District level
- Initiate preparation of block-wise microplans, procurement of logistic materials and printing of stationary like immunization cards, instructions for supervision and for vaccinators, checklists and tally sheets etc.
- Review microplans prepared at Blocks/PHCs/urban areas.
- Identify ice factories/cold storages for procurement of ice or freezing of ice packs.
- Verify functioning and availability of cold chain equipments, like deep freezers, ILRs, vaccine carriers, adequate icepacks and cold boxes.
- Blocks/ PHCs /urban areas to submit micro plans to the district.



- Organize orientation meeting of community, political and religious leaders, media, Private practitioners, media at district headquarters.
- Finalize and release funds to blocks/urban areas.
- Start orientation of supervisors, vaccinators and cold chain handlers.
- Human Resource Deployment.
- Make supervisory visits to identified high risk pockets both in rural and urban areas before campaign to check preparedness and during campaign to monitor activities
- MO to organize meetings/panch sammelans with community and religious leaders.
- Continue orientation of supervisors and vaccinators and cold chain handlers.
- Distribute vaccines and logistics to PHCs.
- Intensify social mobilization; begin with display of IEC materials, rallies, *prabhat pheris*.
- Start miking and public announcements from fixed sites like temples and markets three days prior to activity.
- Implement immunization activities
- Share monitoring and Rapid Convenient Assessment feedback during evening feedback meetings at block/PHC to get feedback from supervisors and plan for re-activity in areas with low coverage after the campaign is over
- Send Block reports to district headquarters in the evening or the next day.
- Evaluate Coverage and Consolidate coverage reports for the district and report to SEPIO & Deputy Commissioner Immunization, MOH&FW, Gol.
- Identify low coverage areas and prepare microplan for re-activity
- Conduct and share feedback and coverage of re-activity with district/ state and National level

The planning process for the campaigns and the timelines for activities should be initiated way in advance. Refer to Table 4 for timelines for activities:

**Table 4: Timeline for activities for JE vaccination Campaigns**

SNo	Activity	Timeline	Level
1	Develop Action Plan (Central Operations group - the UIP division, Vector Borne diseases and partner agencies)	1 year in advance	National
2	Obtain approval from the policy makers and Solicit high level political commitment	1 year in advance	National
3	Estimate Budget and operational costs	1 year in advance	National
4	Logistics timeline /Costs etc. for the vaccination campaign	1 year in advance	National
5	Initiating process for procurement of vaccines and other logistics	1 year in advance	National
6	Training and Operational Guidelines including AEFI and Vaccinator guidelines	6 months before	National
7	Communication Package and Branding for the JE campaigns	6 months before	National
8	Print and Distribute operational Guidelines Disseminate financial guidelines to states	3 months before	National/State
9	National Workshop	3 months before	National
10	Review of cold chain systems at district/sub-district levels	3 months before	State/District/Block
11	State level workshops & Trainings at District/sub-district Levels	2 months before	State/District
12	Prepare & review micro-plans	2 months before	District/Block
12	Orientation of Medical officers/ District trainers	2 months before	State/ District
14	DTF-1	10 weeks before	State/ District
15	Flow of funds for Ops costs to State	1 month before	National
16	District level Inter-sectoral coordination meetings (Health, ICDS, Education departments)	Before campaign/ During campaign for mid-course correction/After campaigns to identify gaps	District
17	Identification and process for relocation of vaccinators from other districts if required)	1 month before	State/District (Secretary Health/ Director Health/DM)
18	DTF-2	1 month before	District

19	Distribution of Vaccines and other logistics to state and districts	1 month before	National/State
20	Training of vaccinators and Supervisions	1 month before	District/Block
21	Flow of funds for Ops costs from state to district	3 weeks before	State
22	Release of fund to PHC/Block	2 weeks before	District
23	DTF-3	2 weeks before	District
24	Meeting with Community/ Religious leaders/ Media Sensitization/ Sensitization of Private Practitioners / IMA/ IAP	2 weeks before	District
25	Media Crisis Management Plan	2 Weeks before	State/ District
26	Distribution of vaccine and logistics to the PHC/BPHC	1 week before	District/Block
27	Orientation of other team members – AWW, ASHA, Teachers	1 week before	Block
28	Pre-campaign monitoring	2 weeks before	National/State/District
29	Miking, drum beating	3 days before	District/Block
30	DTF - 4	3-4 days before	District
31	Campaign monitoring	Concurrent	National/State/District
32	Reporting of relocated Vaccinators to PHC MO	1 day before	Block
33	Meeting of teams with respective supervisor	1 day before	Block
34	Post-campaign coverage Evaluation	1 month after	National/State
35	Post campaign review at state level	6 weeks after	National/State

#### **REMEMBER**

- *High level political commitment and inter-sectoral coordination required*
- *District level ownership by CMO and oversight of all operational aspects by DM are keys to successful implementation of measles catch-up campaigns.*
- *District Task Force should review preparedness and intervene as necessary*
- *The Block Medical officer / Urban Health Officer should ensure a clear, complete, action oriented microplan and should report the completeness of the same to the DTF well in advance of the activity*
- *State and district level training and workshops must be task oriented and conducted according to stringent timelines*

## **7. Microplanning for the JE Vaccination Program**

To ensure that all children in the age group of 1-15 years are given the JE vaccination, it is essential to develop microplans at the block level under the supervision of the Medical Officers.

### **7.1 Components of a Microplan for the JE Vaccination campaign**

1. Estimation of beneficiaries
2. Human Resource and logistics plan with mapping
3. Training plan
4. Cold Chain plan
5. Logistics movement plan
6. Waste Management plan
7. Social Mobilization/IEC/IPC plan
8. AEFI Management plan
9. Supervision plan
10. Contingency plans for Human resources, logistics & Cold chain
11. Monitoring and Evaluation Plan

For smooth implementation of the program, a time line should be prepared for the aforementioned activities. States should ensure that the schedule of RI services is not hampered during the campaign days.

### **7.2 Guidelines for Microplanning**

#### **1. Listing all Sub Centres at the PHCs – assistance may be taken from the following groups**

Anganwadi workers, Health workers, Panchayat, Civil society organizations, self-help groups, workers' unions, School teachers and students, IMA and IAP, Youth organizations like NYK, NSS, NCC, Scouts

#### **2. List all villages, schools and ICDS centres in each Sub Centre Area**

#### **3. Population of each village in the Sub Centre Area**

For the campaign: estimate the population of 1-15 year olds through head count (Form 17: Due list format)

#### 4. Vaccines and logistics requirement

- Estimate for the campaigns based on target group
- Manpower requirement - Required/ Available / Shortfall
- Vehicle requirement Number / Type

#### 5. Session Site Selection

Fixed Session sites with seating arrangements and water facility should be selected; preferably Schools or AWCs or any easily accessible site which is acceptable to all communities. Sessions should be conducted from Village to Village, Ward to Ward. More than one session should not be clubbed together. If the target is large, then more teams should be deployed.

#### 7.3 Estimation of beneficiaries

- All children between the age group above 1 year and below 15 years should be estimated for vaccination with the JE vaccine.
- State specific estimates of population in the age group of 1-15 years should be used to for calculating the target population, vaccines and logistics requirement. It is estimated that the nation average of 1-15 year old age group constitutes of about 33 % of the total population.
- It is recommended that a name based listing (due listing) is done prior to the vaccination campaigns

#### 7.4 Estimation of Vaccines

##### **Note: Packaging of SA 14 14 2 JE vaccine**

- JE vaccine vial is a 5 dose, 2 ml vial
- Diluent contains 2.5ml Phosphate Buffer Solution (PBS) and comes as a 4 ml vial
- The vaccines comes in small box containing 10 vaccine vials a (box size being- 83 mm x 43.5 mm x 38.5 mm)
- The diluent comes in a small box containing 10 diluent vials with the boxes size being 84 mm x 53 mm x 38 mm

- Vaccine should be calculated after considering a wastage multiplication factor of 1.1 for the campaign.
- Total JE vaccine doses required for the campaigns = Total Population x 33% x 1.1

- Total JE vials required for a 5 dose vial= (Total Population x 33% x 1.1) / 5

**Illustration 1: Example of vaccine estimation calculation**

*Population of Village A = 1500*

*Children between the age group of 1-15 years in village A = 1500 x 33 % = 495*

*Vaccine requirement for the village = 495 x 1.1 = 545 doses*

*JE Vaccine vials required for the village = 545/5= 109 vials*

## 7.5 Cold Chain and Logistics planning

- Prior to the campaigns, the Block or urban areas should assess available stock of cold boxes/ ILRs, Deep freezers and ice packs and the mode of transportation, and should estimate the requirement for the campaigns
- Power supply to maintain an effective cold chain should be ensured. Vaccine supply and storage capacity in the ILRs should be judged by the PHCs and the DHQs before demanding for more supply

### 7.5.1 Cold Chain storage space requirement

- 1 small ILR (Haier) with net cold chain space of 45 liter can store - 3214 vials (16070 doses) of vaccine without diluents and 1 Small ILR can store 2647 diluents vials (13235 doses) without vaccine, All diluents do not need to be kept in the ILR, except those which will be used in the next 24 hours.
- 1 large ILR (net capacity of 108 liter) can store - 7714 vaccine vials.
- Vaccine carrier (1.7 liter net capacity ) can store 25-27 vaccine vials (125-135 doses) and 5-27 diluent vials (125-135 doses) in a polythene packet (refer to Table 5 below)

Table 5		Storage Capacity	
Equipment		No. of Vials	No. of doses
1 Small ILR (Haier) – 45 Litres	Vaccines without diluents	3214	16070
	Diluents without vaccines	2647	13235
1 Large ILR – 108 Litres	Vaccines without diluents	7714	38570
1 Vaccine career - 1.7 Litres	Vaccine Vials +diluent vials	25-27	125-135

- In case of heavier workload, 2 independent teams should be employed with equal sets of logistics. Micro plans should have logistics distribution points and plans (*for more details of Cold Chain management guidelines for JE vaccine, refer to Appendix B*).

#### **7.5.2 Dry Cold chain storage space requirement**

- 0.5 ml AD Syringe = 60.6 ml
- 5 ml reconstitution syringe = 57.2 ml
- Dry cold chain space required for AD syringes and reconstitution syringes.
- Per dose dry space requirement =  $60.6 + 57.2 / 5 = 72 \text{ ml}$
- Hub Cutters - 2 hub cutters / team

#### **Example: 2. Cold chain space requirement for JE campaign**

- Estimation of Cold chain Space required for 1 lakh population
- Target population : 33% of total population
- Total children to be immunised with JE vaccine ie.  $100,000 \times 33/100 = 33,000$
- Vaccine doses required =  $33,000 \times 1.1 \text{ (WMF)} = 36300$
- Total cold chain space need (in litres) for storage of JE vaccine =  $36300 \times 2 / 1000 = 72.6 \text{ ml}$  Total cold chain space need (in litres) for storage of JE diluent =  $36300 \times 4 / 1000 = 145.2$  Total space for JE vaccines and Diluents-  $72.6 \text{ ml} + 145.2 \text{ ml} = 217.8 \text{ ml}$

**5 small ILRs of 45 liter net capacity or 2 large ILR of 108 liter net capacity is adequate for both RI & JE campaign**

#### **Example: 3. Suggested Planning: Example**

- Block population (PHC): 150000, Target (33%): 49500
- Vaccine requirement:  $49500 \times 1.1 = 54450$  doses i.e. 10890 vials of vaccine and 10890 vials of diluents
- Duration of campaign: - 15 Days
- Estimated Vaccine requirement/day:  $54450 / 100 = 5445$  i.e. 1089 vials of vaccine and 1089 vials of diluents

**ILR capacity: 2 ILRs of 108 Diluents must only be stored in ILR. To conserve cold chain space only one day's supply of diluents can be kept in ILR. In the absence of adequate ILR or DF, cold boxes can be used for storage of vaccines during a short period (from 2-7 days). Cold box can also be used for keeping diluents cool**

- 24 hrs before vaccination if adequate space not available in the ILR then considering the above equation, the vaccine for 3.5 days should be supplied at a time to the PHC. The replenishment of the next stock of 3.5 days should be made at the end of 3 days.
- If the storage capacity is less, then the transport plan for the vaccines and logistics needs should be formalized with effective budgetary support.

## 7.6 Vaccine transport and delivery

The vaccines should be delivered at the session site through the existing or alternate vaccine delivery system of the routine immunization program. The vaccine delivery plan should also be included in the microplan. Strategy should also be developed for timely replenishment and supply of ice, ice packs and vaccines and other logistics like AD syringes, disposable syringes and red/black bags, hub cutters etc.

## 7.7 Planning for Immunization at Village/ Urban level

The selection of the vaccination site should be based at the service delivery level. The selection of the sites should be based on;

1. Safe injection practices
2. Safe injection storage and delivery
3. Accessibility and acceptability to the target group.
4. Differential strategies should also take into account to reach diverse age groups.

For example, areas where school enrolment is high, schools should be suitable sites for vaccination for children between the age groups of 5 – 15 years age group. In areas where the school enrolment is sub-optimal, the program managers should locate immunization sites to which will be accessible to children who are not regularly attending schools. The Program manager will have to strategically locate sites to maximize coverage of the under 5 age groups e.g. Anganwadi centre, Sub centres, Panchayat Ghar etc. Site selection should also be based keeping in mind the availability of space, shade and water.

***The planning unit for the vaccination programme will be the PHC/Urban Health Centre. The implementation unit will be the HSC or the similar units in the urban area (urban health post/dispensaries). Vaccination sites will be schools/ICDS centres in the villages/urban areas.***

## 7.8 Composition of vaccination teams

There should be around four to five functionaries assigned to each vaccination centre.

- While two of the team members should be ANMs and vaccinators who are trained to vaccinate and are capable of recognizing associated AEFI, the other team members should be local village functionaries.
- One of the vaccinators should be the ANM of the local Sub centre.
- The other vaccinator should be deputed by the district / block / PHC health administration from adjoining area.



- Other members of the team should include ASHAs, teachers, AWWs, link workers, PRI members who assist in the vaccination process like record keeping, managing the queue etc. at the vaccination centre.
- Volunteers (from the local community or the local school children should be identified for mobilizing the children from the houses who will support the vaccination teams. Eg. volunteers could be students/ club members/ community persons/ school personnel)
- One team shall be assigned only one village at a time. Two or more villages should not be clubbed together for one immunization centre
- The activity should always be carried out from within a room designated as the “vaccination centre”
- MO (Medical Officer) PHC (Primary Health Centre) shall be responsible for overall team selection
- Team supervisor will assist the MO, PHC in identifying team members where possible. The roles and responsibilities of the Vaccination Team are given in Table 6.
- *Both vaccinators in the team must receive training on the National Guidelines on JE vaccination, on handling the JE Vaccine, recording & reporting the JE campaign coverage, about AEFI, referral and reporting and the actions to be taken at the vaccinators level and about waste disposal following vaccination.*

**Model Vaccination Team Composition:**

1. 1<sup>st</sup> ANM from local Sub Centre (HSC)
2. 2<sup>nd</sup> ANM / Nurse from within or outside the district or from the adjoining Sub centre depending on the number of beneficiaries
3. Anganwadi Worker (AWW)
4. ASHA / ASHA like member
5. Teacher

**Table 6. Roles and responsibilities of Vaccination team:**

<b>Team Member</b>	<b>During the planning stage</b>	<b>On the day of the JE Campaign</b>	<b>After the Campaign</b>
<b>Vaccinators (2 per team)</b>	<ul style="list-style-type: none"> <li>• Develop micro plan for activity in her sub centre area (local sub centre ANM )</li> <li>• Ensure completeness of micro plan</li> <li>• Vaccination site selection in the village</li> <li>• Identify the third and fourth and fifth member of the team</li> <li>• Orientation of the third and fourth member</li> <li>• IEC and IPC before campaign in her assigned area (through ASHA/AWW/PRI)</li> <li>• Assist in vaccine and logistic transportation planning for her sub centre area</li> </ul>	<ul style="list-style-type: none"> <li>• Vaccinate children after due screening for any contraindication for vaccination</li> <li>• Give specific instructions to parents on any reactions/ AEFI (Adverse events following immunization)</li> <li>• Take appropriate measures in case of any AEFIs.</li> <li>• Ensure completeness and reporting of day's activity in the designated format</li> <li>• Overall responsible and accountable for planning, training and conducting the activity in the centre</li> </ul>	
<b>AWW / ASHA / Link person</b>	<ul style="list-style-type: none"> <li>• Social Mobilization – parent's meeting, IPC etc. in village as awareness campaign</li> <li>• Coordinate with school personnel in preparing the vaccination centre</li> </ul>	<ul style="list-style-type: none"> <li>• Manage queue</li> <li>• Provide logistic support to vaccinators</li> <li>• Repeat instructions of the vaccinator to parents before they leave the centre</li> </ul>	<ul style="list-style-type: none"> <li>• Mobilize absentee children to the PHC for vaccination</li> </ul>
<b>Teacher</b>	<ul style="list-style-type: none"> <li>• Ensure that all staff and children of school know about the activity</li> <li>• Make arrangements in</li> </ul>	<ul style="list-style-type: none"> <li>• Mobilizing and controlling the flow of children.</li> <li>• Assist team for screening children for any contraindication</li> </ul>	<ul style="list-style-type: none"> <li>• Mobilize absentee children to the PHC for vaccination</li> </ul>

	vaccination site for activity	for vaccination <ul style="list-style-type: none"> <li>• Fill up the tally sheets and vaccination cards</li> <li>• Instruct Parents to retain cards</li> <li>• Mobilize the absentee children from the village and send them to the school for immunization.</li> <li>• <i>Assist the team to manage AEFI and allay fears/misconceptions about the vaccination</i></li> </ul>	
<b>Volunteers</b>		<ul style="list-style-type: none"> <li>• Mobilize children from the village to the vaccination centre</li> <li>• Assist in identification of absentee children</li> <li>• In case the teacher is absent, then assist the Vaccinator in screening the children for diseases which are contraindicated for undergoing JE vaccination, filling the Tally sheets, and giving post vaccination instructions to the children.</li> <li>• Instruct Parents to retain cards</li> </ul>	

## 7.9 Estimation of number of days of activity in the village

- Each vaccination team will have at least 2 vaccinators. *Each vaccinator will on an average vaccinate 125-150 (ie. 250-300) children per day, however, in a small hamlet or village where the population of target beneficiaries is less the 150, one vaccinator and the support staff maybe sufficient.*
- The total number of activity days on an average should be around 15 days, however, they should be calculated based on number of beneficiaries per village or specified urban area. The best way of estimation will depend upon the number of beneficiaries in the village/area. (Example 4)

### **Example 4- Calculation of estimated number of days**

*Population of a village A = 1500*

*Estimated number of children between the age-group of 1-15 years =  $1500 \times 33\% = 495$*

*Estimated number of children vaccinated by 1 vaccinator per day = 125*

*Estimated number of children vaccinated by 2 vaccinators per day =  $125 \times 2 = 250$*

*Total number of days required to cover village A =  $495/250 = 2$  days*

## 7.10 Vaccination centre management and logistics

Each team should have the following:

- One vaccine carrier with 4 conditioned ice packs along with adequate quantity of JE Vaccine vials along with diluents supplied by the manufacturer.
- Adequate number of 0.5ml AD syringes and 5ml syringes for reconstitution.
- Adequate cotton swabs.
- Adequate number of vaccination record cards, multiple tally sheets and AEFI forms.
- Hub-cutters, red bags for the non- sharp infectious waste (cut syringe, soiled cotton swabs, unbroken vaccine vials etc) and black polythene bags for non infectious waste like wrappers of used injections.
- Banner to mark the vaccination site.
- Medicines to be carried by ANM – Oral tablets / Syrup- Paracetamol, Avil, injectable steroid (Refer to Vaccinator's training Guide for details
- AEFI Treatment kit – 1 kit per Medical Officer/ Supervisor for 5 teams

### Contents of an AEFI kit

- *Injection adrenalin (1:1000) solution – 2 ampoules*
- *Injection Hydrocortisone (100 mg) – 1 vial*
- *Disposable Syringe (insulin type) having 0.01 ml graduations and 26G IM needle 2 sets*
- *Disposable Syringe (5 ml) and 24/26G IM needle – 2 sets*
- *Scalp vein set – 2 sets*
- *Tablet Paracetamol (500 mg) - 10 tabs*
- *I/V fluids (Ringer lactate/Normal Saline): 1 unit in plastic bottle*
- *I/V fluids (5% Dextrose): 1 unit in plastic bottle*
- *IV drip set: 1 set*
- *Cotton wool + adhesive tape : 1 each*
- *AEFI reporting form (FIR)*
- *Label showing: Date of inspection, Expiry date of Injection Adrenaline and shortest expiry date of any of the components*
- *Drug dosage tables for Inj Adrenaline and Hydrocortisone*
- *At hospital setting, Oxygen support and airway intubation facility should be available.*

### Remember

- *Total number of JE vials that should be carried to the vaccination site = (Total number of estimated beneficiaries x 1.1) / 5 considering that the total number of doses per vial = 5 and the wastage would be 10 %*
- *Total number of AD syringes that should be carried to the vaccination site = (Total number of estimated beneficiaries x 1.1) considering the wastage to be 10%.*
- *Total number of reconstitution syringes = Total number of vials.*
- *Total number of vaccination record cards = Total number of beneficiaries in the village x 1.1 considering the wastage to be 10%.*

### A. Vaccine Handling Guidelines

- Vaccine and diluents should be stored and transported between 2-8 °C under cold chain.
- The diluents can be kept at room temperature **but REMEMBER - 24 HOURS PRIOR TO THE COMMENCEMENT OF THE JE CAMPAIGN IN THE DISTRICT, the required quantity of diluents should be kept in 2-8 °C along with the vaccine vials**

- One vaccine vial and one diluent vial are to be opened at one time and kept outside the vaccine carrier for use. Do not open and close the lid of the vaccine carrier repeatedly. The lid should be opened only when vaccine needs to be taken out.
- Only one Ice pack should be removed from the vaccine carrier for keeping the reconstituted vaccine. This ice pack once taken out should not be put back in the vaccine carrier till the end of the session.
- Before reconstitution always check expiry date of vaccine and diluents, VVM Status, any visible cracks in vials/diluent and **after reconstitution also check for any suspension or visible particles- NOT TO USE VACCINE** if these proper conditions are not met.
- The VVM is on the flip off seal vaccine and once the flip off seal of the vial is opened, the role of the VVM ceases. The vaccine vial should only be opened if the vial is in usable stage of VVM. If the vial is in unusable VVM stage, then the vial should be **NOT BE USED**
- **The reconstituted vaccine should not be used after 2 hours of reconstitution**
- Reconstitute vaccine with diluent at same temperature only. Never use any other diluent for reconstitution
- Reconstitute only one vial of JE vaccine at one time and use the reconstituted vaccine within 2 hours. Time of reconstitution should be noted by the ANM on the vial.
- Never pre-fill syringes

#### **B. Functioning of vaccination centres**

- The booth should begin functioning early (no later than 9 am) and should run for at least 8 hour
- The centre should be located in the shade and as mentioned above, vaccine vials and vaccine carriers should not be exposed to sunlight
- In the event that there are two vaccinators in a team, they should simultaneously vaccinate children in two different rooms.
- If the vaccination is taking place in the same room, then two different tables should be used.
- **Finger marking – The thumb of the left hand of each beneficiary who has been immunized should be marked using a permanent marker/ election ink**

- After immunization the teacher/AWW/members other than the vaccinator should fill in the vaccination card and hand it over to the parent / vaccinee. The counter foil should be retained with the ANM. Parents should be advised to retain the card.
- The tally sheet should be filled in by a member of the team other than the vaccinator (ideally the teacher from the school).
- The vaccinator should inform parents about the signs and symptoms of AEFI (for guidelines on AEFI for JE vaccination refer to Annex E) of the JE vaccine. Clear instructions should be given to parents to take the child to the nearest PHC or to inform the local ANM in the event of any AEFI.
- After vaccination, the children should be observed for half an hour in the centre for signs of AEFI.
- One team member shall maintain the queue. He or she shall also repeat the instructions given by the vaccinator regarding the retention of the vaccination record card and about AEFI in the child.
- The team members, other than the vaccinators, should organize the vaccination centre for effective catering to beneficiaries. See *Appendix F* for Site Plan.
- Any AEFI related information including the AEFI Form (form 8) should be filled up by the vaccinator only.
- Local volunteers from the community and other school children designated by the school authorities should move in the village to mobilize children to the vaccination centre.
- At the end of the activity, the vaccinator should ensure that all medical waste viz. all syringes, needles and open vials are disposed as per guidelines provided.
- Before leaving the premises, key people like teachers, headmasters, village heads, AWWs, school children and local team members should be informed that the eligible absentee children will be vaccinated on the day of subsequent routine immunization at the PHC
- Please Note: Form 17 should be used for by the AWW/ ASHA to make the due list of their assigned areas. For Micro planning, use **Form 6** and for Logistics planning, use **Form 7**. Computerization of Forms 6 and 7 should be done in the Excel sheet provided during the district workshops.

- The microplan booklets should be made after computerization at the planning units and districts.
- The microplan booklets should contain all other formats of planning (District Profile, Vaccine delivery route chart, teams & supervisory maps, IEC plan and logistic planning).
- Microplans from all planning units must be compiled at the District HQ in a booklet form and a soft copy should be maintained in Excel sheets.

**Summary: Vaccination Team with model Role and Responsibilities:**

1. ANM from local HSC – Vaccinating the Beneficiaries - observation of children for AEFI
2. 2<sup>nd</sup> ANM – Vaccinating the Beneficiaries - observation of children for AEFI
3. AWW – Health messages to parents, Crowd management, Tracking the beneficiaries
4. ASHA/ASHA like member – Mobilizing children / families
5. Teachers – Record Keeping
6. Volunteers – Immunization Site & Crowd Management

*(Local Volunteers – club members/ students/ PRI members may be encouraged to participate in community mobilization)*

**C. Forms and Computer based recording and reporting tools for JE vaccination campaigns:**

**(Appendix G)**

Form 1	Vaccination Card
Form 2	Tally Sheet
Form 3	Supervisor reporting format
Form 4	Block reporting format
Form 5	District reporting format
Form 6	Micro planning format
Form 7	Logistic Planning format
Form 8	FIR form (First Information Report Form for AEFIs)
Form 9	PIR form (Preliminary Information Report Form for AEFIs)
Form 10	DIR Form (Detailed Information Report form for AEFIs)
Form 11	Lab Request form for serious AEFI cases sample collection
Form 12	Line list Format for AEFI Cases
Form 13	Supervisory Checklist
Form 14	Monitoring format
Form 15	State Daily Reporting Format: JE Vaccination Campaign
Form 16	Rapid Convenience Assessment format
Form 17	Due list Format



Computer based Tool 1	Micro Planning Tool for computerization of Form 6 & 7.
Computer based Tool 2	Coverage Data Compilation Tool for District
Computer based Tool 3	Coverage Data Compilation Tool for State

**Summary of JE vaccination Campaign Strategy**

<i>Target population</i>	<i>1-15 years (33% of total Population)</i>
<i>No. Of Team Days</i>	<i>About 15 days or should be planned based on availability of manpower Vs number of beneficiaries per village</i>
<i>Estimation of target beneficiaries</i>	<i>Through head count of the village (Due list)</i>
<i>Sessions</i>	<i>Fixed Site- School or AWC</i>
<i>Strategy for Vaccination</i>	<i>Village to Village, Ward to Ward, to be completed at a stretch via sector approach</i>
<i>Team Members</i>	<i>5 – 2 ANMs, 1 AWW, 1 ASHA, 1 Volunteer</i>
<i>Injection load</i>	<i>Injection load per team = 300 (150 per vaccinator)</i>
<i>No. of Supervisors</i>	<i>1 Supervisor per 5 teams</i>
<i>Calculation of Vaccine doses</i>	<i>Total Population * 33/100*1.1 WF</i>
<i>Calculation of Diluents</i>	<i>Total Population * 33/100*1.1 WF/ 5</i>
<i>Vaccine Careers</i>	<i>1 per vaccinator (2 per team)</i>
<i>Emergency kits</i>	<i>1 kit per Supervisor (for 5 teams)</i>
<i>Finger marking</i>	<i>Left thumb nail</i>
<i>Rapid Convenience Assessment Survey (RCA)</i>	<i>To monitor the completeness of the campaigns and recommend corrective actions (re-activity) in areas where coverage is incomplete or low</i>
<i>Marker Pens</i>	<i>1 pen per 150 children - At least 2 per session site</i>
<i>Red plastic bags</i>	<i>1 per 50 syringes</i>

## 8. Supervision

High quality supervision is essential for the success of the campaign. Additional Medical Officers at PHCs should be involved in supervision. In case MOs are not available in desired numbers, then supervisors should be selected from existing health supervisors, Block level ICDS and other key Block level government functionaries.

1. All supervisors must receive training prior to the activity in technical as well as operational aspects of the program.
2. Along with the MO of PHCs or Urban Areas, the supervisor will assist in the selection of the team members.
3. One supervisor will supervise five teams. The supervisor should fill supervisory checklist **(Form 13)** for every team while supervising. The feedback of the supervision must be shared with the MO during the evening meeting at the PHC.
4. The supervisor must be familiar with the area, prepare supervisory maps with the day-wise activity of his/her teams.
5. Supervisors should be independently mobile and should be able to carry logistic support with them.
6. Supervisors should use their supervisory formats and checklists to supervise the teams in the field.
7. It is mandatory for the supervisor to interact with his/ her team members prior to the activity to discuss the plans.
8. The following activities are expected to be carried out by the supervisor :
  - a. Assist the BMO in understanding the plan of activity of his/her team
  - b. Assist in the selection of the vaccinators appropriate to the area and the community.  
Ensure that both the vaccinators are trained in conducting the JE vaccination program.
  - c. Participate in the selection of the vaccination site in the village.
  - d. Ensure a comfortable workload per team.
  - e. Help vaccinators to identify local volunteers.
  - f. Visit the vaccination teams at the site of the activity to:
    - Identify last minute absenteeism of vaccinators, shortage of vaccines/ logistics and solve any problems that may crop up.

- Ensure that volunteers assist the teams by moving house to house to mobilize the beneficiaries to the immunization site.
  - Ensure that the record of vaccinations is maintained properly and that parents are provided with a counter foil of the immunization card of the vaccination with clear instructions to retain the same.
  - Ensure proper completion of the tally sheets.
  - Ensure that proper information about AEFI is provided to the parents.
- g. Ensure that vaccines and logistics have been provided to the teams as per plan.
  - h. AEFI kit (1 Kit for 5 teams)
  - i. Use the Supervisory checklist at the time of the visit to the vaccination sites and evaluate coverage by conducting monitoring House to house on the day after the session is completed
  - j. Identify and report the low coverage area and plan the develop a re-activity microplan for these areas in coordination with the MOIC
  - k. Assist the Medical officer to identify and replace poor performing vaccinators.
  - l. Collect, compile and analyze data from vaccination teams and submit them to the BMO/PHC
  - m. Attend all the evening meetings at Blocks and provide a proper feedback to the Medical Officer

## **9. Monitoring and Evaluation**

### **9.1 Monitoring by State and District Observers and External Monitors**

Observers/ External Monitors from the State and District level should be assigned districts/blocks/urban areas which should be visited prior to the campaigns to review the preparedness of the activities. During the campaigns, to ensure the quality of the program, it is necessary for the observers to monitor the implementation of the activities. The objective of the monitoring would be to identify any constraints which are likely to affect the implementation of the program and find resolutions for combating bottlenecks in the smooth functioning of the service delivery.

### **9.2 Preparatory phase**

All the National observers/ External Monitors should attend the DTF meetings and provide feedback to the State Family Welfare Secretary on the quality and effectiveness of the meetings. Observers should also review the micro plans to ensure that all the following components are covered:

- All the geographical areas have been included 3 logistic calculations and cold chain plan are realistic and adequate.
- The team composition as per the norms. All the team members such as the vaccinators, supervisors, mobilizers and teachers are identified and a training plan is made for them
- Areas requiring special attention have been identified and plans have been developed to cover them
- IEC/ Social Mobilization plans have been developed and documented

### **9.3 Implementation phase**

During the implementation phase, the observers should visit their allotted districts/ blocks/ urban areas during to assess the quality and the completeness of coverage of children 1 year to 15 years of age, a Rapid Convenience Assessment (RCA) will be conducted by the Observers/ External Monitors.

### **9.4 Rapid Convenience Assessment (RCA)**

RCA is an extremely useful tool to uncover pockets of un-immunized children and take corrective actions. Qualitative and quantitative assessment on the immunization activity by the observers/ monitors should be utilized for mid-course corrective actions like retraining the vaccinators, review of micro-plans etc. or immediate corrective actions like repeating the

activity in an area where significant number of unimmunized children are found after completion of activity. Briefing about the methodology to be used for RCA/ monitoring will be conducted for the Observers/Monitors before the JE vaccination campaigns. Standardized monitoring formats will be used for making rapid convenience assessments (RCA) of the quality of activity in an area (Form 16 *Appendix G*).

### **9.5 Methodology for RCA**

National Observers/ External Monitors are expected to conduct as many RCAs as possible. It is imperative that at least one RCA should be conducted daily in areas where campaign session has already been completed. The Observers/ Monitors should try to identify missed communities, especially in isolated areas at the farthest point from the vaccination site, socially segregated groups, street children, working children in small enterprises or markets, etc.

#### **Steps to conduct the RCA-**

Step 1 - The RCA should be started from a central location, and any direction should be picked randomly by tossing a coin.

Step 2 - Then the assessment should begin with the first house facing the observer. Identify and tally 20 target-age children in 20 households. If a household has more than one eligible child, include only one randomly selected child from each household. To do this, list the eligible children at the backside of the form and assign each a number (1, 2, 3, etc.), and use the first number of the serial number on a money bill to select and record only one child.

Step 3 - You may have to visit more than 20 houses if any of the houses do not have any children.

While conducting the RCA the Observer / Monitor should assess the coverage and act in the following manner:

1. If any children are found unvaccinated then they should be sent to the nearest vaccination site that is conducting a session on that day or to a fixed site of that area.
2. If 2 or 3 children are found unvaccinated then the supervisor/authority should be informed to motivate and mobilize all the missed children to visit nearest campaign site or routine immunization session site.
3. If 4 or more children are found un-immunized, the vaccination team should revisit the area to immunize all missed children.

4. If any AEFI is noticed, direct the guardian to the nearest health facility/AEFI management centre.

## **9.6 Post campaign phase**

### **Process level assessment**

Following the campaign, review meetings should take place at District, State and National levels to identify the strengths and weaknesses of the activities. Supervision and monitoring questionnaires used during the campaign should be collected and analyzed in order to provide quantitative information related to the process of implementing the activity. In addition, it will be important to qualitatively document the impressions and experiences from the field. It is important that all stakeholders – personnel and staff involved in the planning and service delivery aspects of the activity as well as the community and beneficiaries – participate in this process to document best practices and lessons learned to ensure the highest quality of campaigns in the future.

### **Output level assessment**

The outcome of the catch-up campaign is measured by the proportion of the target population (children 1 year to 15years) who were vaccinated during the campaigns. There are two approaches to estimate JE campaign vaccination coverage: Administratively based on campaign field reports and estimated target population. Conventional household surveys using cluster sampling methodologies. The first approach can be problematic if target population – denominator information – is not current or up to date. The second approach is often used to validate administrative coverage and is seen as the gold standard for assessment of the coverage attained during the JE vaccination campaign.

## **9.7 Evaluation of the impact of the campaign**

Impact of the campaign is related to the reduction in measles related morbidity and mortality as a result of the measles catch-up campaign and the increased immunity of the population to the virus. This is measured through sensitive laboratory supported measles surveillance.

***Key Points To Remember***

- *Senior officers from district should start monitoring preparedness well before the campaign.*
- *Unbiased and reliable observations by observers and monitors will help pinpoint problems.*
- *Observers and monitors should be supportive and help solve problems identified.*
- *RCA is an extremely useful tool to uncover pockets of missed children/area and take corrective actions*
- *Post activity coverage evaluations should be planned in advance.*

## 10. Recording and Reporting

1. A vaccination card with a counter foil (**Form 1**) should be used to record the vaccination. One portion of the card should be handed over to the parents with clear instructions for preserving it as evidence of the JE vaccination. The counterfoil should be retained by the ANM of the subcentre. The ANM should submit the counterfoil to the PHC for record keeping.
2. A tally sheet (**Form 2**) should be used to record the number of children immunized; details of the vaccines and syringes used and returned every day to the Supervisors.
3. All AEFIs should be reported immediately using the AEFI FIR form (**Form 8**) to the MO-PHC.
4. At the end of each day, each Supervisor should go through all the tally sheets of all his/her teams, to compile the information and submit a consolidated report using the reporting form for the Supervisors (**Form 3**).
5. At the end of each day, each Block/urban area should send the District Immunization Officer (DIO) a report (**Form 4**) of all the children immunized and any AEFI reported.
6. The district should compile the report (**Form 5**) and send a consolidated report to both to the State Immunization Officer and to the Deputy Commissioner (UIP), MoHFW, Government of India on the day following the activity and a summary report at the end of the activity ( Fax No. 011-23062728/ 23062126 or email to (jeindia2007@yahoo.co.in)
7. Computerization of the coverage report should be carried out at the PHC and the District HQs. The data compilation tool should be provided during the district workshop, for this purpose. The district should e- mail the compiled updated copy of the tool (updated coverage data) daily, to the MoHFW (jeindia2007@yahoo.co.in).

**\* Please refer to the *Appendix G* for the forms**



## 11. IEC and Social Mobilization

Effective information, education, and communication (IEC) and social mobilization are critical in ensuring that children are not missed during the immunization campaign. ANMs will identify and train village influencers for community mobilization through IPC.

- Advocacy and social mobilization efforts are crucial for ensuring the successful introduction of the JE immunization program.
- The aim of the activity is to inform the general public and health care workers about the advantages and benefits of the JE vaccination.
- The extent of social mobilization may vary from place to place, depending on the perceived needs and specific settings.
- Most importantly, field initiatives should be emphasized by involving the following groups:
  - Anganwadi workers
  - Health workers
  - Panchayat and PRI members
  - Civil society organizations, self-help groups, workers' unions
  - School teachers and students
  - Local IMA and IAP and Indian Red Cross branch
  - Youth organizations like NYK, NSS, NCC, Scouts

Types of communication that can be considered, include the development and distribution of posters/booklets / district/regional newspaper inserts and special programmes on local radio and TV channels; outdoor publicity through banners that inform the public about the vaccine.

The communication plan should address the following issues:

- Target group
- Time
- Place
- Retention of Immunization cards by parents
- Possible AEFI & remedial measures

The cost of carrying out social mobilization and advocacy initiatives can be estimated by preparing a detailed plan of the activities with budget estimates.

***Key messages to be considered:***

***Japanese Encephalitis (JE) could kill or disable your child. Immunization will save them***

***Bring your child on \_\_\_\_\_ (date) to the health centre for JE immunization.***

## 12. Media communication guidelines during AEFI

The media is an important gateway to inform the public and shapes their views and attitudes towards vaccines and immunization. In the long-term, building partnerships with the media is key to keeping the public regularly informed about immunization, its benefits, and to motivate families and communities to make use of immunization services.

### Basic guidelines for understanding and working with the media:

#### 12.1 Media preparedness: having a media plan in place

- a. Develop a database with information packages and updates.
- b. Conduct orientation workshops and field visits.
- c. Work through the communication cell (where it exists).
- d. Set up a spokesperson system.
- e. Prepare a media release.
- f. Select dissemination channels for the media release.

Negative media coverage of AEFI can have significant impact on public trust in vaccines. Some reactions to vaccines are inevitable; however attempts should be made to minimize such reactions. Plans must be in place to respond appropriately when an AEFI occurs. Effective communication for dealing with the media should be planned before an immunization campaign starts and as part of the on-going communication support to routine immunization programs. For developing an effective plan, keep a few key points in mind:

1. Develop a plan which must include strategies on how to deal with the public concern on this issue, and the steps being taken to minimize the potential harm.
2. Train the staff on media crisis management.
3. Plan a budget

#### Box 1

##### Understanding media needs

The media is likely to publicize events where there are deaths or AEFI, where the national press has unearthed "ominous facts", or where they have obtained information before the health professionals have done so. Health professionals may become the centre of a crisis if they are accused of not having done their job properly or were found not to be truthful.

##### The media will ask the '6 Ws'

**Who** is affected/is responsible?  
**What** has happened? What is being done?  
**Where** has it happened?  
**When** did it happen?  
**Why** did it happen?  
**Will** it happen again?

##### The media likes

- A fast response
- Accuracy and simplicity
- Statistics with explanation
- Context (part of a wider picture)
- Comments or explanation from the highest authority possible

4. The selected media crisis spokesperson/ team should practice responses to potential "issues" around AEFI.
5. In the plan other groups and individuals that have public respect and authority should be included to endorse and strengthen key messages.
6. In certain situations where media coverage is likely to raise public concerns about immunization, it is important to first communicate with professional organizations, health professionals and workers and then with the media.

**12.2 The media plan:** The media plan must consist of all the following:

### **1. Database**

- Create a list of print and electronic media journalists covering the health beat (local, national and international media), and establish a rapport with them, i.e., ensure that a two-way communication process is established and there is regular exchange of information.
- Keep the media informed through emails/ letters/ faxes by sending regular updates on any plans, programs, decisions, etc. Find opportunities to sensitize media routinely about health aspects like benefits of immunization and its impact globally and nationally.\*
- Update any changes in the media list on a quarterly basis, and ensure that any change in phone numbers, addresses, etc is updated
- Always use a database where updates can be done immediately in the master copy. Mention "the date of update" on the page or the file name for easy recall.

***Note: \*Sensitization should also focus about on how an isolated adverse event if not handled well can cause loss of public confidence and result in increased mortality and morbidity of vaccine preventable diseases.***

### **2. Develop information packages**

An information package may contain the following prototypes both in hard copy and in electronic format stored on a CD:

- A sheet containing frequently asked questions (FAQs) on JE disease, JE immunization and AEFI
- Specific Fact Sheet or a Technical Brief
- Recent advancements (updates)
- Case studies

- Graphs and illustrations
- Photographs
- Contact addresses of spokespersons that media can talk to
- Any other audience-appropriate materials on immunization that also includes AEFI.

Ensure that monthly or quarterly updates are prepared on routine immunization or on new developments in immunization which can be shared easily with the media, including the health personnel involved in the immunization and even the community.

*Note: All the old and outdated material in the information package must be checked and removed and permanently discarded.*

### **3. Work through a communication cell**

- A national communication committee for immunization should be formed and support should be sought from the national AEFI committee in the communication plan.
- The communication cell should be the central unit for coordinating the communication response to an AEFI at the national level which should be composed of representatives of the Ministry of Health and other government organizations/ institutions and partner agencies,
- The Communication staff in the state and district-level IEC bureaus involved extensively in immunization activities must also be part of this communication committee and the communication cell/AEFI committee must look into four steps for the management of AEFI and prevention of crises in advance, notably:
  1. Anticipate. Do not wait until a crisis occurs. Prepare for the unavoidable.
  2. Train vaccination personnel at all levels to respond positively and adequately.
  3. Confirm all the facts before making any public statements.
  4. Prepare a plan to react to a crisis when it occurs.

### **4. Set up a spokesperson system**

- An appropriate spokesperson or several spokespersons in the different agencies, should be identified in advance
- The spokesperson should be a trusted person who is a good communicator who has the ability to speak with authority. S/he but may not necessarily be a medical expert, but must have competent knowledge of the immunization programme.

- A list of potential spokespersons with their contact details should be prepared before an immunization campaign starts and it should be shared with all concerned focal points at the district, state and national levels. This will help to limit the possibility of conflicting messages coming from different sources.
- Ensure that the spokesperson has experience or some training in dealing with the media.

While communicating about AEFI it is important for the spokesperson to remember that trust is a key component of the exchange of information at every level. Talking about risk estimates that are later shown to be incorrect should be avoided. The spokesperson should also avoid making premature statements about the cause of the event before the investigation is complete. If the cause is identified as programme error, do not lay personal blame on anyone. Instead, talk about system-related problems which resulted in the programme error(s) and mention steps being taken to correct the problem.

## 5. Develop prototype media releases

The press statement must specifically answer the 6 W's for journalists: Who, What, Where, When, Why, and Will it happen again (see Box 1). It must mention the name and contact details of the sender/ or an alternative spokesperson whom the journalists can contact if they have further questions. At the end of the communication "for more information, contact..." and the key positive messages such as "immunization saves children's lives" should always be kept ready.

### Box 2.

#### Qualities of a good spokesperson:

- Ask the interviewer for an agenda – specific questions or issues – so that you are prepared well in advance to answer, collect relevant data.
- Know and practice what you want to say in one minute or less. If you can't summarize your news in one minute, it is too complicated or it lacks focus.
- Show true interest in your subject, believe in what you are addressing, and demonstrate that you are entirely convinced about the statements you are communicating. This is the only way to get the reporter interested and to persuade the reporter – and public – to support your position.
- Cite tangible evidence during interview to back up your key points – data/research/ statistics/anecdote. Carry this data in a written format or fax later. The reporter is likely to cite your data – and cite it accurately!
- Avoid defensive comments. Be proactive, not reactive, while arguing your case. Anticipate what the reporter might counter question and prepare well.
- Think of questions you hope you won't be asked and prepare answers for them. Rehearse well.

## 12.3 Identify dissemination channels for the media release

Different media channels such as Newspapers, Radio channels and TV channels should be identified and used for communicating during the time of need,

### 1. Managing media when an AEFI has occurred

#### a. Managing a crisis situation

- b. Get your messages ready
- c. Prepare a media release
- d. Call a media conference.
- e. Monitor media: Responding to substantive inaccuracies and rumors.
- f. Techniques for difficult interview situations.

## 2. Management of crisis situations

Every single AEFI must be investigated in detail although all AEFI cases may not be crisis situations. A crisis often occurs from lack of action rather than from taking appropriate action on AEFI. The Media interest is usually greatest initially when relatively little is known which is why rumors flourish and can cause huge potential harm. If required then a media conference should be called early, even if there is only very limited information to give. This will prevent the circulation of rumors and will build a rapport with the reporters. At the end of the media conference, inform the media that further conferences will be held when more details of the AEFI investigations are available. Regular contact with the media should be maintained about the progress of the investigation and the results of the AEFI investigation should be shared.

### 3. Keep some messages ready

The key messages should have simple, short and memorable phrases which are retained with the audience with a long lasting impact even after you have left. The messages should indicate the benefits of immunization and must convey that the lack of immunization would put children in a vulnerable position at great risk of disease and complications and that the benefits of immunization are well proven in preventing diseases". Use short sentences, quotes from key officials may be used after seeking their permission. The quotes must be positive and carry the key messages.

#### Box 3.

##### Local media

May have broken the story and need to be engaged. May be read and believed by more people in the community than national media. Could be stringing for national/ international press.

##### National media

Seen by government and national opinion leaders. Has a wide reach and influences national agendas.

##### International media

Seen and read in headquarters of international organizations. Has resources to produce investigative reporting. Can influence national agendas.

- Examples of some effective messages are: “Immunization is the most cost-effective health intervention”, Immunization is the right of every child’, Vaccine-preventable diseases caused millions of deaths and/or disability before the introduction of vaccines”, “Vaccines do cause some reactions, but these are rarely serious and hardly ever cause long-term problems (have data ready and available to substantiate this fact), but the situation would return without continued use of vaccines”.
- The final message conveyed should be ‘the AEFI is currently being investigated, but is likely to be coincidental/due to a local problem (depending on type of event), and the immunization programme must continue to keep the population safe from disease”.
- An assurance that corrective action has been taken or will be taken should be included and reference to any relevant publication, video material or web sites should be given.
- Name and contact details of the sender of the press statement should be on the top and the matter should be of maximum 1 page. (400-500 words max).
- Use short sentences, quotes from key officials may be used after seeking their permission. The quotes must be positive and carry the key messages.
- In addition, monitoring media coverage and reporting trends, especially the local media, and meeting with opponents and supporters from the media, are part of good communication practices. You may have to issue corrections (rejoinders) if incorrect reporting continues.

#### **4. Call a media conference**

Media conferences need to be used judiciously, as there are also dangers, especially if preparation for it is weak and the journalists are assertive (see Box 3). Especially when different stakeholders will be present, it is all the more difficult unless everything is planned well in advance.

Media conferences may need to be conducted when there is considerable "buzz" about the AEFI and there is a need to provide accurate facts and de-sensationalize the story. A media conference gives all the reporters the same access to the information (i.e. no exclusive coverage). Thus, they may be less likely to ‘sensationalize’ the events. A media conference provides an opportunity for the health authorities to voice their support for immunization and the approach being taken to investigate the problem.



It is vital to prepare before any media contact with:

- Key messages.
- Answers for likely and awkward questions.
- Identifying which issues not to respond to (e.g. blaming an individual or speculating).

Consider the following important steps when preparing for the media conference:

- a. Use the communication cell/AEFI committee and pre-identified spokesperson(s) to talk to the media.
- b. If there are several members on the panel, agree beforehand on the key message(s) in response to the AEFI.
- c. Agree on roles of each panel member beforehand, including the type of questions (media, political etc. each panel member may best handle); decide who will take the lead in the press conference.
- d. Don't contradict each other in the press conference unless it is critical to clarify something incorrect that has been said.
- e. Have a media kit ready and share it with journalists. The media kit may consist of a press statement (or press release) with all the essential information, supplementary background information (e.g. on the benefits of immunization) and a set of frequently asked questions (FAQs) about immunization.

## 5. Monitor-media

**Responding to substantive inaccuracies and rumors: 5 actions.** When an unfortunate AEFI occurs, substantive inaccuracies can get reported; for example, regarding the number of AEFI cases, gravity of the case, allegations of negligence, or simple rumours about vaccine

### Box 4

**Some tricky questions that the spokesperson needs to be well prepared to answer (questions documented from the field over the last few years)**

- Why does the government provide vaccines which cause bad reactions/death?
- Why don't health authorities train vaccinators so that these accidents are avoided?
- Why are injections for vaccines and other medical procedures still dangerous in this our state/country?
- Why are vaccines still given which damage our children with serious side effects?
- Why are parents not told the truth about vaccines? Is there something that is being hidden?

### Questions on specific vaccines

- Have there been episodes where children have died after getting reconstituted JE vaccine?
- Why should our children get JE vaccine?
- Are vaccines contaminated with other organisms (bugs) from during the manufacturing process?

procurement. These inaccuracies have the potential to further a crisis or problem unless quickly corrected.

The communication cell/AEFI committee should move very quickly to correct them, because the longer misinformation remains in the information environment, the more difficult it becomes to correct. You could take the following actions:

1. Begin by analyzing the rumour, its level and potential to cause damage.
2. Anticipate how situations might evolve following your response, and prepare for it well before responding.
3. Deal with a simple mistake with a simple solution. If it is an isolated mistake, overreacting will only attract more attention to the problem. Instead, make a polite call to the reporter and apprise him of the error. Offer to help the reporter with correct data and facts then and in the future.
4. If the rumor is confined to a small audience, correct it within that group only. If the error is widely reported, you may call a media conference to present the correct facts before it leads to further damage or proves detrimental to your programme goals.
5. Plan how you could prevent future rumours.

## **6. Post-AEFI actions**

Strategies should be made on what to do when caught unprepared by a reporter and on what to do when you are misrepresented.

### **➤ Keep your promise to the media**

- If a commitment has been made with the media about giving an update, it should be kept. And updated information about the investigation findings should be provided by the promised date. If the findings have not reached you, ensure that you at least inform the media because they would be expecting answers from you. Delays can happen to investigations, and media understands this.
- When you are talking to media, you are actually talking to the public. A good speaker should be selected as the media crisis spokesperson from the district. Pre-interview checklist and Post-interview checklists should be developed.

### **➤ Provide answers to unanswered questions**

During media conferences, if a question could not be answered for any reason – for example due to absence of data, or if you were unprepared to answer the questions – get back to the

media with the answers as soon as possible.

➤ **Keep media informed about subsequent development**

If any decision or action is taken at the highest levels following AEFI investigations or during the investigations, and the public must know about it, keep the media informed through a press release or hard copy document.

➤ **What the public wants to hear from you**

- While reassuring the public when they are under stress is a good move, avoid sounding over-reassuring. Express genuine concern about the situation in a calm, sincere manner.
- The public has a tendency to think that the damage is more serious than it actually is. It is better to provide the true estimate, and use words that make it sound that the damage is actually less serious than one thought. The public is reassured by such a thought.
- Tell people what to expect. If there are possibilities of future negative outcomes, it is good to let people know.
- Offer only what you know. Acknowledge uncertainty. If a question cannot be answered, it is best to say that the answer at that moment was not available, and that all efforts were being made to find out the missing answers. Emphasize that a process is in place to learn more. Describe the process in simple terms.
- Be regretful, not defensive. Say, “We are sorry ...” or “We feel terrible that” .Don’t use “We regret,” which sounds very formal as if you’re preparing for a lawsuit.
- Acknowledge the public’s fears. Don’t tell people they shouldn’t be afraid. They are afraid and they have a right to their fears. It is a question of their children’s lives, after all.

**Box 5**

**Remember – For TV interviews –**

- Practice keeping your answers to about 20 seconds and make sure that you smile, sit erect and maintain open body language; use simple hand gestures; project energy.
- Maintain eye contact – not ‘camera contact’ and also use the interviewer’s name once near the beginning of the interview.
- Dress conservatively. Subdued colours lend a sense of authority. Stripes or small patterns become fuzzy on screen; bright colours can make you seem less serious, especially when you are discussing AEFI.
- If the interview is in a studio, arrive early and if it's a field interview, select a background location that has to do with children – a children’s park, a vaccination centre, and similar setting.

**Remember - During print interviews:**

Pay attention to how the interviewer paraphrases you. Correct her if necessary.

- Use “We wish....” If you are yet to receive answers to ongoing investigations. Say, “We wish we knew more at this moment.” Public will find you sincere.
- Ensure public does not hear mixed messages. Mixed messages create panic. Panic doesn’t come from bad news, but from mixed messages.
- Find out and close all avenues from where conflicting messages might be emerging. Give the public one credible source for information, which they can turn to for help.
- Understand and be sensitive to the culture of the audience. You don’t want to make matters worse.
- Answer the “what if” questions if they are asked (though it is impractical to fuel them yourself). The public will have apprehensions and is looking for expert answers. People need to be emotionally prepared if matters are expected to worsen. But remember that your answer to the what-if questions describes actions being taken to arrest the situation from worsening.
- Give people things to do. People often participate collectively in an emergency situation. Even individual actions are taken. Simple actions in an emergency will give people a sense of control.
- Ask people to bear the risk and work toward solutions with you. If you acknowledge the risk’s severity and complexity, and recognize people’s fears, you can then ask the best of them.

#### **12.4. Cardinal qualities- What the public wants to see in you**

It is essential to present information to the media in a way that will generate a sense of credibility and confidence by being:

- Be Honest, clear, avoid jargon; use simple phrases and give examples to clarify meaning. Be serious – jokes can be disastrous and the subject is rarely amusing anyway. Create a strong, compassionate and a competent image for yourself and the service.
- Body language – it is of critical importance in perceptions. Offer an open body language. Tightly clenched fists or arms folded across chest will show you to be defensive and stressed.
- Responsible – don’t be defensive, but accept responsibility appropriate to your position and avoid blaming someone else (e.g. “We will see if there is any truth in the report”).
- Responsive – hold a daily media conference if that is what is required to meet the needs of the public and media; regular contact helps build a trust with the media.

- Positive – reframe the situation in positive terms; use terms such as “vaccine safety” (which has a positive connotation) rather than “adverse event”.

#### **What to do when caught unprepared by a reporter**

1. Find out the reporter’s objective. If possible ask for specific questions, or request the reporter to email/fax you a set of questions.
2. Ask for time, at least some time. Even 15 minutes can help you get access to data, or call other people or an expert for information, etc. Most reporters oblige.   
?? Determine the reporter’s deadline and get back by that time.
3. If you decide not to do an interview, let the reporter know and help, if possible, to find an alternative interviewee.
4. Be aware that the reporter probably already has a story focus and only a few words of yours might be quoted.

#### **If you’re misquoted**

1. Consider its seriousness/implications:
  - a. If it is really serious, send and ask in writing for a correction.
  - b. If it’s not, use it as an opportunity to educate and build relationships by making a simple phone call. You may even get a story out of this relationship building as you educate the reporter]
2. Call and discuss at a time of day when reporters are less likely to be busy. [The best time is between 11am to 2pm.
3. If it’s very serious, ask for the editor or producer for corrigendum

#### **Box 6.**

#### **Remember to keep Details of a Print/ TV/ Radio interview**

Keep copies of this format ready and use every time there is a communication with a reporter.

1. Media outlet, Name of reporter doing interview with Phone/Fax/Email:
2. Interview Date and Time and whether in person or specific location or by phone:
3. Focus of interview/agenda:
4. Has the reporter been briefed? If yes, by whom?
5. Is it in response to a press release?
6. Any materials sent in advance:
7. Expected publication/ broadcasting date:
8. Photos/ shots required? To be shot/sent and by what time and date should photos and data required sent/ to be sent?
9. Will you have opportunity to look at story before it is published? Asked reporter?

4. Call right away if it is on radio; the story will likely run more than once and you want to stop it.

### **References**

*The information provided in this section has been adapted from various sources – published and web-based – and credit to all is acknowledged with thanks.*

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2. *IMPACS media communication toolkit*. Institute for Media, Policy and Civil Society, Canada, 2001
3. *Communicating in a crisis: Risk Communication Guidelines for Public Health Officials*. Centre for Mental Health Services, SAMSHA.
4. *Crisis and Emergency Risk Communication Guide*. Fulton, Sandy Martinez, and the Centres for Disease Control and Prevention (CDC)

### 13. Introduction of JE Vaccine in Routine Immunization

#### Government of India's strategy:

- Introduction of the live attenuated SA 14-14-2 JE vaccine into Routine Immunization, after six months, following the JE Vaccination Campaign
- Should be introduced to new cohorts aged between 16 – 24 months
- Should be given along with the DPT Booster dose and Measles second dose (in states/districts applicable).
- It is safe to administer JE vaccine, Measles vaccine (2<sup>nd</sup> dose) and DPT booster at the same time since all three will be given at different sites

#### Rationale:

- To vaccinate the new cohort of children who did not receive JE vaccine during the campaigns because they were underage.

**SA 14-14-2 JE Vaccine – Dosage and Administration –Currently JE vaccine under routine immunization is given as a single dose but as per the revised GoI guidelines, JE vaccine will also be administered to infants aged 9 months along with Measles vaccine from April'2013 onwards.**

#### Do's and Don'ts

- Do not immunize the beneficiary if he/she has any of the underlying medical conditions or allergies as mentioned on page no. 25 in *Appendix A* in the Contraindications section.
- Necessary precautions should be taken before immunizing the beneficiary (Refer to page no. 26, Precautions section)
- AEFIs should be managed and reported as per GoI Guidelines given for all vaccines under RI.

#### Reporting

- Reporting the JE vaccine coverage under Routine Immunization should be done along with the other RI vaccines in the same format.
- Immunization Cards should have the column for reporting JE vaccine coverage
- **The RI reporting formats should be modified to include the JE vaccine coverage.**
- **For reporting RI coverage the following must be used:**

- ***ANM Tally sheets***
- ***Session Report***
- ***Report Compilation Sheet***
- ***PHC Report***
- ***District Report***
- Reports should be entered in the HIMS database under the JE vaccine coverage section
- Reports should be sent to the UIP division of the State Health Department, which should subsequently be sent to the UIP division of the Ministry of Health and Family Welfare.

### **Procurement of Vaccine**

- Before introduction of JE vaccine under RI, the RI microplan should be modified to include the details such as target population of beneficiaries aged between 16 -24 months
- Please Note: once the JE vaccine begins being administered along with Measles Vaccine at 9 months of age, the estimation of target beneficiaries for 2 doses of JE vaccine will (for 9 months and 16-24 months) will have to be done and formats will have to be modified accordingly
- A demand for the JE Vaccine along with 1.33 wastage factor should be sent by the Districts to the State Health Department's UIP division which should subsequently send the demand to the Ministry of Health and Family welfare, well in advance, before introducing the JE Vaccine in RI.
- Cold chain space and dry space assessment should be estimated well advance (refer to page)



**Appendix A. Product Information Sheet for SA 14-14-2 JE Vaccine  
Japanese Encephalitis Vaccine, Live**

**Product Information Sheet – Multiple dose vials**

Japanese Encephalitis Live Vaccine is a sterile, lyophilized vaccine for subcutaneous use, prepared by packaging the SA-14-14-2 Japanese Encephalitis (JE) virus in a monolayer of the primary hamster kidney cell culture. The efficacy and safety of this vaccine has been demonstrated in several clinical trials.

**Target Age Group:** 1-15 years

**Contraindications**

1. Fever
2. Severe malnourishment
3. Acute infectious disease
4. Ear infection
5. Tuberculosis
6. Heart, liver and kidney problems
7. Pregnancy
8. Allergy
9. Convulsions
10. Person treated with any immunosuppressive therapy
11. Person with a proven or suspected hypersensitivity of Kanamycin or Gentamicin.

**Adverse Reactions**

1. The Global Advisory Committee on Vaccine Safety has reviewed all the AEFI data following the administration of this vaccine. They have considered the vaccine as safe for use in children above 1 year of age. The experience of the campaigns in India in 2006 has also ruled out any association of serious adverse events with the vaccine.
2. Some minor reactions have been reported after vaccination in about 0.005% cases which have subsided within a few days, like Fever (increased temperature above 37.5 °C), nausea , rashes, local inflammation at the site of Injection

## Precautions

1. The health care provider should enquire from the beneficiary or his/her guardians before administering the vaccine about history of hypersensitivity, anaphylactic reactions (urticaria, dyspnoea, perioral oedema, oedema of larynx), if any have been reported following any previous injections or food intake. In case there is a history of any of the above, then the vaccine should not be administered.
2. Auto Disable syringe should be used for administering vaccination.
3. Remove the plastic tab of the flip-off cap. DO NOT REMOVE THE RUBBER STOPPER. Reconstitute only with the supplied diluents containing phosphate buffer solution. Shake the vial thoroughly and take precautions not to touch the rubber stopper.
4. DO NOT USE SPIRIT FOR CLEANSING THE SKIN before injecting. The upper arm is the site of the injection. Use only clean water for cleansing the skin before injecting.
5. Take precautions that the vaccine **should not** be injected into a muscle.
6. Needles should not be recapped and the hub of the needles should be cut immediately with the hub cutter as per GoI guidelines.
7. If any symptoms are observed after the JE vaccine has been administered, such as - fever, rashes, convulsions, etc, consult a doctor immediately.

## Handle with Care

1. The color of the reconstituted vaccine should be transparent orange, red or light pink. The vaccine should be inspected visually for extraneous particulate matter and or abnormal discoloration prior to administration. If either of these conditions exist, then the vaccine should not be administered.
2. The vaccine should be reconstituted just before use and left over vaccine in the vial should be disposed in the red plastic bag after **two hours** of reconstitution

## How is the vaccine supplied?

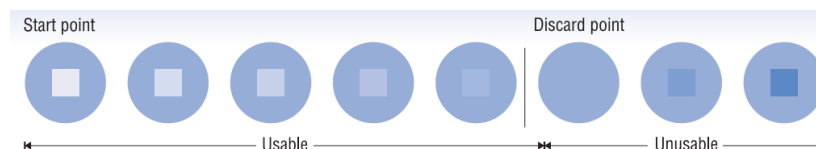
Vial, containing 5 doses of lyophilized vaccine and diluents containing 2.5 ml per vial are supplied separately.



## VVM (Vaccine Vial Monitor)

The JE vaccine vials are supplied with VVMs. The VVMs are stuck on top of the cap of the vial. Once the cap is opened, the VVM's role ceases to exist.

***Before reconstituting the vaccine, it must be ensured that VVM is in a usable stage as explained in the figure below.***



### VVM's interpretation:

- According to the GoI's guidelines, the VVM is to be interpreted as USABLE and UNUSABLE only. The color change of the VVM is a continuous process. The color depicts the extent of the chemical polymerization reaction which is determined by the cumulative time and temperature exposure.
- Once the vial is opened, the VVM becomes ineffective and after reconstitution, the vaccine must be utilized within 2 hours.
- Hence, the ANM ensure that the time of reconstitution is recorded on the vial and that he or she keeps track of the time at which the 2 hours lapse.

### Facts about VVM on JE vaccine vials

#### What is VVM ?

VVM is a device containing a heat sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time.

#### How does it work ?

The combined effects of time and temperature cause the inner square of the VVM to darken, gradually and irreversibly.

- The lower the temperature, the slower the colour change.
- The higher the temperature, the faster the colour change.

#### What are the stages of VVM ?

There are only two stages of VVM, "Usable" Stage - where the square is lighter than the circle. "Unusable" Stage - where the square matches or darker than the circle.

#### What is the importance of VVM ?

VVM is a tool indicating whether the vaccine has been exposed to excessive heat over time. VVM also signals whether the vaccine is likely to have been damaged. It clearly indicates the health workers whether the vaccine can be used.

**Storage:** The vaccine should be stored between **2-8 °C** and must be protected from light. ***After reconstitution, the vaccine should be used within 2 hours. Do not freeze the reconstituted vaccine.***

**Expiry Date:** The vaccine should be used before the expiry date stated on the label.

**Manufacturer:** Chengdu Institute of Biological Products, Chengdu, CHINA.

## Details for Administration of JE Vaccine

<b>Type of vaccine</b>	Live attenuated SA-14-14-2 JE vaccine
<b>Packaging</b>	Multi-dose vials with 5 doses as a lyophilized powder that looks like a milky-white crisp cake Diluent vial of 2.5 ml
<b>Reconstitution</b>	The vaccine should be reconstituted with the supplied diluent only. After reconstitution it turns into a transparent orange red or light pink. <b>The reconstituted vaccine should not be used beyond two hours of reconstitution</b>
<b>Schedule</b>	One dose (0.5 ml) containing not less than 5.4 log PFU of live JE virus)
<b>Administration of Vaccine</b>	1) Vaccine should be administered with Auto Disable (AD) syringes only. 2) The vaccine should be injected sub-cutaneously in the upper left arm (below the usual site of the BCG Scar). Clean water should be used for cleansing the skin and dry the area with sterile cotton before injection. 3) Needles should not be recapped and should be disposed as per GOI guidelines.
<b>Finger Marking</b>	Following the administration of the injection, the thumb of the left hand should be marked by election ink or a permanent marker.
<b>Vaccine vial and diluent storage</b>	Stored and transported between 2°C to 8°C and should be protected from sunlight. ( Remember the diluent should also be kept at 2-8 degrees 24 hours prior to the commencement of the JE campaigns

## Appendix B: Cold Chain Management guidelines

### Storage of SA 14 14 2 JE Vaccine

SA 14-14-2 JE vaccines should be stored at a temperature of 2 - 8 °C. The diluents can be kept at room temperature **but REMEMBER - 24 HOURS PRIOR TO THE COMMENCEMENT OF THE JE CAMPAIGN IN THE DISTRICT, the required amount diluents should be kept in 2-8 °C along with the vaccine vials**

### **VVM (Vaccine Vial Monitor) Guidelines:**

The JE vaccine vials are supplied with VVMs which atop the flip off seal/ cap of the vial. Once the cap is opened, the VVM's role ceases to exist. **Before reconstituting the vaccine, it must be ensured that VVM is in a usable stage.**

### Preparations before vaccine arrival at district

- It should be ensured that Walk in Cooler (WIC) main unit where available and stand by unit are in working condition maintaining a temperature of 2-8 °C.
- The power supply position should be checked
- Appropriate authorities concerned with the power supply to the district should be intimated of the vaccine arrival by the District Magistrate.
- Standby generator facility to run the WIC in case of power failure should be ensured.
- One portion of the WIC should be kept clear with adequate space for storing JE vaccine and diluents

### Receipt of the vaccine

- Vaccine is dispatched from central stores to the districts in refrigerated vans which maintain the adequate temperature of 2-8 °C.
- Immediately after the arrival of the refrigerated van and before unloading the vaccine at the district stores, the cold chain officer must check:
  1. The data logger (if available) in the van
  2. The temperature recorder (The temperature recorder is located in the front panel of the vehicle near the driver seat)

### **Unloading the Vaccine**

- Care should be taken to avoid any direct contact of the vaccine packet with direct sunlight.
- The vaccine should preferably be unloaded in shade or after sun set. *(If the vaccine storage site has the facility of ramp the rear of the vehicle could be placed at ramp level which is usually covered. This will prevent direct contact of the packet with heat)*
- The vaccine is packaged in an inner box made of thermocole. This box has an outer covering made of cardboard.

### **Storage of Vaccine**

The vaccine and diluents should ideally be stored in the Walk In Cooler (WIC) wherever available.

### **Additional vaccine storage site at the district**

- Due to huge volumes of vaccine received for the campaign, JE Vaccines and Diluents may also be stored at Cold Storage sites inside or near the district. One person should be made responsible to monitor that the temperature is maintained between 2 to 8 °C.
- Particularly with frequent power cuts, the Compressors are run for a shorter period (to save on Diesel for running the Generator) which results in the temperature rising at times beyond 10 °C. In such locations, precaution should be taken to ensure that the Generators are always in working condition and temperature monitoring is done 4 times a day. The temperatures should be recorded by district health staff designated exclusively for this purpose.
- The Manager of the Cold storage is to be briefed of the importance of maintaining the Temperature of the cold storage between 2-8 °C only.
- The Manager and the Focal person of the Campaign and the designated person for monitoring should share their telephone / mobile numbers so that they can be contacted at any time in case of any emergency.
- The Government authorities should be requested to advise the electricity authorities to provide uninterrupted electric supply so as to avoid any sort of difficulty in maintaining the desired temperature of the cold storage to prevent frequent storage.
- If a Cold storage is used for storage of the JE Vaccines and diluents then they should be stored preferably in the first floor of the Cold storage and ensure that the Vaccines and Diluents are not placed near the door/ entrance of the Cold storage

- Vaccines and Diluents should be stored in the original packing, i.e., Outer Cardboard box and then inside, the thermocole box in which the Vaccines are kept.
- Although it is recommended that the Diluents may be kept up to a temperature of 2 - 30 Degree C, in the summer months, the ambient temperature is high, which would affect the quality. DILUENTS SHOULD ALSO BE KEPT WITH THE VACCINES.

### **Storage at the PHCs**

Prior to the JE campaign, the following steps should be taken to ensure that:

1. One small ILR with thermometer (temperature meter) should be available for storage of the vaccines and diluents (*The ILR should be connected with the Voltage stabilizer*).
2. One Deep freezer should be available to freeze ice packs.
3. Ensure that the Generator is in proper working condition.
4. Adequate vaccine carriers are available along with ice packs and Cold boxes are available
5. Proper records of stocks should be maintained at the PHC level and stock monitoring should be done daily.

At PHC level, one person may be exclusively designated to - maintain and monitor the stock of JE vaccines and diluents, to ensure that the recommended temperature is maintained in the ILR and to monitor the temperature at least twice a day.

**Vaccine vials and Diluents should not be stored in Deep freezer.**

### **Storage in vaccine carriers**

- Vaccine carrier(1.7 liter net capacity ) can store 25-27 JE vaccine vials and 25-27 diluent vials in a polythene packet
- Four conditioned ice packs which properly fit in the groove provided in the vaccine carriers should be placed.
- Partially frozen ice packs should not be supplied with the vaccine carrier
- Vaccine vial packs and the diluents packs should be kept side by side and fit in well in the vaccine carrier.
- After placing the vials in the carrier, the lid should be properly closed.
- Only one set of vials (One Vaccine and one Diluent) should be taken out at a time from the vaccine carrier to be administered. All other vials should remain in the vaccine carrier.
- During summer months, the ice pack inside the vaccine carrier melts faster and the temperature lasts for a shorter duration. It is, therefore absolutely essential to ensure that

a **standby Vaccine carrier** is taken by each team to the village/ sub – centre. The standby Vaccine carrier should be used 3 hours after the first vaccine carrier has been used. All vaccines which are un-used in the first vaccine carrier should be shifted to the standby vaccine carrier.

- Vaccine vials and diluents should be kept in polythene packs to accommodate / carry more vials. However, since the packing of the JE vials and diluents is compact and good quality, it is not required to keep the vials in a polythene envelope.
- Unused vaccine vials should be checked properly by the PHC staff while receiving the same in the evening and the VVM stage should be noted and only those should be used or stored which are in usable VVM stage.
- These vials should be stored separately in the ILR and the pack should be marked, so as to easily enable its identification as a “Vial returned”.



## Appendix C. Adverse events occurring after JE vaccination

### Instruction for Medical Officers

The live attenuated JE vaccine has been used since 1988 and has an excellent safety record. However it may cause some minor reactions. Most of the reactions are related to program errors (viz. An event caused by an error in vaccine preparation, handling or administration, for example, bacterial abscess at site of injection due to unsterile injection or wrong diluent). These can be reduced to a minimum by taking simple precautions listed below. Please ensure that these are communicated to the health workers during the training sessions before the immunization sessions.

### Strategies to reduce program errors

- Use only sterile AD syringe for injections.
- The packaging of the ADS should be checked before usage. In case the packaging is torn, the ADS should not be used, instead a fresh syringe must be used.
- Ensure adequate syringes & needles for dilution and adequate distribution of the diluents.
- Always use fresh sterile syringe for reconstitution on every vial of vaccine.
- Reconstitute the vaccine only with the diluent provided with the vaccine.
- Train health workers in the proper procedures for reconstituting the vaccine and appropriate techniques for administration.
- **Discard the live attenuated JE vaccine 2 hours after reconstitution.**
- Plan the disposal of the immunization waste (syringe & needle, used vials etc) as per guidelines.
- DO NOT store drugs and other substances in the ILR/DF; it is to be used exclusively for vaccine.
- Train health workers appropriately so that they observe safe injection practices.
- Investigate any program operational error so that it is not repeated.

The health staff should be equipped to identify and respond/manage the adverse events that may still occur. The SA-14-14-2 JE vaccine is a comparatively safe vaccine, with no major side effects recorded. However the few minor side-effects, including those caused by programmatic errors, that have been reported are: ***Mild Fever, Rash, Injection site tenderness and Irritability***

## **Appendix D: Protocol for investigation of all cases of Adverse Events Following Immunization with live attenuated SA14-14-2 JE Vaccine**

Following vaccination campaigns it is important to undertake a detailed investigation of all cases as per the national guidelines for AEFI. All cases should be investigated and documented to establish the cause of sickness and death in these children, especially taking appropriate clinical specimens (including CSF in all neurological events). Case investigations should compliment clinical care.

### **District AEFI Committee:**

The existing AEFI Committee under the chairmanship of the Chief Medical Officer of Health should be activated and briefed at the district prior to the campaigns. Other members of the committee will comprise of the following:

1. Pediatrician/Physician
2. District Laboratory Representative (a Pathologist or a Microbiologist or any Senior Laboratory staff / Medical Officer trained in clinical pathology).
3. District Malaria Officer
4. District Immunization Officer
5. Drug Inspector

For details of the AEFI committee and the roles and responsibilities of the members, please refer to the National AEFI guidelines.

### **Forms to be filled up in AEFI: FIR, PIR, DIR**

1. **FIR: First Information Report (FIR) (Form 8, Appendix G)**– To be reported in the first 24 hours The purpose for the FIR is to provide the most basic information of the event to all levels and it acts as the reference point for further investigations in a time bound manner.
2. **PIR: Preliminary Investigation Report (PIR) - (Form 9, Appendix G)**– To be reported within 7 days. The primary reporting (notification) of the FIR form will usually be done by completing “section A”, i.e. the first *information* by any health worker including the ANM, AWW, ASHA, ICDS, Health Supervisor, community mobilizer, private practitioner, RMP etc. The form will be submitted to the Medical Officer who can also be the first person to report the case) of the nearest Government rural or urban Health Centre as soon as the event is brought to their notice.

- The Medical officer should complete “section B”, first *investigation* of the FIR and submit the same to the DIO within 24 hours of notification of the event.
  - The DIO should complete the final details in “section C” in the FIR and submit with KIND ATTENTION: SEPIO and DC- UIP MOHFW, GoI within next 24 hours (**Fax Number: 011-23062728**) .
2. **Detailed Investigation Report (Form 11 Appendix G):** Detailed Investigation Report (DIR) (Form 10 Appendix G)- To be reported within 90 days of submitting the FIR. The purpose of the DIR is to guide the program managers at all levels to review the comprehensive data and information of the AEFI(s) to arrive at a possible cause for the occurrence (causality assessment) of this event. The State/ regional AEFI committee will review and monitor quality of investigation and final assessment reports based on the investigation reports submitted by the district committees and arrive at a final conclusion on causality. The State AEFI committee could request for assistance from the national AEFI committee if necessary. Complete FIR and PIR

- ✓ *ALL serious AEFIs should be reported in standard forms (FIR, PIR and DIR) through the fastest available means*
- ✓ *For EVERY reported serious AEFI case, the district / state program officer has to ensure that all the 3 forms FIR, PIR, DIR and cased summary are completed on time and submitted as outlined.*

### **Maintenance of data and records**

**State level:** In addition to a copy of the FIR, PIR and DIR of all the AEFIs reported, the SEPIO should maintain a database of all reported AEFIs in the form of a line list (Annex 5). An annual review of data of all serious AEFI should be done by the state AEFI committee. This will help the state to take appropriate action and improve AEFI surveillance. Feedback should be provided to all stakeholders.

**National level:** The National level AEFI database is maintained in MoHFW. It is regularly updated following receipt of FIR, PIR and DIR.

Periodic routine data analysis should be carried out at the district, state, and the national level. The monitoring of reported data includes the following information:

- Number of AEFIs reported
- Geographic and temporal distribution of AEFIs reported (look for clustering)
- Number and type of adverse events reported by antigen (e.g. Injection site abscess,

seizures, HHE, etc.).

- Geographic distribution of possible programme related adverse events like abscesses
- Clustering of adverse events according to batch
- Silent blocks/corporation/districts/states not reporting AEFI data

MoHFW has developed software (tool) for recording data of reported serious AEFIs. This generates basic (Time, Place and Person) analysis. All states need to maintain an AEFI database using this tool.

#### **AEFI reporting by a private health facility / practitioner.**

The district authorities (DIO/ CMO or the Block MO) should ensure that the key private health facilities and focal persons are identified and are sensitized about the AEFI reporting system for vaccines supplied by GoI. Reporting of an AEFI

It is never appropriate to discontinue immunization while awaiting the completion of the AEFI investigation.

from any private health facility or a practitioner should trigger an investigation by the district health authorities. Feedback of AEFI investigation and causality assessment should be provided. The reporting channels, documentation and timelines remain the same. Professional bodies like IAP, IMA, Medical Colleges, Partner agencies like WHO, UNICEF, PATH and others should also be involved in AEFI reporting.

#### **Illustration of investigation of a case of AEFI specific to JE vaccine admitted in a hospital:**

This process runs parallel to the clinical management of the case.

1. FIR, DIR and PIR forms should be filled up as mentioned above and sent to the District, State and the National within the prescribed time
2. CSF sample should be collected **ONLY** if the patient has neurological symptoms and the CSF samples should be sent to the District in cold chain. A serum sample also should be collected and sent to District in cold chain (Note 1: CSF sample collection is essential to determine the etiology of the encephalitis particularly in a child vaccinated recently with JE vaccine. Every attempt should be made to collect CSF. In the rare event of not being able to collect CSF specimens, serum samples should be collected. Note 2: Adequate amount of CSF should be collected for laboratory testing and validation)

***All records related to the AEFI case must be retained for at least 12 months following the investigation of the case.***

**Illustration of investigation of an AEFI case specific to JE vaccine that died before investigation:**

1. FIR, DIR and PIR forms should be filled up as mentioned above and sent to the District, State and the National within the prescribed time
2. Autopsy must be carried out in all deaths which have occurred before investigation. (In case of deaths following investigation and admission in a hospital autopsy must also be carried out for further clues to the aetiology)
3. Brain tissue should be collected and transported in cold chain to District Immunization officer for further histo-pathological investigation.

**Submission of Investigation report**

The completed investigation reports (FIR, PIR and DIR) and other relevant records need to be submitted by the State to the GoI within 30 days of submission of the DIR by the district. Copies of all records must be accompanied with an AEFI case summary.

**Guidelines for collection and shipment of samples for Laboratory investigation in a major AEFI case following vaccination with live attenuated SA14-14-2 JE vaccine:**

Collection of laboratory specimens in all children who are admitted in a hospital with any illness within 15 days of vaccination with live attenuated SA14-14-2 vaccine is a critical criterion for determining the cause and any association of the illness with the vaccine.

Following samples need to be collected in all children who are admitted in a hospital with any illness within 28 days of vaccination with live attenuated SA14-14-2 vaccine. Lab request form (**Form 11**) needs to be filled by DIO and sample collected need to be sent to designated lab.

1. Cerebrospinal Fluid (CSF) ( Only in children presenting with any neurological signs and symptoms)
2. Serum
3. Stool ( if the child presents with Acute Flaccid Paralysis-AFP)

**Cerebrospinal Fluid Collection:**

1. CSF is the sample of choice in all children who are admitted to a hospital with any neurological illness and have been vaccinated with live attenuated SA14-14-2 JE vaccine within the past 15 days.
2. Every attempt should be made to collect sample immediately following admission of the child. But there is need to exercise caution for doing a lumbar puncture in an

unconscious child or comatose child. If there are localizing signs, lumbar puncture should be avoided.

3. In case necessary equipment and expertise is unavailable at the hospital, please inform the District Immunization Officer.
4. The DIO will arrange to collect the CSF sample immediately by sending an expert with necessary arrangements from the District.
5. At least 1- 2 ml of the CSF must be collected.
6. Following collection of the CSF in a sterile tube, make two aliquots of 1 ml each for further testing in the laboratory.
7. Send samples in screw capped vials to prevent leakage. Put adhesive tape on the cap of tube further preventing any leakage
8. Before the process of collection of the samples please paste a label on the outer wall of the sterile tube. The label should have the name, age of the patient and the date of specimen collection.
9. Transfer the sterile tube(s) with the specimen in a specimen carrier (vaccine carrier earmarked for sample sending) with four frozen icepacks
10. Fill up the Laboratory Requisition Form (LRF) i.e. Form 11.
11. Send the Specimen carrier containing the specimens and four frozen ice packs along with the Laboratory Request Form (as in the Operational Guideline Hand Book) immediately to the DIO by a special messenger.
12. Please intimate the DIO over the phone that the samples have been dispatched to him.
13. The DIO will receive the samples. He will match the record on the Laboratory Request Form with the information on the FIR of the concerned patient. DIO will also check the same for the label on the test tubes containing the specimens.
14. The DIO will check the condition of the ice packs in the specimen carrier. If required DIO will replace four fresh frozen ice packs in the specimen carrier.
15. Immediately following check of records on the FIR, LRF and the labels on the specimen tubes, DIO will dispatch the specimens to National institute of Virology, Pune.
16. The specimen will be accompanied by two copies of the LRF. One copy will be retained at the laboratory and the second copy will be used as receipt and returned to the DIO.
17. DIO will intimate Assistant Commissioner (AC-UIP) immediately following dispatch of the samples to the laboratory. A copy of the LRF will be faxed to the office of the AC-UIP in New Delhi ( FAX NO. : 011- 23062728).

18. DIO will also follow up with the designated person in NIV Pune (name to be intimated later by AC – UIP after 48 hours of dispatch of the sample).
19. The laboratory will receive the sample and comment on condition of the sample and cold chain on receipt on the duplicate LRF.
20. The CSF may be tested for Chemistry, Microbiology and antibody testing (in particular JE IgM) in the laboratory.

#### **Blood Collection:**

1. Blood/Serum is not the sample of choice in a sick child vaccinated with live attenuated SA14-14-2 JE vaccine
2. However blood samples may be collected for routine, biochemical and specific tests ( e.g. tests for malaria parasite) to determine the cause and progress of illness in the child
3. In the rare event where CSF samples cannot be collected, paired blood samples must be collected. Blood samples will be collected on the day of admission and on the 10<sup>th</sup> day or at discharge or death, whichever is earlier.
4. Collect 5 ml of blood in plain sterile tube, allow to clot and separate serum. Send the serum and blood clot in separate tubes. To prevent haemolysis do not freeze the blood before separating serum.
5. Before the process of collection of the samples please paste a label on the outer wall of the sterile tube. The label should have the name, age of the patient and the date of specimen collection.
6. Transfer the sterile tube(s) with the specimen in a specimen carrier (vaccine carrier earmarked for sample sending) with four frozen icepacks.
7. Fill up the Laboratory Requisition Form (LRF) (Form 11).
8. Send the Specimen carrier containing the specimens and four frozen ice packs along with the Laboratory Request Form (as in the Operational Guideline Hand Book) immediately to the DIO by a special messenger.
9. Please intimate the DIO over the phone that the samples have been dispatched to him.
10. The DIO will receive the samples. He will match the record on the Laboratory Request Form with the information on the FIR of the concerned patient. DIO will also check the same for the label on the test tubes containing the specimens.

11. The DIO will check the condition of the ice packs in the specimen carrier. If required DIO will replace four fresh frozen ice packs in the specimen carrier.
12. Immediately following check of records on the FIR, LRF and the labels on the specimen tubes, DIO will dispatch the specimens to National institute of Virology, Pune.
13. The specimen will be accompanied by two copies of the LRF. One copy will be retained at the laboratory and the second copy will be used as receipt and returned to the DIO.
14. DIO will intimate the AC-UIP immediately following dispatch of the samples to the laboratory. A copy of the LRF will be faxed to the office the AC-UIP of the in Delhi ( FAX NO. : 011- 23062728)
15. DIO will also follow up with the designated person in NIV Pune (name to be intimated later by the AC-UIP after 48 hours of dispatch of the sample).
16. The laboratory will receive the sample and comment on condition of the sample and cold chain on receipt on the duplicate LRF.
17. If CSF samples have been collected it is not necessary to send the serum samples to NIV, Pune for further testing. The serum samples in that case can be tested at the district laboratory for biochemical, routine and specific test like presence of malarial parasite.

**Stool samples:**

1. Please inform the Surveillance Medical officer (SMO)/ DIO if the child presents with AFP.
2. Stool samples will be collected and sent to the designated laboratory as per NPSP guidelines.
3. The cover letter should be addressed to the Director NIV, Pune. And the samples should be sent to the address below.

**NIV Pune- Contact details**

The Director, National Institute of Virology,  
Sus Road campus, Pashan Pune 411 021 Maharashtra  
Kind Attn : Dr V.P. Bondre, Scientist C,  
Japanese Encephalitis Group mail: acm1750@rediffmail.com, vpbondre@gmail.com  
Tel: 020-26002290, 020-26006390 ;  
Fax: 020-26122669, 020-25871895



## Laboratory Aspects of AEFI

Laboratory testing of samples is not mandatory following AEFI particularly if the cause is evident such as a coincidental event or a program error. However, laboratory testing is at times required to confirm or rule out the suspected cause. As per the Central Drug Standard Control Organization (CDSCO) the following laboratories have the legal mandate for testing:

Laboratory testing for implicated vaccines/ diluents/ logistics should be requested only on a clear suspicion and not as routine, and never before the working hypothesis has been formulated.

- Vaccines and diluents for sterility and chemical composition at CDL Kasauli
- Syringes and needles for sterility at CDL Kolkata

### For biological samples,

- Histopathology, body fluids etc can be done at laboratories identified and approved by the district / state AEFI committees and
- Autopsy specimens at approved and accredited state forensic laboratories

Only the appropriate specimen in the correct quantity required for the investigation should be collected. Laboratory specimens should be accompanied by clear supporting documents (LRF, FIR, PIR and other relevant document), reasons for specimen collection and any additional information required by the investigators.

**Table Activities and responsibilities for specimen collection following an AEFI**

	Activity	Responsibility
1	Decision to collect sample (samples should be collected as soon as possible and sent only if the district AEFI committee decides)	<ul style="list-style-type: none"><li>• District AEFI committee that includes local drug inspector. If required consult state AEFI committee</li></ul>
2	Decision to temporarily suspend the use of implicated batch of the vaccine/diluent/logistics	<ul style="list-style-type: none"><li>• MoHFW Govt of India.</li><li>• The local drug authority representative after discussion with the AEFI committee.</li></ul>
3	Collection and sending of samples	<ul style="list-style-type: none"><li>• The Drug Inspector &amp; DIO</li></ul>

4	Decision on type of samples that need to be collected	<ul style="list-style-type: none"> <li>Based on recommendations of the District AEFI committee.</li> <li>The Drug Inspector may also collect additional samples as he considers appropriate.</li> </ul>
5	Packaging & Cold Chain of samples	<ul style="list-style-type: none"> <li>Drug Inspector and DIO</li> </ul>
6	Sealing of specimen using “official lac seal”	<ul style="list-style-type: none"> <li>Preferably by Drug Inspector; in case the drug inspector is not available, then by DIO using the CMO’s seal</li> </ul>
7	Transportation of samples to laboratories	<ul style="list-style-type: none"> <li>Preferably DIO and/ or Drug inspector</li> </ul>
8	Laboratory for sending specimen	<ul style="list-style-type: none"> <li>Identified laboratories as described in this chapter</li> </ul>
9	Funding	<ul style="list-style-type: none"> <li>The expenses for activities related to AEFI surveillance, AEFI case management, transportation of vaccine and other AEFI related activities can be made from the available funds under Part C (Immunization) of NRHM PIP (under the provision for ‘State specific activities’) after due approval by competent authority at block/district/state level.</li> <li>All expenses towards testing of vaccines in CDL Kasauli and Kolkata will be borne by the respective laboratories.</li> <li>NIV Pune will bear the expenses related to testing of samples for adverse events occurring following JE vaccination.</li> </ul>
10	Reporting of laboratory results/ reports	<ul style="list-style-type: none"> <li>The laboratory as a rule will forward a copy of the report to CDSCO, AC (UIP) MoHFW, State immunization officer, State Cold chain officer</li> </ul>

		<p>and State drug authority.</p> <ul style="list-style-type: none"> <li>Laboratories will also send a copy of the laboratory results to all persons with contact details (complete address with pin code, phone and fax numbers and email address) mentioned in the LRF.</li> </ul>
11	Sharing Laboratory results	<ul style="list-style-type: none"> <li>DIO to share with <ul style="list-style-type: none"> <li>District cold chain officer,</li> <li>Drug Inspector</li> <li>Block Medical officer reporting the case</li> <li>Private health facility reporting the case.</li> </ul> </li> </ul>

### 5.1 Testing of vaccine/ diluents at CDL Kasauli

On the receipt of adequate samples with proper and complete documentation, CDL Kasauli tests vaccines and diluents for physical aspects, sterility, abnormal toxicity and biochemical identity. Tests for potency are not applicable in AEFI cases (it is related to efficacy rather than safety of vaccines). Laboratory tests are performed and results dispatched to the sender in approximately 30-45 days.

#### 5.1.1 Sample collection

The DIO and Drug inspector should be involved in the collection of adequate quantity of implicated vaccine/ diluent samples from the site of occurrence of AEFI and last vaccine storage point and shipping the same in cold chain to the CDL Kasauli as early as possible.

- First collect each vaccine / diluent as described in table 5.2. Prepare four sealed sets with equal quantity and
  - Send 1 set to CDL Kasauli laboratory.
  - Retain 1 set at the site of collection (PHC/CHC or district HQ).
  - Retain 2 sets with the drug inspector.
- The desired quantity of vaccines or diluents must be collected from the next available vaccine storage point if the numbers outlined in table 5.2 are not available at the last vaccine storage point.
- It is important that the quantity required by the CDL Kasauli must not be compromised.

### Packing of samples

- Separate plastic zipper bags should be used for packing different vaccine and diluents.
- The name, age, date of collection, AEFI epid number and point of collection of vaccines/ diluents should be mentioned only on the label of each plastic zipper bag.
- All the packed zipper bags (separate for vaccines and diluents) should then be put in a bigger zipper bag.
- The big zipper bag should be placed in a card board box, tied with a string from all sides and an “official lac seal” affixed by the drug inspector (fig 5.1 and 5.2). The CMO’s “official lac seal” may be used if the “official” lac seal of the drug inspector is unavailable.

#### Address for shipment of vaccines and diluents

To the Head,  
Central Drugs Laboratory,  
Central Research Institute,  
Kasauli – 173 204.  
Himachal Pradesh.  
Email : [ncikasauli@bsnl.in](mailto:ncikasauli@bsnl.in) ;  
Phone: 0179-2272046, 2272060  
Fax: 0179-2272049, 2272016

Fig 5.1



Fig 5.2



### Documentation and transportation of sample to laboratory

- The completed LRF (Annex 4) also sealed with the same “official lac seal” should accompany the samples sent to the laboratory. The “official lac seal” ensures that the samples and details sent to laboratory are not tampered / changed during transportation.
- Ensure that the completed investigation forms (FIR, PIR) also accompany the samples to the laboratory.
- Vaccines and diluents are tested simultaneously, therefore freeze dried vaccines (BCG, Measles, and JE) should be accompanied by their respective diluents.

- The sample should be transported to the laboratory under cold chain (vaccine carrier with ice packs or thermocol boxes with icepacks) preferably through a messenger.
- CDL laboratory Kasauli accepts samples received on all days of the week. The messenger carrying the samples to CDL Kasauli must insist on getting the 'sample received receipt' for official record. This receipt will also provide details on the condition of samples received in the laboratory. (issue of receipt will not be possible in cases when the samples are received on weekends).
- Samples may also be sent by courier that has experience in handling biological products and can also **guarantee** delivery up to CDL Kasauli within the stipulated time under the stipulated conditions.

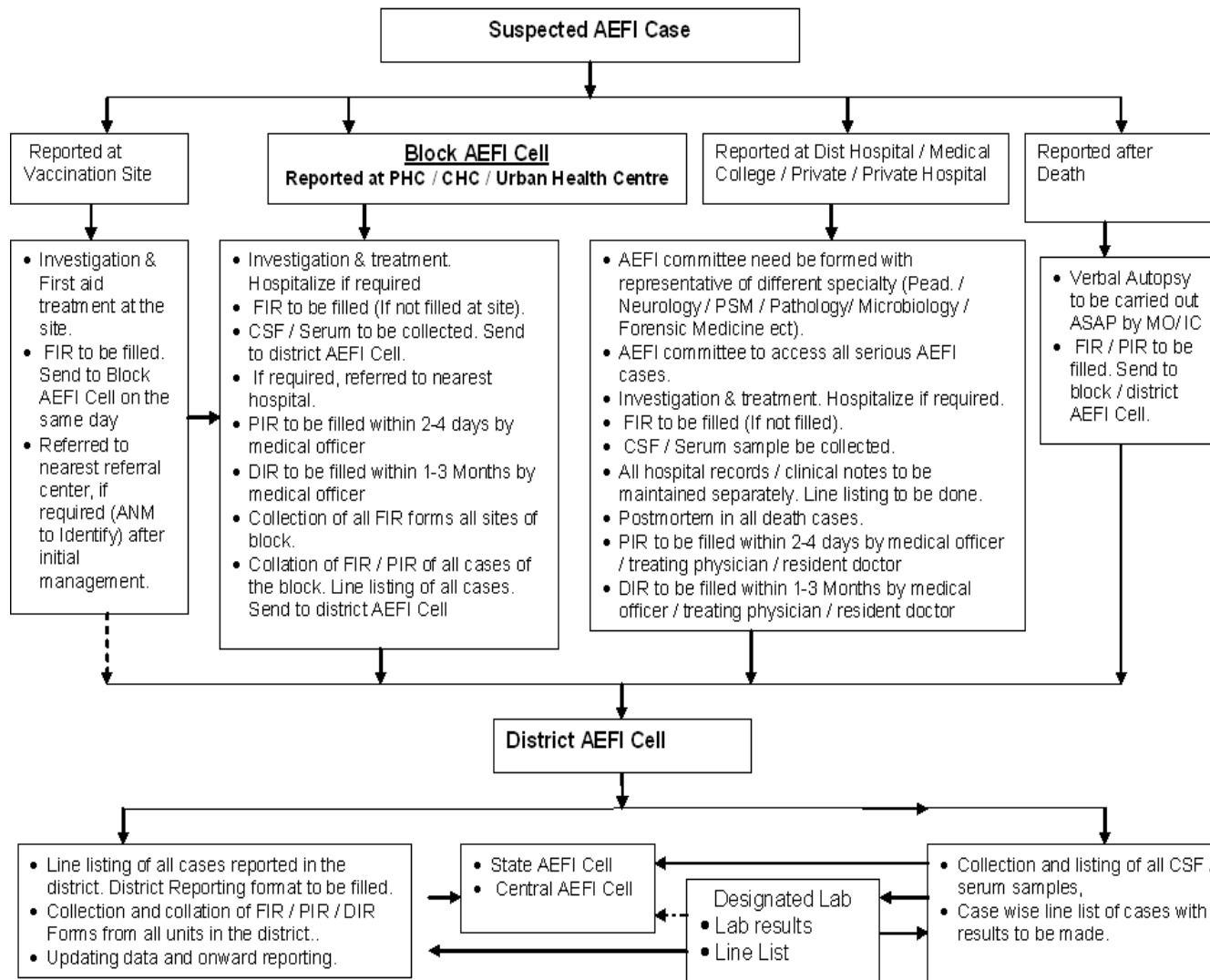
**Table showing Quantity of implicated vaccine / diluents to be collected**

Vaccine	Quantity to be collected		Quantity to be shipped to CDL Kasauli for testing	
	unused vaccine vials / ampoule  (A)	unused diluent vials/ ampoule  (B)	unused vaccine vials/ ampoules (one fourth of total samples collected )  (C)	unused diluent vials/ ampoule (one fourth of total samples collected )  (D)
JE vaccine	01 dose X 120 vials	120 diluents	01 dose X 30 vials	30 diluents
	OR 05 dose X 60 vials	60 diluents	OR 05 dose X 15 vials	15 diluents
	OR 10 dose X 40 vials	40 diluents	OR 10 dose X 10 vials	10 diluents

### Recording & Reporting

1. Every case will be identified by unique EPID Number given by DIO.
2. Line listing of all AEFI cases will be done on **Form 12**. Computerization of line list is to be done in the Excel sheet provided during the workshop.
3. Line list will be maintained at Block and at the District HQ.
4. Updated line list will be send to MoHFW along with daily coverage report.

**JE Vaccination Campaign India      AEFI Management & Reporting: Protocol to be followed**



## GUIDELINES FOR MANAGEMENT OF AEFIs

(Adapted from MLM Training Module V, Annexure 5)

Adverse Event	Symptoms	Management
Anaphylaxis (very rare)	<p>Within Minutes</p> <ul style="list-style-type: none"> <li>Acute decompensation of circulatory system.</li> <li>Hypovolemic shock</li> <li>Altered sensorium</li> <li>Laryngospasm/oedema</li> <li>Acute respiratory distress</li> </ul>	<ul style="list-style-type: none"> <li>Adrenaline <b>(1:1000)</b></li> </ul> <p>Dose : 0.01 ml/kg body wt. SC/IM immediately (for dosage of Adrenaline for different age groups please refer to the Box in page 72.</p> <ul style="list-style-type: none"> <li>Cardiopulmonary resuscitation</li> <li>IV volume expanders</li> <li>Oxygen Inhalation</li> <li>Hydrocortisone injection IV</li> </ul>
Bacterial abscess or Sciatic nerve injury May be <b>due to</b> contamination of vaccine or lack of sterilization	<p>Within 72 hours fluctuant or firm abscess with or without fever</p>	<ul style="list-style-type: none"> <li>Antibiotic</li> <li>Antipyretics</li> <li>Drainage (if needed)</li> </ul>
Moderate local reaction	<p>Non fluctuant swelling / redness 3 -10 cms at the site of injection</p>	<ul style="list-style-type: none"> <li>Paracetamol Syr.</li> </ul> <p>(Dose: 10 mg / kg bd.wt per dose orally – can be repeated every 6 – 8 hrs). Paracetamol Syr has 125mg/5ml</p>
Severe local reaction	<p>Non fluctuant swelling / redness 10 cms in size or larger at the site of injection</p>	<ul style="list-style-type: none"> <li>Paracetamol (dose as above)</li> </ul>
Seizure/s with/without fever (rare) or convulsions.	<p>By 24 - 48 hours</p> <p>Always generalized</p> <p>Simple or Complex</p>	<ul style="list-style-type: none"> <li>Anticonvulsants e.g. Injection Diazepam (Dose: 0.3 mg/kg /dose slow IV)</li> <li>Can be repeated after 30 minutes.</li> <li>Antipyretics</li> <li>IV fluids if need be</li> </ul>
Hyperpyrexia	<p>By 12-24 hours</p>	<ul style="list-style-type: none"> <li>Antipyretics</li> <li>Tepid water sponging.</li> </ul>

**Adrenaline dosage:** 1:1000 adrenaline (epinephrine) at a dose of 0.01ml/kg up to a maximum of 0.5 ml injected intramuscularly (or subcutaneously in very mild cases)

If the weight of the patient is unknown, an approximate guide is:

Less than 2 years	0.0625 ml (1/16 <sup>th</sup> of a ml)
2-5 years	0.125 ml (1/8 <sup>th</sup> of a ml)
6-11 years	0.25 ml (1/4 of a ml)
11+ years	0.5 ml (1/2 of a ml)

**\* To measure and administer the dosage of Adrenaline, Insulin syringes may be used**

#### **Recommendations of AEFI Committee:**

National level committee of experts which was formed on 13<sup>th</sup> July 2006 “to review State investigation reports & to investigate the Adverse Events following Immunization (AEFI) following vaccination with live attenuated SA-14-14-2 vaccine against Japanese Encephalitis (JE) in high risk districts covering 4 States of the country” has recommended that

- Case investigations and laboratory tests conducted following an AEFI have been inadequate. Standard case records and reporting formats, sample collection and investigation at designated laboratories, data collection and analysis, epidemiological investigations and causality assessment following AEFI need to be strengthened and reinforced by the State and National authorities.
- The protective efficacy and vaccine effectiveness should be measured and monitored in those JE-endemic areas where the vaccine is used on a long term basis using epidemiological skills and expertise.
- Improved case records will stimulate better clinical investigation and diagnosis. The Government may address this problem through appropriate channels.



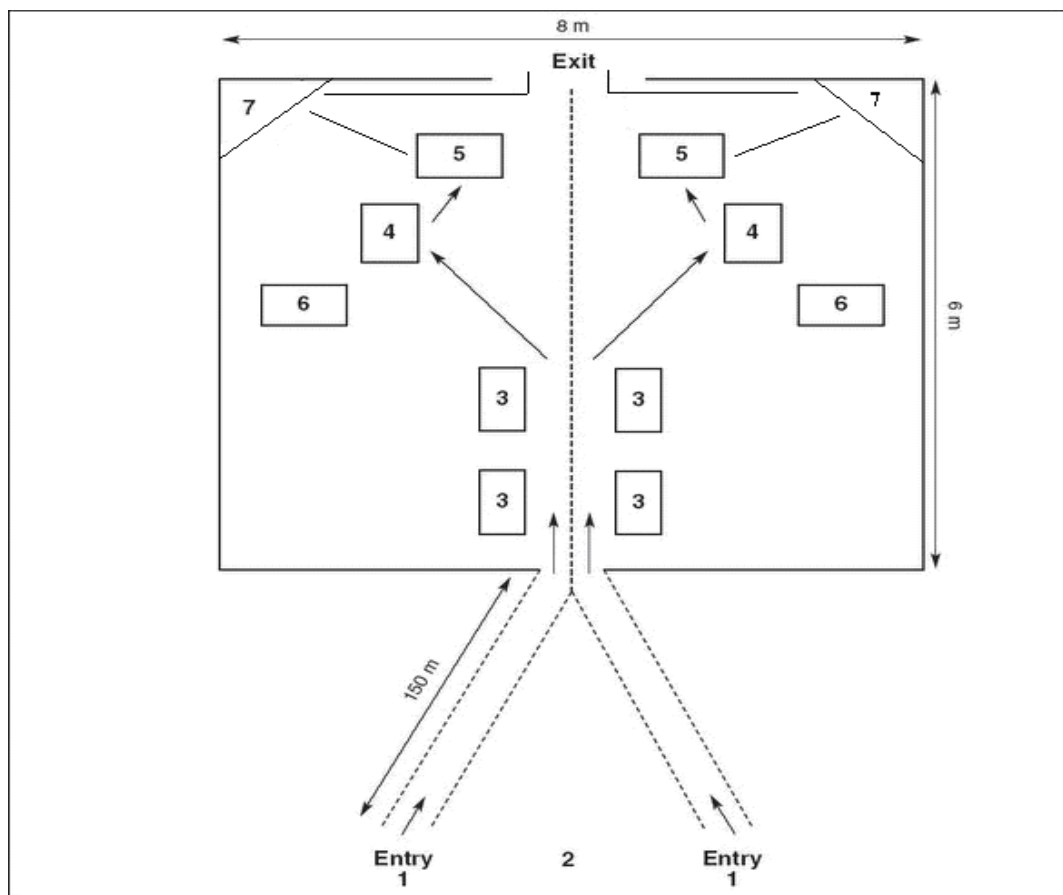
## APPENDIX E

### Disposal of biomedical waste generated at Outreach Points/outside District Hospitals/ CHCs/ PHCs

- Step 1      Immediately after administering the injection, remove the needle from the **AD syringe** using the hub cutter.
- Step 2      The cut needles will get collected in the **white translucent container of the hub cutter**.
- Step 3      Collect used vials and cut syringes in **red bag** or red container.
- Step 4      Carry the collected vials, cut syringes, and white container of hub cutter (containing the needles) to the District Hospital/CHC/PHC for further disposal.

Items	Colour code	Disinfection	Disposal
<b>Cut syringes</b>	RED bag	Boil waste in water for at least 20 minutes OR Autoclaving OR Chemical Treatment	After disinfection :Recycle or Land fill
<b>Used vials and Diluents</b>	RED bag	Local autoclaving OR Chemical Treatment	After disinfection :Recycle or Land fill
<b>Cut Needles/Sharps</b>	Blue/White Translucent puncture proof container	Disinfect with household bleach at 0.5% chlorine solution OR Chemical Treatment	After disinfection : Dispose in Pit / Tank
<b>General waste</b>	BLACK bag	No disinfection required	Disposal in secured land fill
Chemical Treatment shall be done using at least 1% hypochlorite solution or any other equivalent chemical reagent. It must be ensured that chemical treatment ensures disinfection.			

## Appendix F. Vaccination Site Plan



Quantity & Quality of Vaccination is vastly enhanced by effective organization of the vaccination site. The above diagram shows two vaccination teams working simultaneously at one centre e.g. a school and its organization of corners for various activities to be conducted at the Vaccination Centre. The above pictorial representation gives a sufficient room for placement of manpower and systematic conduction of immunization and related activities in an average room of 8x6 m.

**Point1. Entry points with canvas pillars for children to stand in the queues, managed by Volunteers / AWW**

**Corner 3. Screening for Contraindications and Registration**

**Corner 6. Health Education**

**Corner 4. Immunization counter**

**Corner 5. Recording / Reporting**

**Corner 7. Observation room for vaccinated children**

**Appendix G. Forms for Micro planning, Recording and Reporting**

**Form 1 Vaccination Card: JE Vaccination Campaign 20\_\_**

**Form 1 Vaccination Card: JE Vaccination Campaign 20\_\_**

<b>Japanese Encephalitis Vaccination Campaign</b>	<b>Japanese Encephalitis Vaccination Campaign</b>
Name: _____	Name: _____
Age in yrs: _____	Age in yrs: _____
Sex: _____	Sex: _____
Fathers Name: _____	Fathers Name: _____
Village: _____	Village: _____
Sub Centre: _____	Sub Centre: _____
PHC: _____	PHC: _____
District: _____	District: _____
Date of vaccination: __ __ / __ __ / __ __ __ __ (Day) (Month) (Year)	Date of vaccination: __ __ / __ __ / __ __ __ __ (Day) (Month) (Year)
Any Adverse Events: _____	Any Adverse Events: _____
[TO BE RETAINED BY VACCINATOR] [To be retained at the Sub Centre]	[TO BE RETAINED BY BENEFICIARY]

## Japanese Encephalitis Vaccination Campaign Village / Urban Vaccination Site Tally Sheet

**Name of Vaccinator: 1. Resident: \_\_\_\_\_ 2. Supporting: \_\_\_\_\_**

**Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ **Day:** 1/2/3/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20 **Estimated no. of beneficiaries in the village/ urban site:**

**B. Tally of vaccine and logistics:** *(to be calculated at the end of every day)*

	Received	Used	Balance	Expiry date (If more space is required write at the back)
Vaccine vials (5 doses per vial)				
AD syringes				
Syringe for reconstitution (5 ml)				

**Signature of Vaccinator**\_\_\_\_\_

**Form 3 Supervisor's Form: JE Vaccination Campaign 20\_\_**

**Japanese Encephalitis Vaccination Campaign  
Supervisor's Daily Coverage Report Form**

PHC: \_\_\_\_\_

Date: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

Block: \_\_\_\_\_

Day of Activity: 1/2/3/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20

District: \_\_\_\_\_

	1 to 5 years		5-10 years		10 to 15 years		Total		Grand total (M+F)	Vaccine Vials			AD Syringes			Disposable Syringes		
	M	F	M	F	M	F	M	F		Received	Used	Balance	Received	Used	Balance	Received	Used	Balance
Team 1																		
Team 2																		
Team 3																		
Team 4																		
Team 5																		
Team 6																		
<b>TOTAL</b>																		

\_\_\_\_\_  
Name

\_\_\_\_\_  
Signature

Supervisor's comments:

1. How many immunization centres were visited? \_\_\_\_\_
2. I distributed additional vaccine and syringes to team/s during my supervisory visit: Yes/No (If Yes: Which team? \_\_\_\_\_ )
3. I am satisfied with the overall activity in my area: Yes/ No ( If No please give reasons in a separate sheet of paper highlighting reasons and add to this sheet)

**Form 4: Block Daily Reporting Format: JE Vaccination Campaign 20\_\_**

**Japanese Encephalitis Vaccination Campaign  
Block Daily Coverage Compilation Form**

District: \_\_\_\_\_ Block: \_\_\_\_\_ PHC: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Day of Activity: 1/2/3/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20

	1 to 5 years		5-10 years		10 to 15 years		Total		Grand total (M+F)	Vaccine Vials			AD Syringes			Disposable Syringes		
	M	F	M	F	M	F	M	F		Received	Used	Balance	Received	Used	Balance	Received	Used	Balance
Supervisor 1																		
Supervisor 2																		
Supervisor 3																		
Supervisor 4																		
Supervisor 5																		
Supervisor 6																		
Supervisor 7																		
Supervisor 8																		
Supervisor 9																		
<b>TOTAL</b>																		

**Compiled Report till Date**

	1 to 5 years		5-10 years		10 - 15 years		Total		Grand total (M+F)	Vaccine Vials			AD Syringes			Disposable Syringes		
	M	F	M	F	M	F	M	F		Received	Used	Balance	Received	Used	Balance	Received	Used	Balance
(A) Today's Coverage for Block / PHC																		
(B) Cumulative Data till Previous Day for Block / PHC																		
(C) Cumulative Data till Date (Today's Coverage + Cumulative Data till Previous day for Block / PHC) (C=A+B)																		

\_\_\_\_\_  
Medical Officer In charge  
Operational Guide for Japanese Encephalitis Vaccination in India, MoHFW, November 2012

\_\_\_\_\_  
Signature

**Form 5: District Daily Reporting Format: JE Vaccination Campaign 20\_\_**

**Japanese Encephalitis Vaccination Campaign  
District Daily Coverage Compilation Form**

State: \_\_\_\_\_ District: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Day of Activity: 1/2/3/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20

	1 to 5 years		5-10 years		10 to 15 years		Total		Grand total (M+F)	Vaccine Vials			AD Syringes			Disposable Syringes		
Block / PHC	M	F	M	F	M	F	M	F		Received	Used	Balance	Received	Used	Balance	Received	Used	Balance
<b>TOTAL</b>																		

**Compiled Report till Date**

	1 to 5 years		5-10 years		10 - 15 years		Total		Grand total (M+F)	Vaccine Vials			AD Syringes			Disposable Syringes		
	M	F	M	F	M	F	M	F		Received	Used	Balance	Received	Used	Balance	Received	Used	Balance
(A) Today's Coverage for District																		
(B) Cumulative Data till Previous Day for District																		
<b>(C) Cumulative Data till Date</b> (Today's Coverage + Cumulative Data till Previous day for District) (C=A+B)																		

\_\_\_\_\_  
**Chief Medical Officer**

\_\_\_\_\_  
**District JE Program Officer**







<b>Form 8</b>															<b>FIR : Page 1/2</b>														
<b>Section A FIRST INFORMATION REPORT (FIR)</b> (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): <b>Death / Hospitalized / Cluster* / Disability</b>																													
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.)																													
<div style="display: flex; justify-content: space-between;"> <span>P I N -</span> <span>P H O N E -</span> </div>																													
Date of Vaccination										Time of Vaccination																			
Name of recent Vaccine(s) given:										Time of first symptom																			
Date of first symptom										Time of first symptom																			
Current status (encircle)										Death / Still Hospitalized / Recovered & Discharged / Left Against Medical Advice (LAMA)																			
Date of Death										Time of Death																			
Additional Information:																													

\* use separate form for each case in a cluster

<b>Section B: FIRST INVESTIGATION REPORT (FIR)</b> (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): <b>IND (AEFI) /</b> 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										Age (in months)										Sex		Male		Female					
Date of Notification										Date of Investigation										Time of Vaccination					Time of Onset				
Date of Vaccination										Time of Vaccination										Time of Onset									
Date of Onset										Time of Hospitalization																			
Hospitalization No/ Yes Date										Time of Hospitalization																			

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 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 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	M	Y	Y
Proposed date of preliminary investigation	D	D	M	M	Y	Y
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)

Form 8					
<b>Section A PRELIMINARY INVESTIGATION REPORT (PIR)</b> (To be reported to State & GoI within 7 days of submitting FIR)					
<b>(Only for Serious Adverse Events Following Immunization - Death / Hospitalized / Cluster / Disability)</b>					
DWO/RCHO/District Nodal Officer to complete all details in BLOCK letters only					
State	District				
Case ID	IND (AEFI) / Site 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/ BRHC/ Dist Hospital/ State Hospital/ Medical College/ 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	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, P.W. 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/VitA/ 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 1 <sup>st</sup> , 2 <sup>nd</sup> , 3 <sup>rd</sup> , 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 PIR					
<b>Section B Relevant Information of the patient prior to Immunization:</b>					

Name	Case Id Number	IND (AEFI)	State Code	District Code	Year	Serial No.	PIR : Page 2/7
Past H/o similar event	Yes / No	If 'Yes', specify					
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	Yes / No						
• Currently pregnant?	Yes / No						
• Currently Breastfeeding	Yes / No						
Family History of any disease or allergy	Yes / No						
• Natal history	• Full term / pre mature / post dated						
• Delivery	• 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						
<b>Section C Details of first examination* of serious AEFI case</b>							
<p><b>*Instructions – Attach copies of ALL available documents and then complete additional information NOT AVAILABLE in existing documents</b> (case sheet, discharge summary, case notes, post mortem reports etc). i.e.</p> <ul style="list-style-type: none"> <li>If Patient has taken medical care - <u>Attach copies of all available documents</u> (including case sheet, discharge summary, laboratory reports and post mortem reports - if available) <u>and complete only additional unavailable information below</u></li> <li>If patient has not taken medical care – Complete this form fully</li> </ul> <p><b>• If the investigator has disagreement with the findings in any of the document(s) mentioned above, the same may be expressed here with justification</b></p>							
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 1 <sup>st</sup> 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)						
Neck	Neck Stiffness: Present / Absent						
Chest	Auscultation Normal / Crepts / Rhonchi Heart sounds Normal / Murmur						

Name	Case ID Number	IND (AEFI) /	PRK . Page 3/7								
	(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											
Section D Details of immunization provided at the site on the day AEFI reported											
Number of beneficiaries immunized for each antigen 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 / Unknown	
• Within the first few doses of the vial administered/ Within the last doses of the vial administered/ Unknown	
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 _____	
c) Is this case a part of a cluster?	Yes / No
a. If yes, How many other cases have been detected in the cluster?	
b. Did all the cases receive vaccine from the same vial?	Yes / No
c. 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)

**Last vaccine storage point:**

• Temp of ILR ( $^{\circ}$ C)	
• Temp of deep freezer ( $^{\circ}$ 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 of vaccination?	Yes No
• Conditioned ice-pack used?	Yes No

Specific key findings/additional observations and comments:

**Syringes and Needles Used:**

• Are AD syringes used for immunization?	Yes No
--	--------

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

Specific key findings/additional observations and comments:

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

• Reconstitution procedure (encircle) Same reconstitution syringe used for multiple vials of same vaccine? Same reconstitution syringe used for reconstituting different vaccines? Separate reconstitution syringe for each vaccine vial? Separate reconstitution syringe for each vaccination?	Yes	No	NA
	Yes	No	NA
	Yes	No	NA
	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 many AEFI reported from the centre that distributed the vaccine in last 30 days?		
• Training on RI received by the vaccinator : (If Yes specify date of last training _____)	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 site (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: \_\_\_\_\_
- Unknown: \_\_\_\_\_

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



Name	Case Id	Number	IND (AEFI)	State Code	District Code	Year	Serial No.	PIR : Page 6/7
			expiry					
c) Any biological product (CSF, Blood, Urine, etc) sent for testing? <i>If yes, specify details of the lab; attach copy of report if available</i>							Yes	No
<i>Note: for AEFI resulting within 28 days following JE vaccine, send sample of CSF, Serum to nearest NIV lab in Pune or Gorakhpur.</i>								
d) Was local drug inspector involved in collecting additional samples?							Yes	No
e) Other investigation, specify the findings and attach report.								
<b>Section H Preliminary Assessment (working hypothesis of AEFI committee):</b>								
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:								
<i>*If an event is suspected to be related to vaccine(s)/ diluent(s), 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.</i>								
Attached copies of reports / documents etc with this PIR:								
1. 2. 3. 4. 5. 6.								
<b>District AEFI Committee that conducted the preliminary investigation</b>								
Name		Designation			Phone #		Signature	
1.								
2.								
3.								
4.								
5.								

Name	Case Id Number IND (AEFI) / State Code / District Code / Year / Serial No.	PIR : Page 7/7
6.		
7.		

<b>Section I</b>	
<b>DIO/ District Nodal Person (Officer forwarding this report)</b>	
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 / Email: [aefiindia@gmail.com](mailto:aefiindia@gmail.com))**

**Important Laboratory Addresses:**

Send Vaccines and Diluents to	Send syringes and needles to	Send Biological specimens to
CDL Kasauli	CDL Kolkata	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	The Director, National Institute of Virology, Sus Road campus, Pashan Pune 411 021 Maharashtra Kind Attn : Dr V.P. Bondre, Scientist C, Japanese Encephalitis
Email : <a href="mailto:ncdkasauli@bsai.in">ncdkasauli@bsai.in</a>	Email: <a href="mailto:cdlkol@gmail.com">cdlkol@gmail.com</a>	Email: <a href="mailto:acm1750@rediffmail.com">acm1750@rediffmail.com</a> , <a href="mailto:vpbondre@gmail.com">vpbondre@gmail.com</a>
Phone: 0179-2272046 0179-2272060	Phone: 033-22299021 033-22870513	Tel: 020-26002290, 020-26006390
Fax: 0179-2272049 0179-2272016	Fax : 033-222 99380 033-222 99541	Fax: 020-26122669, 020-26871895

**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*

Form 10				
<b>Section A</b>				
<b>DETAILED INVESTIGATION REPORT (DIR)</b>				
(To be reported by district AEFI committee to State & GoI within 90 days of filling FIR)				
<b>(Only for Serious Adverse Events Following Immunization - Death / Hospitalized / Cluster / Disability)</b>				
DIO to fill page 1 to 4 and 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 College/ Other specify _____				
Site Address:				
Name of Reporting Officer :	Date of filing this 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	Age (in months)			
Father's Name	Sex			
Mother's Name	Male Female			
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	Time of Vaccination			
Date of Onset	Time of Onset			
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			
Date of Post Mortem	Time of Post Mortem			
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 (if sent for testing)		Yes / No			
9.	Any other document relevant to case		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 (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

Patient Name

Case Id Number IND (AEFI) / State Code / District 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

D	D	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---

**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 this 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.	Doctor's prescription/treatment record for AEFI	Yes / No	
7.	Doctor's prescription/treatment record for other illness	Yes / No	
8.	Laboratory result of vaccine (if sent for testing)	Yes / No	
9.	Laboratory result of syringes/other drugs (if sent for testing)	Yes / No	
10.	Any other document relevant to case	Yes / No	If Yes, specify & attach report

**Conclusion of State AEFI committee on causality**

Probable underlying cause of the adverse event:

Type of Adverse Event suspected based on 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 State AEFI Committee members who conducted the causality assessment			
Name	Designation	Phone #	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			

Date of review of this case	D	D	M	M	Y	Y	Y	Y	Date of submission of report to GoI								
-----------------------------	---	---	---	---	---	---	---	---	-------------------------------------	--	--	--	--	--	--	--	--

*\*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 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 (UIP),  
Immunization division of Govt. of India, MOHFW, Nirman Bhawan,  
New Delhi – 110108.  
(Fax No. – 011 23062728. or Email : [aefiindia@gmail.com](mailto:aefiindia@gmail.com))**

Section C		For use at National Level (Office of Assistant Commissioner- UIP)						
Date of receipt of DIR from District		D	D	M	M	Y	Y	Y
Date of receipt of DIR from State (with Causality assessment report)		D	D	M	M	Y	Y	Y

<b>FORM 11</b>		<b>AEFI – LABORATORY REQUESTION FORM (LRF)</b> (To be completed by Drug Inspector/DIO. LRF should be accompanied with specimens) (For Serious Adverse Events Following Immunization)														
AEFI category (Encircle): <b>Death / Hospitalized / Cluster / Disability</b>																
<b>State</b>						<b>Case ID</b>	<b>IND (AEFI) /</b>		<b>State Code</b>	/	<b>District Code</b>	/	<b>Year</b>	/	<b>Serial No.</b>	
<b>District</b>																
<b>Block</b>																
Name of Drug Inspector/DIO:								Date of filling LRF :								
Designation:								Mobile No.:								
Land Line (with STD Code) :								Fax No.:								
<b>Case Name</b>																
<b>Date of Birth</b>																
	D	D	M	M	Y	Y	Y	Y		<b>Age (in months)</b>				<b>Sex</b>	Male	Female
<b>Complete Address of the Case with landmarks (Street name, house number, village, block, Tehsil, PIN No., Telephone No. etc.)</b>																
<b>P</b>	<b>I</b>	<b>N</b>	<b>-</b>							<b>P</b>	<b>H</b>	<b>O</b>	<b>N</b>	<b>E</b>	<b>-</b>	
<b>Date of vaccination</b>										<b>Date of Onset</b>						
		D	D	M	M	Y	Y	Y	Y			D	D	M	M	Y
<b>Date of collection of specimen</b>										<b>Time of collection of specimen</b>						
		D	D	M	M	Y	Y	Y	Y			H	H	M	M	( AM PM )

**1. Precise description of samples:****a) For vaccine/diluents specimens: (to be transported in reverse cold chain)**

Mention vaccine/diluent	Quantity Sent	Name of Manufacturer (in BLOCK Letters)	Batch No.	Manufacturing Date	Expiry Date

**b) For logistics specimens: (AD, Reconstitution, Disposable syringes)**

Mention Logistics	Quantity Sent	Name of Manufacturer (in BLOCK Letters)	Batch No.	Manufacturing Date	Expiry Date

**c) For Biological product specimen: (CSF, Blood, Urine, etc)**

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Name of AEFI Case:	Case ID	IND (AEFI) /	State Code /	District Code /	Year /	Serial No.
--------------------	---------	--------------	--------------	-----------------	--------	------------

2. Test requested:

3. Preliminary clinical diagnosis (working hypotheses) of district AEFI committee:

4. Name & complete address of officials to whom laboratory results should be sent:

Send to	Complete address	Phone/Fax	Mobile	Email-ID
State Drug Controller				
State Cold Chain Officer				
State EPI Officer				
District Immunization Officer (DIO)				
Others (specify)				

**To be completed by lab officials after receiving the specimen**

Date of receipt of specimen at laboratory	D	D	M	M	Y	Y	Y	Y
Name of person receiving specimen(s) at laboratory								
Condition of specimen upon receipt at lab ( <i>encircle</i> )	Good*		Poor		Unknown			
Comments by pathologist, virologist or bacteriologist:								
Date specimen results sent from this lab	D	D	M	M	Y	Y	Y	Y
Name of laboratory professional								
Signature								
Landline No. :	Fax No.:			Email Id:				

\* Criteria for "good" condition: Samples sent as per AEFI guidelines.

## Form 12: AEFI Line Listing Format: JE Vaccination Campaign 200

[illegible]

# Form 13: Supervisor's Checklist

## JE Vaccination Campaign 20\_\_

Name of the Block/Planning Unit: -----

Date: -----

Name & Designation of the supervisor: -----

Day 1/2/3/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20

Respond with appropriate responses or Y/N		Site 1	Site 2	Site 3	Site 4	Site 5
Observe	Name of the vaccination site and time of the visit					
	Type of site (Urban ward (U) / Rural area (R) / Educational Institution(E) / Hard-to-reach (H)					
	Is this site as per microplan?					
	Are the vaccinators present as per the micro plan?					
	Are the other team members present as per the micro plan?					
	Does the vaccination site have visible IEC (Banners/Posters)?					
	Are team members managing the crowd well?					
	Vaccine and diluents are stored in vaccine carrier (VC with 4 ice packs)					
	VVM being checked before reconstitution?					
	Is the ANM writing the time of reconstitution is noted on the label of the vial					
	Reconstituted vial is kept on 1 ice pack removed from the vaccine carrier					
	Only one vial is reconstituted at a time?					
	Whole of diluent is used for reconstituting a vial?					
	Are the vaccinators keeping multiple pre-filled syringes?					
	Are the vaccinator's asking the beneficiaries about medical history for conditions contraindicated for JE vaccine*					
	Vaccinators administering the vaccine through Subcutaneous route?					
	Vaccinators administering the vaccine to the left arm beneath the BCG scar?					
	Is the ANM keeping the sterile part of the syringe untouched during reconstitution, drawing vaccine and administering vaccine?					
	Tallying is done correctly immediately after vaccinating each child					
	Used syringes are not recapped?					
Used syringes are being cut using hub cutter immediately after use?						
Are the vaccination cards and the counterfoils being filled up for the beneficiaries?						
Interview ANM/s	How was vaccine distributed for the session sites? 1>AVD 2> Supervisor 3> ANM- write the appropriate responses no. In the column					
	Does the vaccination site have all necessary logistics?					
	Is a functional hub cutter available at session site?					
	Are AEFI reporting form and investigation form present at the site?					

	Do the Vaccinators know what to do in case of a serious AEFI (primary care, referral and reporting)?					
	Whether social mobilization is being done by house visits to invite beneficiaries?					
Verify	Are adequate JE vaccine vials are present at the session site [Adequate = (no. of target beneficiaries x 1.1)/5]					
	Are adequate AD syringe (0.5 ml) is present at the session site [Adequate = no. of target beneficiaries x 1.1]					
	Does the number of AD syringes used coincide with the number of beneficiaries immunized in the tally sheet?					
	Are any Ice packs inside the vaccine carrier completely melted? Write the appropriate response as 1/2/3/4					
	Is the VVM (vaccine vial monitor) in usable stage?					
	Are adequate Reconstitution syringes is present at the site [Adequate = # of JE vaccine vials supplied]					
	Are JE vaccine and diluents are made by the same manufacturer?					
	Are all the JE vaccines, diluents and syringes within date of expiry?					
	Do the number of vials used and beneficiaries vaccinated as per tally sheet match reasonably?					

Name of Supervisor

Signature Of Supervisor

## COMMENTS AND OBSERVATIONS

Supervisor should visit the area where campaign was done on previous day. S/he should survey at least 20 children in households across the village / urban ward (including areas which are isolated or on the border of the ward/sub-block or on the farthest

Name of Sites visited		Site 1	Site 2	Site 3	Site 4	Site 5	Total
a	No. of Sites Visited						
b	Number of 1-15 year old children in those households						
c	Number of children found not vaccinated in campaign						
d	Percent of unvaccinated children (c/b x 100)						

If 1 - 3 children (out of 20) are found 'missed' (un-immunized) at a site, request the guardians to take their children to the nearest site where vaccination is going on today.  
If 4 or more children (out of 20) are found un-immunized at a site, plan for a repeat immunization activity in the area

## Form 14 JE Vaccination Campaign Monitoring Format

**Name of Monitor:** \_\_\_\_\_ **Designation:** \_\_\_\_\_ **Organization** \_\_\_\_\_

**District:** \_\_\_\_\_ **Block/ Urban Planning Unit:** \_\_\_\_\_ **Subcentre:** \_\_\_\_\_

**Name of vaccination site:** \_\_\_\_\_ **Type: School / SC / AWC / Others (Pl specify)** \_\_\_\_\_

**Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_ **Time of visit:** \_\_\_\_:\_\_\_\_ AM/ PM

At Vaccine Distribution Point (Observe and Enquire)				
1	Is a copy of the campaign microplan available?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
2	Is the vaccine stored at correct temperature of 2 to 8 0 C in ILR?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
3	Whether proper method of freezing ice pack s is being followed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
4	Drugs for AEFI management are available in the facility?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
5	Is waste disposable pit present?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
6	Is the collected wastes are kept in a secure place?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
At the Session Site (Observe and Enquire)				
1	Whether the session is being held as per Microplan	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
2	Are Team members present at vaccination site as per microplan - <input type="checkbox"/> ANM1 <input type="checkbox"/> ANM 2 <input type="checkbox"/> ASHA <input type="checkbox"/> AWW <input type="checkbox"/> Teacher/Volunteer			
3	Are adequate quantities of the following items available?	<input type="checkbox"/> Poster	<input type="checkbox"/> Banner	<input type="checkbox"/> Others
a.	Immunization Card <input type="checkbox"/> Yes <input type="checkbox"/> No	b. JE Vaccine Vials and equal no. of JE diluents	<input type="checkbox"/> Yes <input type="checkbox"/> No	
c.	0.5 ml AD Syringe <input type="checkbox"/> Yes <input type="checkbox"/> No	d. 5 ml Reconstitution syringes	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4	Are the following logistics available?			
a.	Cotton <input type="checkbox"/> Yes <input type="checkbox"/> No	b. Clean Water <input type="checkbox"/> Yes <input type="checkbox"/> No	c. Hub Cutters <input type="checkbox"/> Yes <input type="checkbox"/> No	d. Red & Black bags <input type="checkbox"/> Yes <input type="checkbox"/> No
5	Are emergency kits and emergency phone numbers available?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
6	Are the vaccinators screening beneficiaries for contraindications	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
7	Vaccinator Checking the VVM whether usable?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
8	Vaccinator using sterile 5ml disposable syringe for reconstitution of JE vaccine?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
9	Vaccinator pre-Filling multiple AD syringes at the same time?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
10	Vaccinator using new sterile AD syringe for administering the JE vaccine each time?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
11	Vaccinator administering correct dose at correct site	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
12	Vaccinator writing the time of reconstitution on the vaccine vial	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
13	Does the vaccinator know for how long the vaccine can be used after reconstitution?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
14	Is vaccination card / Counter foil being filled for each beneficiaries	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
15	Are the numbers of filled cards matching with consumed doses?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
16	Vaccinator making beneficiaries wait for ½ hour following vaccination for observation?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
17	Using Hub cutters to cut the hub of the needles after vaccinating?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
18	Are the vaccinators aware that used syringes need to be sent back to the PHC/CHC for disposal?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
19	Do vaccinators know what to do in case of an AEFI?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
20	How did the beneficiary come to know about the campaign?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
(Interview 5respondents at each site & write the number for each respondent)				
1. Drum beating 2. Miking 3. Radio/ TV Newspaper				
4. Poster/ Banner 5. JE Hand Bill 6. School Teacher/Student 7. Other				

\_\_\_\_\_  
Signature of the Monitor

**Form 15: State Daily Reporting Format: JE Vaccination Campaign 20\_\_**

## Japanese Encephalitis Vaccination Campaign State Daily Coverage Compilation Form

State: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Day of Activity: 1/2/3/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20

[illegible]

**Compiled Report till Date**

	1 to 5 years		5-10 years		10 - 15 years		Total		Grand total (M+F)	Vaccine Vials			AD Syringes			Disposable Syringes		
	M	F	M	F	M	F	M	F		Received	Used	Balance	Received	Used	Balance	Received	Used	Balance
(A) Today's Cumulative Coverage for State																		
(B) Cumulative Data till Previous Day for State (above Total)																		
<b>(C) Cumulative Data till Date</b> (Today's Coverage + Cumulative Data till Previous day for State) (C=A+B)																		

SEPIO

State JE Program Officer

**Note: Reporting formats and IEC material can be printed in the local language.**

## Form16. JE Vaccination Campaign- Rapid Convenience Assessment

Name of the Observer: \_\_\_\_\_ Designation: \_\_\_\_\_  
 Organization: \_\_\_\_\_  
 Date of Monitoring: \_\_\_\_\_ Date of Activity: \_\_\_\_\_  
 State: \_\_\_\_\_ District: \_\_\_\_\_ Block: \_\_\_\_\_  
 Village/Mohalla: \_\_\_\_\_  
 Area: Urban/Rural H2R/High-risk population: Yes/No \_\_\_\_\_

*National or Independent Observers are expected to conduct as many RCAs as possible (at least one) daily. The assessment should be conducted only in the areas where campaign sessions have already taken place. Try to identify and focus on missed communities, especially in isolated areas at the farthest point from the vaccination site which should include socially segregated groups, street children, working children in small enterprises or markets, etc. Start in a central location and to decide where to start from, toss a coin to pick a direction at random. Begin with the first house facing you. Identify and tally 20 target-aged children in 20 households. If a household has more than one eligible child, include only one randomly selected child from each household. To do this, list the eligible children on the back of the form, assign each child a number (1, 2, 3, etc.), and use the first number of the serial number on a money bill to select and record only one child. You may have to visit more than 20 houses if any of the houses does not have any children. If any children were unvaccinated, send them to the nearest vaccination site that is open on that day or to the fixed site of that area. If 2 or 3 children are found unvaccinated, inform the supervisor/authority to motivate and mobilize all missed children to visit nearest campaign or routine immunization session site. If 4 or more children are found un-immunized, the vaccination team should revisit the area to immunize all missed children. If any AEFI is noticed, direct the guardian to the nearest health facility/AEFI management centre.*

**Mark the following questions and tick accordingly in the appropriate column:**

*I. Did the child receive JE vaccine during this campaign? If yes, tick under RECEIVED column and if No, then tick under MISSED column and write name & address on the back side of this page.*

*Put serial number of AEFI in the boxes of REPORTED AEFI column:*

**II. AEFI- Did the child has any AEFI after vaccination? Write the following code numbers: 1 Injection site abscess; 2 Any condition required seeking service of a doctor or hospital; 3 Any condition required hospitalization; 4 Death; 5 Others (explain on the opposite side)**

**Question: (if child was unvaccinated): "Why was the child not vaccinated during the campaign?"**

Put a tick against the most important reason by guardians/ caregivers the missed children give for not vaccinating their children with JE vaccine																				Total
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1. Children received JE vaccination during the campaign																				
2. Children who have missed JE vaccination during the campaign																				
3. Children with AEFI with JE vaccine																				
1. Parents didn't know about the campaign																				
2. Parents didn't know about the place or date of the campaign																				
3. Parents didn't think that the campaign was important																				
4. The child was sick																				
5. There was no vaccine at the session site																				
6. There was no vaccinator at the session site (check whether she/he went to the vaccination site on the scheduled date or not)																				
7. Fear of Injection																				
8. Fear of AEFI																				
9. Very long queue																				
10. Travelling																				
11. Others																				

**Any other Comments:**

# Form 17 JE Vaccination Campaign- 20\_\_

## Beneficiary Due List

District  
Subcentre  
Village/ Urban Area

Block

Name of ANM:  
Name of ASHA/ AWW:

PHC/UHC

Sno	Father's Name	Name of Beneficiary	Age	Sex (M/F)	School Going (Y/N)
1					
2					
3					
4					
5					
6					
7					
8					
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50					



## **Appendix H**

### **States of India Reporting AES and JE Cases**

1. Andhra Pradesh
2. Arunachal Pradesh
3. Assam
4. Bihar
5. Delhi
6. Haryana
7. Goa
8. Jharkhand
9. Karnataka
10. Kerala
11. Maharashtra
12. Manipur
13. Meghalaya
14. Nagaland
15. Tamil Nadu
16. Uttarakhand
17. Uttar Pradesh
18. West Bengal

**Appendix I**  
**List existing JE Sentinel Sites**

Sl. No.	Name of the States	No. of Sites	Year of Establishment	Name of Sentinel sites/ Institutes
1	Andhra Pradesh	6	2007-08	1. Medical College, Kurnool
				2. Veterinary Biological Research Institute, Hyderabad
				3. Govt. Medical college, Guntoor
				4. MGM Hospital, Warangal
				5. Institute of Preventive Medical , Hyderabad
				6. King George Hospital Andhra Medical College, Vishakhapatnam
2	Assam	9	2007-08	1. Assam Medical College, Dibrugarh
				2. Sivsagar Civil Hospital , Sivsagar
				3. Jorhat Civil Hospital, Jorhat
				4. Lakhimpur Civil Hospital, Lakhimpur
				5. GolaGhat Civil Hospital (IDSP), Golaghat
				6. Guwahati Medical college, Guwahati
				7. Baptil Mission Hospital, Tezpur
				8. Barpeta Medical College, Barpeta
				9. Silchar Medical College, Silchar, Cachar
3	Bihar	3	2007-08	1. Patna Medical college & Hospital, Patna
				2. Sri Krishana Medical College & Hospital Muzaffarpur
				3. Anugreh Narain Magadh Medical Hospital, Gaya
4	Delhi	11	2011-12	1. Babu Jagivan Ram Hospital, Jahangirpuri
				2. Dr. Bheem Rao Ambedkar Hospital, Rohini
				3. Maharishi Valmiki Hospital, Bawana
				4. Lok Nayak Hospital, Delhi Gate
				5. GTB Hospital, Dilshad Garden
				6. Chacha Nehru Bal Chikitsalaya, Shahadara
				7. Lal Bahadur Shashtri Hospital, Mayur Vihar
				8. Hindo Rao Hospital, Bara Hindu Rao
				9. Deen Dayal Upadhaya Hospital, Hari Nagar
				10.Pt. Madam Mohan Malviya Hospital , Malviya Nagar
				11.Sanjay Gandhi Memorial Hospital, Mangol Puri
5	Goa	3	2007-08	1. Goa Medical College, Goa
				2. North Goa District Hospital, Goa
				3. South Goa District Hospital, Goa
6	Haryana	3	2007-08	1. General Hospital Sector-6, Panchkula
				2. State Laboratory, Karnal
				3. Civil Hospital, Ambala City
7	Jharkhand	3	2011-12	1. Rajendra Institute of Medical Science (RIMS), Ranchi
				2. MGM Hospital, Jamshedpur
				3. Patliputra Medical college Hospital, Dhanbad

8	Chandigarh	1	2007-08	1. PGI Chandigarh,
9	Karnataka	5	2007-08	1. VIMS, Bellary
				2. District Surveillance Unit, Kollar
				3. Public Health Institute, Bangalore
				4. Karnataka Institute of Medical Science, Hubli
				5. Manipal Institute of Virus Research, Manipal
10	Maharashtra	5	2007-08	1. District Hospital, Bhandara
				2. District Hospital, Gondia
				3. Indira Gandhi Medical College, Nagpur
				4. District Hospital, Wardha
				5. District Hospital, Gadchiroli
11	Manipur	1	2007-08	1. J.N. Hospital Poompat, Imphal
12	Nagaland	1	2007-08	Civil Hospital, Dimapur
13	Tamil Nadu	5	2007-08	1. King Institute of Preventive Medicine, Guindy, Chennai.
				2. Madurai Medical College, Madurai.
				3. District Hospital, Thanjavur
				4. KAP Viswanathan Medical College, Annal Gandhi Memorial Government Hospital, Puthur, Trichy.
				5. Government Medical College, Villupuram.
14	West Bengal	3	2007-08	School of Tropical Medicine, Kolkata
				Burdwan Medical College, Burdwan
				North Bengal Medical College hospital, Darjeeling
15	Kerala	1	2007-08	1. District Hospital, Kottayam
16	Uttar Pradesh	17	2007-08	1. District Hospital, Siddharthnagar
				2. District Hospital, Maharajganj
				3. District Hospital, Kheri
				4. District Hospital, Basti
				5. District Hospital, S. Kabir Nagar
				6. District Hospital, Saharanpur
				7. District Hospital, Gorakhpur
				8. BRD Medical College, Gorakhpur
				9. District Hospital, Bahraich
				10. District Hospital, Kushinagar
				11. District Hospital, Gonda
				12. District Hospital, Balrampur
				13. District Hospital, Sultanpur
				14. District Hospital, Deoria
				15. KG Medical College, Lucknow
				16. District Hospital, Raibareli
				17. Regional Laboratory Swasthaya Bhawan, Lucknow
	Total	77		

## **Appendix J**

### **List of Apex Laboratories**

1. National Institute of Mental Health & Neuro-Sciences,Bangalore.
2. Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow.
3. Post Graduate Institute of Medical Sciences, Chandigarh.
4. All India Institute of Medical Sciences, Delhi.
5. National Institute of Cholera & Enteric Diseases,Kolkatta.
6. Regional Medical Research Centre (ICMR),Dibrugarh.
7. Kings Institute of Preventive Medicine, Chennai.8
8. Institute of Preventive Medicine, Hyderabad.
9. National Institute of communicable Diseases, Delhi
10. National Institute of Virology, Pune
11. B.J. Medical College, Ahmedabad, Gujrat
12. State Institute of Virology, Allepy, Kerala

## Appendix K

### JE Vaccination Campaigns 2006 - 2010

#### List of States/ Districts which have completed JE vaccination Campaigns

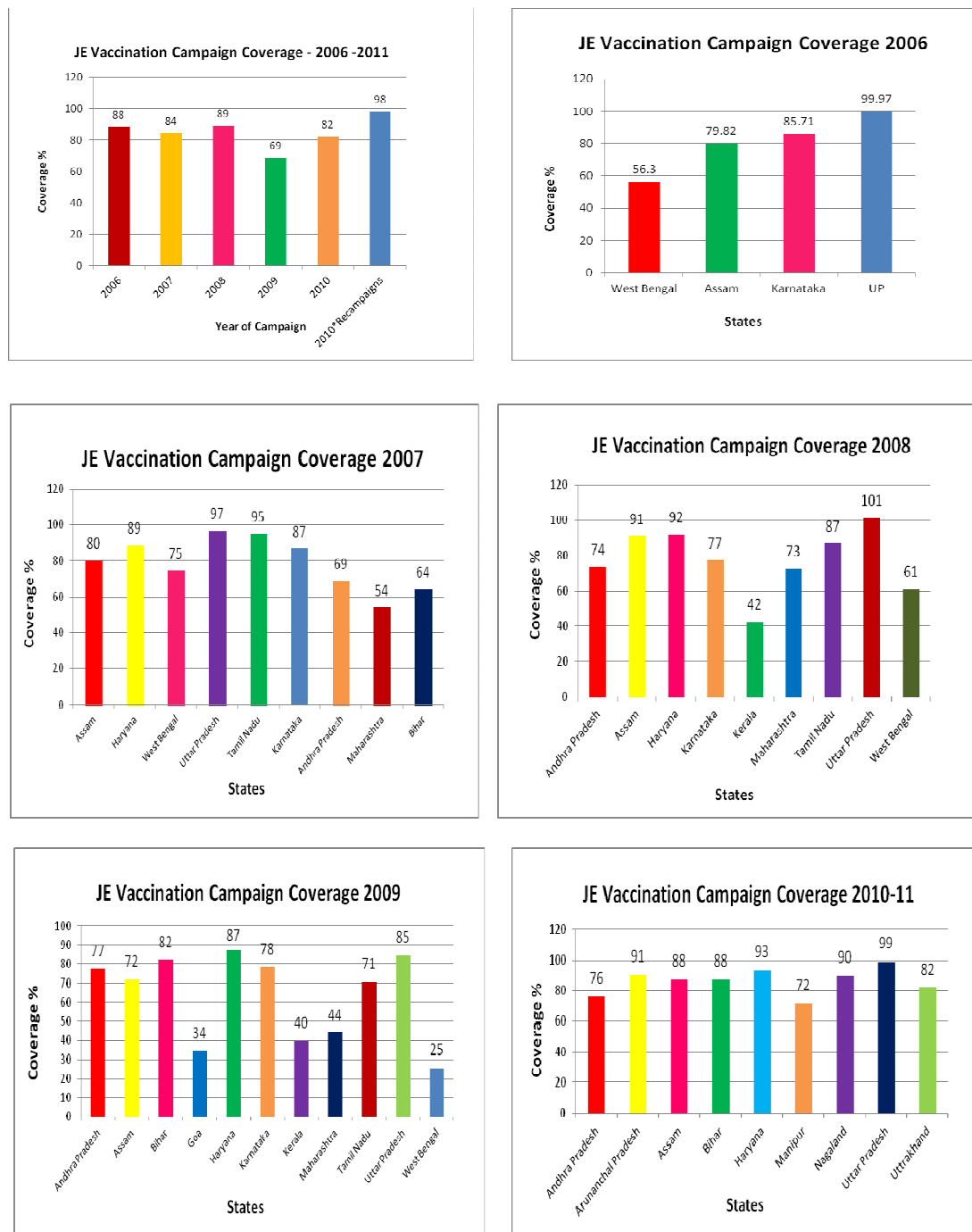
S. No	State	Name of Districts
1	Andhra Pradesh (10 Districts)	Warangal, Kurnool, Adilabad, Nellore, Medak, Krishna, Mehbub Nagar, Nizamabad, Khammam and Nalgonda
2	Arunanchal Pradesh (1 District)	Lohit
3	Assam (11 Districts)	Dibrugarh, Sivsagar, Golaghat, Jorhat, Dhemaji, Tinsukia, Kamrup, Lakimpur, Sonitpur, Nagaon, Udalguri
7	Karnataka (8 Districts)	Bellary, Kolar, Chikballapur, Raichur, Koppal, Mandaya, Bijapur, Dharwar
8	Kerala (2 Districts)	Allepy, Thiruvananthapuram
9	Maharashtra (8 Districts)	Amravati (Dist & Corp), Bhandara, Nagpur (Rural), Yeotmal, Gadchiroli, Washim, Beed, Latur
10	Manipur (5 Districts)	Imphal East, Imphal West, Thoubal, Bishnupur, Chandel
11	Nagaland (2 Districts)	Dimapur, Mokongchung
12	Tamil Nadu (10 Districts)	Kaddalore, Villupuram, Virudh Nagar, Madurai, Perambalur, Thiruvarur, Trichy, Tanjavur, Thiruvanamalai, Chayyar
13	Uttar Pradesh (36 districts)	Lakhimpur Kheri, Deoria, Gorakhpur, Kushinagar, Maharajganj, Sant Kabir Nagar, Siddharth Nagar, Ambedkar Nagar, Balrampur, Barabanki, Bahraich, Gonda, Mau, Rai Bareilly, Sharanpur, Shravasti, Sitapur, Basti, Azamgarh, Ballia, Bareilly, Faizabad, Hardoi, Luckow, CSM Nagar, Prabudhnagar
14	West Bengal (5 Districts)	Burdwan, Birbhum, West Midnapur, Hoogly, Howrah
15	Uttrakhand	Udham Singh Nagar

#### Summary of JE vaccination coverage for 2006 – 2010

Year	No. of Districts covered	Total Population	Target population- 1-15 years	Total JE vaccination campaign coverage	JE vaccination campaign coverage %
2006	11	29420139	10533944	9310031	88.38
2007	27	64088203	21149107	17842943	84.37
2008	22	58294561	19237205	17104170	88.91
2009	30	80676673	26623302	18258366	68.58
2010	19	28640098	9451232	7740725	81.9
2010*R	9	23211927	7659936	7495380	97.9
<b>Total</b>	<b>118</b>	<b>284331601</b>	<b>94654726</b>	<b>77751615</b>	<b>82.14</b>

2010\*R-Re-campaigns

Graph 3.State wise JE vaccination coverage reported from 2006 - 2012



## Appendix L

### JE vaccines available in the Market or under development

Vaccine type	Strain & substrate	Producer	Remarks on licensure & marketing
<b>Inactivated, Purified</b>	Nakayama strain <i>Mouse-brain</i>	Biken – Japan Green Cross – Korea Vabiotech - Vietnam GPO - Thailand	International, Local & regional, Local, Local & regional
	Beijing 1 strain <i>Mouse-brain</i>	Kaketsuken, Biken, Kitasota – Japan	Production stopped, bulk storage.
	P3 strain <i>PHK or Vero cells</i>	Several – China	Domestic only.
<b>Live, attenuated</b>	SA14-14-2 strain on <i>PHK</i>	<u>Chengdu</u> - China	Marketed for both domestic use and for use in Nepal, S.Korea, Sri Lanka and India. Prequalification status: Product Summary File under preparation.
	SA14-14-2 strain on <i>PHK</i>	Wuhan, Lanzhou – China	Marketed for domestic use in China only.
<b>Under development</b>	SA 14-14-2 strain <i>Vero cells</i>	Intercell, Biological Evans – India	Under various stages of development and licensing.
	Beijing 1 strain <i>Vero cells</i>	Biken – Japan Kaketsuken - Japan	Submitted for licensing for paediatric use locally in Japan. International marketing plans not known.
	SA 14-14-2 pr M&E in 17D YF backbone	Sinophy Pasteur, Bharat Biotech, Pancea – India	Under various stages of development and licensing,

## Appendix M

Prototype for Calculating Budget- District Information for JE Vaccination Campaigns																																							
S. No.	State						District	Total Population	Target Population (1-15 years)	Population of 1-2 year olds	Population 1-15 Years	Total Blocks	No. of PHCs	New PHC	No of CHCs	No. of Sub Centres	Total Villages	ANMs	ASHAs	AWWs	AWC	Staff Nurse	LHVs	Total No. of Teams (Note: 2 Vaccinators/ team)	No. of team days	Total no. of Supervisors	Total no. of Medial Officers	Total no. of vehicles per block	Total no. of ILRs	Total no. of Deep Freezers	Total no. of vaccine carriers	Total no. of Ice packs	Total no. of Cold boxes						
1																																							
2																																							
3																																							
4																																							
5																																							
6																																							
7																																							



## APPENDIX N - IEC PROTOTYPES

Wall Painting - Size - 3 feet X 4 feet



Street Banner – Size- 72” X 18 ”





**सिर्फ एक बार टीका लगवाओ  
जैपेनीज़ इन्सीफलाइट्स  
से जान बचाओ**

**1 साल से 15 साल तक के सभी बच्चों के लिए ज़रूरी**

आपके बच्चों के बचाव का ये मौका न गुंके  
**अप्रैल 4 से अप्रैल 11 तक**  
**जैपेनीज़  
इन्सीफलाइट्स  
टीकाकरण**  
आपके गाँव में








## मच्छरों से फैलने वाली बीमारियों की रोकथाम के लिए।

- बिस्तर पर मच्छरदानी का उपयोग करें।
- रहने वाले कमरे में मच्छर भगाने वाली अगरबत्ती या दूसरी दवाइयों का उपयोग करें।
- पूरी बाजू की कमीज और पैन्ट पहनिए ताकि शरीर ढका रहे और मच्छर काटने से होने वाली बीमारी रोक दी जा सके।
- जहाँ कहीं भी पानी इकट्ठा होता हो, उसमें मिट्टी भर कर मच्छर प्रजनन रोक जा सकता है।
- पानी के बर्तन या टंकी को ढक कर रखिए।
- घर के आस-पास झाड़ियाँ साफ कीजिए और परिवेश को साफ रखिए।
- कोशिश करें कि सुअर और अन्य मवेशियाँ तथा आपके निवास स्थान, साथ-साथ या बहुत करीब न हों।
- अगर आपके परिवार या पड़ोस में किसी बच्चे को तेज़ बुखार है तो कृपया उसे नजदीक के अस्पताल में ले जाएँ जहाँ दाखिले और उपचार की सुविधा हो।
- बीमारी का शुरु में पता चल जाने से और उपचार जल्दी शुरु हो जाने से बच्चे की जान बचाई जा सकती है।



### सिर्फ एक बार टीका लगवाओ जैपेनीज़ इन्सीफ्लाइट्स से जान बचाओ

**1 साल से 15 साल तक के सभी बच्चों के लिए जरूरी**

जैपेनीज़ इन्सीफ्लाइट्स-एक जानलेवा बीमारी

नहीं होने देगे किसी को इस बारी

सिर्फ एक बार टीका लगवाकर


निभाइए माता-पिता होने की जिम्मेदारी



A-4 Size - Back


### जैपेनीज़ इन्सीफ्लाइट्स टीकाकरण आपके गाँव में

कित एक नया टीकाकरण अभियान क्या सब बीमारियाँ हमें हो होती हैं?





मालव?


अरे माँ जैपेनीज़ इन्सीफ्लाइट्स कोई ऐसी-वैसी चीज़ नहीं है। 1 साल से 15 साल तक के बच्चों को होने वाली जानलेवा बीमारी है ये।




### जैपेनीज़ इन्सीफ्लाइट्स टीकाकरण आपके गाँव में


वर्षाकाल के समय और उसके बाद जमे हुए पानी में पल रहे संक्रमित मच्छरों के मनुष्य को काटने से जैपेनीज़ इन्सीफ्लाइट्स हो सकता है। जैपेनीज़ इन्सीफ्लाइट्स से घसित बच्चे को तेज़ बुखार, सिरदर्द, गर्दन में अकड़न, उबसीनाला, बेहोशी, झटके, मरोड़, लकड़ा और बाद में मृत्यु हो सकती है। इस बीमारी के शिकार एक तिहाई बच्चों को आजीवन मानसिक और शारीरिक अंगतता भी हो सकती है।





तो इससे कोई बचाव?

इससे एक असान बचाव है जैपेनीज़ इन्सीफ्लाइट्स का टीका जो 1 साल से 15 साल तक के सभी बच्चों को लगवाना जरूरी है। अपने बच्चों को इस जानलेवा बीमारी से बचाने का ये मौका न चूके। अब बच्चों के लिए हमारी भी तो कोई जिम्मेदारी है ना।





**माता-पिता होने की जिम्मेदारी निभाइए  
1 साल से 15 साल तक के अपने बच्चों को  
जैपेनीज़ इन्सीफलाइटिस से बचाइए**



**यूनिसेफ द्वारा स्वास्थ्य एवं परिवार  
कल्याण मंत्रालय, भारत सरकार हेतु प्रकाशित।**

**स्वास्थ्य कार्यकर्ताओं के लिए जे0 ई0  
टीकाकरण हेतु जानकारी**



**आपके बच्चों के बचाव का ये मौका न हूके  
मौका छूट न जाए  
जैपेनीज़  
इन्सीफलाइटिस  
टीकाकरण  
आप के गाँव में**




<div style="background-color: #90ee90; padding: 5px; margin-bottom: 5px;"><b>JE जापानी इन्सेफलाइटिस क्या है ?</b></div> <p>जापानी इन्सेफलाइटिस एक गंभीर तथा मानसिक विकलांगता पैदा करने वाली बीमारी है । जापानी इन्सेफलाइटिस विषाणु द्वारा होती है ।</p> <div style="background-color: #90ee90; padding: 5px; margin-bottom: 5px;"><b>JE प्रसारण रास</b></div> <p>जापानी इन्सेफलाइटिस (JE) के विषाणु मच्छरों द्वारा फैलाया जाता है ये मच्छर असुरक्षित पानी के खेतों तथा पानी के तलाबों में रहते हैं । संक्रमण में बाद विषाणु मनुष्य के मस्तिष्क एवं रीढ़ की हड्डी (Spinal Cord) सहित, केंद्रीय नशी तंत्र में प्रवेश कर जाता है ।</p> <div style="background-color: #90ee90; padding: 5px; margin-bottom: 5px;"><b>JE के लक्षण क्या है ?</b></div> <p>शुरुआत में बच्चे जैसी बीमारी को लगाने के समय बुखार, अजीर्ण, उल्टा, लगातार मतवाला होना, दिल दर्द, जलती आंखें तथा घबराहट हो सकती है । अगले अवसर यह बीमारी 30 प्रतिशत से अधिक इन्सेफलाइटिस (एक खतरनाक संक्रमण, मस्तिष्क में सूजन पैदा करने वाला रोग ) का रूप धारण कर सकती है इस अवस्था में तेजी पक्षाघात (पैरालाइसिस) मूर्छा (कोमा), या बोल ना पाने जैसे लक्षणों से ग्रसित हो सकते हैं ।</p> <div style="background-color: #90ee90; padding: 5px; margin-bottom: 5px;"><b>JE बीमारी होने का खतरा किसको है ?</b></div> <p>एशिया के देशों तथा खेतों होने वाले क्षेत्रों में जहाँ पर JE विषाणु आम होते हैं, ऐसे क्षेत्रों में रहने वाले लोगों में संक्रमण होने का विशेष खतरा रहता है । अधिकतर क्षेत्रों में बड़े लोगों को वर्षा 1 और 15 आयु के बच्चों में इस बीमारी का अधिक खतरा होता है । फिर भी व्यक्त लोगों में भी यह संक्रमण हो सकता है । विशेष कर तब, जब गये क्षेत्र में विषाणु प्रवेश करता है ।</p> <div style="background-color: #90ee90; padding: 5px; margin-bottom: 5px;"><b>क्या JE बीमारी का इलाज है ?</b></div> <p>JE बीमारी का इलाज नहीं है । इस वाइरस के विरुद्ध एंटीबायोटिक दवाएं करगर नहीं हैं । और न ही एंटी वाइरस दवाएं खोजी जा सकती हैं । फिर भी रोगी को उचित देखभाल द्वारा मृत और विकलांगता के खतरे को कम किया जा सकता है ।</p> <div style="background-color: #90ee90; padding: 5px; margin-bottom: 5px;"><b>जापानी इन्सेफलाइटिस (JE) को कैसे रोकना जा सकता है ?</b></div> <p>टीकाकरण ही JE (मस्तिष्क ज्वर) को रोकने का सबसे अच्छा रास्ता है । मच्छरों के काटने से बचने के लिए व्यक्तिगत सुरक्षा भी जरूरी है ।</p> <div style="background-color: #90ee90; padding: 5px; margin-bottom: 5px;"><b>भारत में JE टीकाकरण</b></div> <p>जापानी इन्सेफलाइटिस को नियंत्रित करने के लिए भारत सरकार ने जे.इ. महामारी फैलने वाले देशों के संबंधित जिलों में, वार्षिक तरीके से, जे.इ. टीकाकरण का कार्यक्रम को शुरू करने और बढ़ाने का निर्णय लिया है । एल.ए. 14-14-2 टीके का प्रयोग किया जायेगा । 1-15 वर्ष आयु के समस्त बच्चों को एक टीकाकरण कार्यक्रम (भारत वैक्सीनेशन) के तहत अति, संवेदनशील जिलों में शुरू करेंगे ।</p> <div style="background-color: #90ee90; padding: 5px; margin-bottom: 5px;"><b>SA 14-14-2 JE टीका क्या है ?</b></div> <p>एल.ए. 14-14-2 टीकाकरण को जिन प्रयोग किया जाता है । इस टीके की 0.5 मिलीली मात्रा को दाहिने हाथ में खाली मांस के बाईली और बाएं हाथ के मोठे लगाया जाता है ।</p>	<div style="background-color: #90ee90; padding: 5px; margin-bottom: 5px;"><b>क्या SA 14-14-2 JE टीका सुरक्षित है ?</b></div> <p>SA 14-14-2 JE टीका सुरक्षित है तथा अधिकतर लोगों में टीका लगाने के बाद कोई खतरा इन्फेक्ट या सूजन नहीं होता ।</p> <div style="background-color: #90ee90; padding: 5px; margin-bottom: 5px;"><b>SA 14-14-2 JE टीका किसको लगाना चाहिए ?</b></div> <p>सभी बच्चे जो कि 1 से 15 साल के बीच में है टीकाकरण अभियान के दौरान JE वैक्सीन लेनी चाहिए ।</p> <div style="background-color: #90ee90; padding: 5px; margin-bottom: 5px;"><b>किन परिस्थितियों में SA 14-14-2 JE टीका नहीं लगाना चाहिए</b></div> <ul style="list-style-type: none"> <li>• किसी को पहले SA 14-14-2 JE टीका लगाने पर इसकी गंभीर प्रतिक्रिया हुई थी ।</li> <li>• टीके के किसी कम्पनेन्ट (जिनेटिन, जेन्टासाइसिन, कालामाडसिन या अन्य किसी कम्पनेन्ट के प्रति गंभीर प्रतिक्रिया होती हो ।</li> <li>• कोई व्यक्ति जो एड्स के लक्षणों या इम्यूनोसुपेसिव बीमारी से ग्रसित हो,</li> <li>• यदि महिला गर्भवती हो ।</li> <li>• यदि बुखार 38.5 डिग्री सेल्सियस से अधिक हो तो ऐसी स्थिति में टीका स्थगित कर देना चाहिए । तथा जैसे ही बुखार उतर जाये, टीका लगाने का प्रयास करना चाहिए ।</li> </ul> <div style="background-color: #90ee90; padding: 5px; margin-bottom: 5px;"><b>SA 14-14-2 JE टीका का रखरखाव</b></div> <ul style="list-style-type: none"> <li>• पाउडर के रूप में उपस्थित JE वैक्सीन 2-8 डिग्री के बीच रखें</li> <li>• वैक्सीन को 2.5 ml डिस्पोजेबल सिरिंज से वैक्स (reconstitute) करें ।</li> <li>• वैक्स (reconstituted) को वैक्सीन एक ठंडी और अंधेरी साफ कंटाइनर पर रखें और उसे सीधे सीधे सूखने को रोखनी से बचावें</li> <li>• वैक्स वैक्सीन ज्यादा से ज्यादा 2 घंटे में इस्तेमाल करें ।</li> <li>• वैक्स वैक्सीन को दोबारा फ्रीज न करें ।</li> </ul> <div style="background-color: #90ee90; padding: 5px; margin-bottom: 5px;"><b>वैक्सीन के दुष्प्रभाव</b></div> <p>जे.इ. वैक्सीन के कोई गंभीर दुष्प्रभाव नहीं है । कुछ बच्चों में अकड़न, सूजन इंजेक्शन की जगह पर हो सकते हैं । JE वैक्सीन जे.इ. बीमारी का कारण नहीं बनता ।</p> <div style="background-color: #90ee90; padding: 5px; margin-bottom: 5px;"><b>SA 14-14-2 JE टीका मुख्य निर्देश</b></div> <ul style="list-style-type: none"> <li>• एक समय पर जे.इ. वैक्सीन का एक ही सौम्य पैकाज करें और इस पैकाज वैक्सीन को 2 घंटे के अन्दर इस्तेमाल करें</li> <li>• जिस बैरियर पर JE सौम्य पैकाज है उससे बच्चे को न हटायें ।</li> <li>• अगर बच्चा टीकाकरण में अनुपस्थित है तो उसे पास के पी.एच.सी में लेकर टीका लगावें ।</li> <li>• टीकाकरण से कोई गंभीर दुष्प्रभाव की स्थिति में तुरंत Supervisor या Medical Officer को सूचित करें ।</li> </ul>
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## Notes