सत्यमेव जयते

Operational Guide Japanese Encephalitis Vaccination in India

September 2010

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Department of Family Welfare
Ministry of Health and Family Welfare
Government of India

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Abbreviations

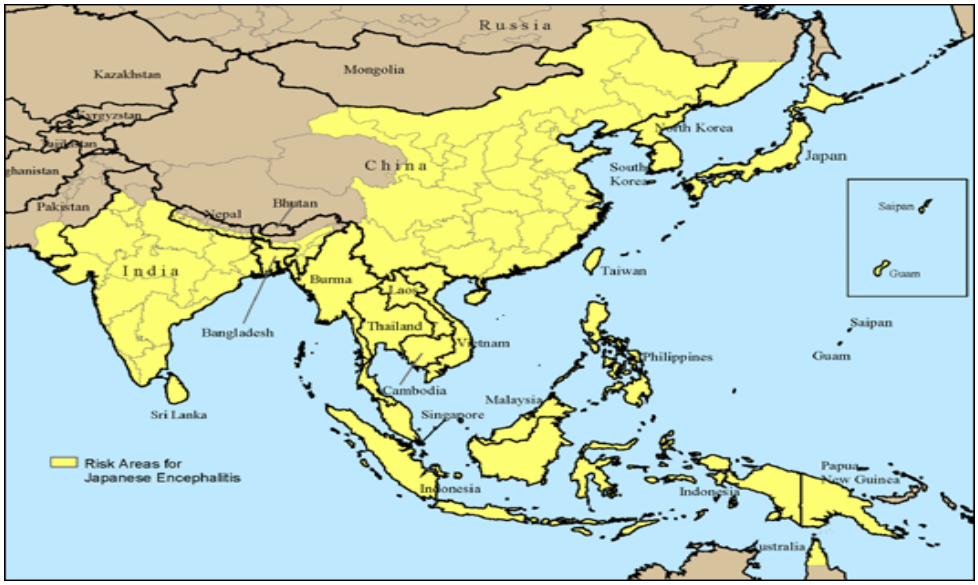
AC (UIP)	Assistant Commissioner (Universal Immunization Program)
AEFI	Adverse Event Following Immunization
AES	Acute Encephalitis Syndrome
AFP	Acute Flaccid Paralysis
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
AWW	Anganwadi Worker
BMO	Block Medical Officer
BPHC	Block PHC
CDC	Centers for Disease Control
CDL	Central Drug Laboratory
CDIBP	Chengdu Institute of Biological Products, China
CHC	Community Health Center
CDSCO	Central Drug Standard Control Organization
CHC	Community Health Centre
Commissioner FW	Commissioner Family Welfare
CMO/ CS	Chief Medical Officer/ Civil Surgeon
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 Pediatrics
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 center
PHC MO	Primary health center Medical Officer
PIR	Preliminary investigation report
RIT	Regional Investigation Team
RI	Routine Immunization
SC	Sub center
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 Procedures
WNV	West Nile virus

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

1. Background

Japanese encephalitis is the leading viral cause of Acute Encephalitis Syndrome (AES) *in Asia. The disease primarily affects children under the age of fifteen 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 19th 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 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.

Definition of Acute Encephalitis Syndrome (Source WHO)

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.*

2. The Epidemiology of Japanese Encephalitis

2.1. The JE Virus

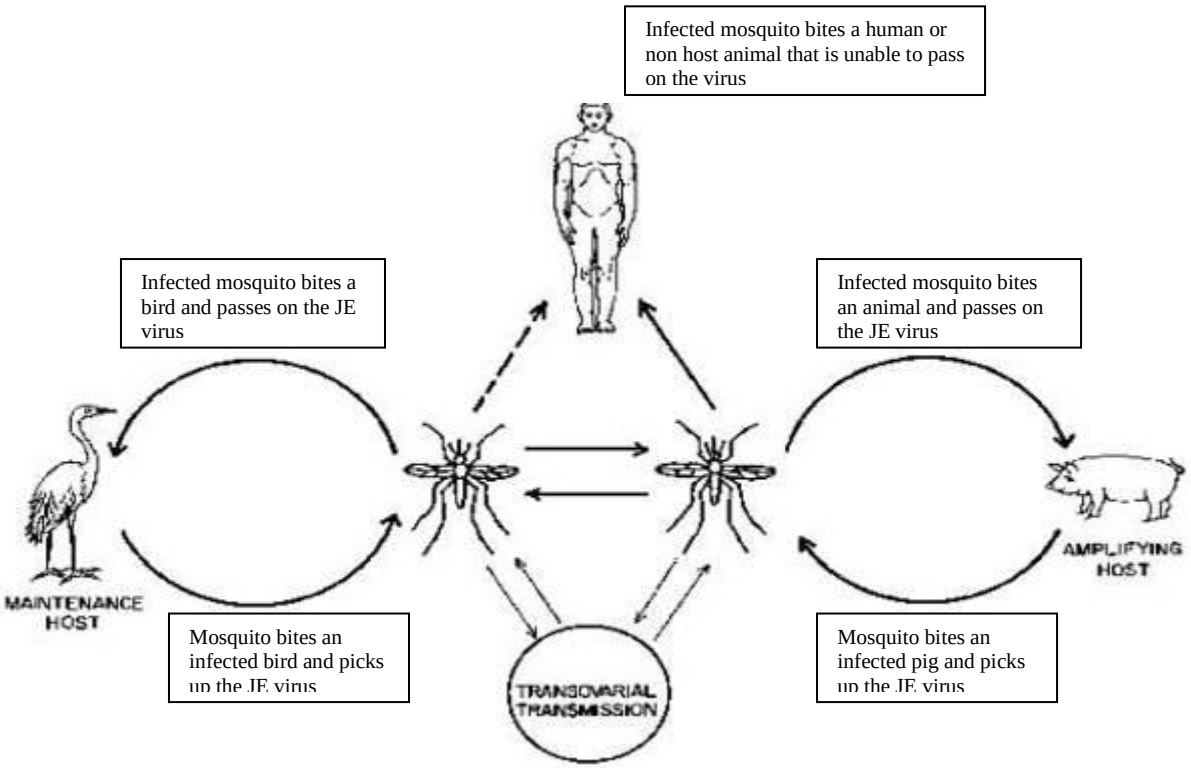
The JE virus (JEV) is a member of the genus Flaviviridae, together with the Yellow Fever virus and Dengue Virus. The JE virus belongs to the same serological group as the West Nile virus (WNV) and the St. Louis Encephalitis Virus (SLEV).

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. tritaeneorhynchus).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. Current Scenario 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. In subsequent years, outbreaks have occurred in various States and UTs in the country. The first major JE epidemic was reported from the Burdwan and Bankura districts of West Bengal in 1973 followed by another outbreak in 1976. Outbreaks have been reported from states like Uttar Pradesh, West Bengal, Assam, Andhra Pradesh, Karnataka, Bihar, Tamil Nadu, Haryana and other states through the years.

Table 1- Transmission season for the 15 states undertaken/ to be undertaken in the JE campaigns – Source NVBDCP- 8th March 2010

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

The Directorate of National Vector Borne Disease Control Programme (NVBDCP) has been monitoring the incidence of JE in the country since 1978. Though cases of JE have been reported from 26 States and UTs occasionally since 1978 repeated outbreaks have been reported only from 12 States. Till 2005, JE was reported as suspected JE, however, as per the revised guidelines prepared by NVBDCP, JE is being reported under the umbrella of Acute Encephalitis Syndrome. States which have been reporting

AES/ JE cases is attached in Annexure – H, Page 81. Table 2 below shows the highlights the case load in some of the states during last 7 years (2003–2009*).

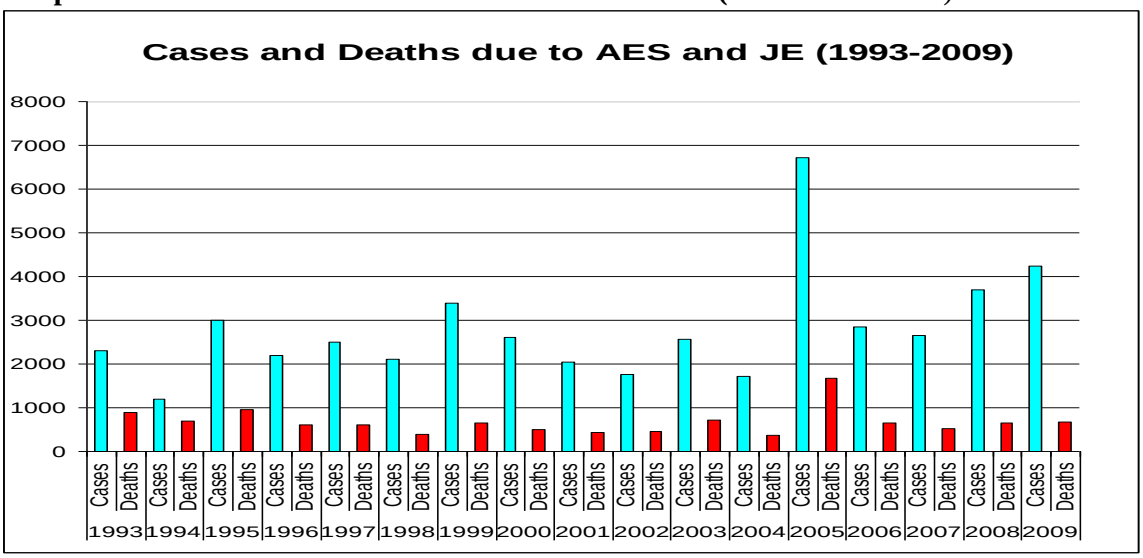
Table 2. AES and JE Cases and deaths in states during last 7 years (2003–2009*).

Sl. No.	Affected States/UTs	2003		2004		2005		2006		2007		2008		2009	
		C	D	C	D	C	D	C	D	C	D	C	D	C	D
1	Andhra Pradesh	329	183	7	3	34	0	11	0	22	0	6	0	14	0
2	Assam	109	49	235	64	145	52	392	119	424	133	319	99	462	92
3	Bihar	6	2	85	28	192	64	21	3	336	164	203	45	325	95
4	Delhi	12	5	17	0	6	0	1	0	0	0	0	0		
5	Goa	0	0	0	0	4	0	0	0	27	0	39	0	66	3
6	Haryana	104	67	37	27	46	39	2	1	32	18	13	3	12	10
7	Karnataka	226	10	181	6	122	10	73	3	32	1	3	0	246	8
8	Kerala	17	2	9	1	1	0	3	3	2	0	2	0	3	0
9	Maharashtra	475	115	22	0	51	0	1	0	0	0	24	0	1	0
10	Manipur	1	0	0	0	1	0	0	0	65	0	4	0	6	0
11	Nagaland	0	0	0	0	0	0	0	0	7	0	0	0	9	2
12	Punjab	0	0	0	0	1	0	0	0	0	0	0	0		
13	Uttrakhand											12	0		
14	Tamil Nadu	163	36	88	9	51	11	18	1	37	0	144	0	265	8
15	Uttar Pradesh	1124	237	1030	228	6061	1500	2320	528	3024	645	3012	537	3073	556
16	West Bengal	2	1	3	1	12	6	0	0	16	2	58	0		
	Total	**2568**	**707**	**1714**	**367**	**6727**	**1682**	**2842**	**658**	**4024**	**963**	**3839**	**684**	**4482**	**774**

State-wise cases and deaths due to suspected AES (as on 31.12.2009) *Source NVBDCP website: http://www.nvbdcp.gov.in/je-cd.htm* ***C=Cases, D=Deaths*** **Including 9 cases and 4 deaths from Jharkhand (Palamu and Chatra district) in year 2008. ** Including 243 cases and 41 deaths from Bihar and 10 cases and 4 deaths each from Nepal in year 2009. Data by NVBDCP and states till 31.12.2009*

The Case Fatality Rate (CFR) due to AES/ JE in India has been around 17 % with wide variations in states. Annual reported cases due to JE range between 1714 and 6727 while deaths due to JE range between 367 and 1684 (Graph 1).

Graph 1. Cases and deaths due to JE in India 1993–2009 (Source: NVBDCP)



In the past, attempts have been made in India to vaccinate children against JE. However the inadequate availability of the mouse brain derived JE vaccine has limited the campaigns to small geographical areas.

Following the sustained JE vaccination in the Perambulur district of Tamil Nadu since 1995 and in the high risk villages of Andhra Pradesh since 1999, there has been some impact in reducing the case load and the incidence of the disease in these areas.

JE Campaigns in India

Following the massive outbreak of JE in 2005 in the districts of Eastern Uttar Pradesh and the adjoining districts of Bihar, vaccination campaigns were carried out in 11 of the highest risk districts of the country in 2006, 27 districts in 2007, 22 districts in 2008 and 30 districts in 2009. Children between the age group of 1 to 15 years were vaccinated with a single dose of SA14-14-2 vaccine. Mass vaccinations will continue through 2010 to cover all the 109 endemic districts. Following the mass campaign, the vaccination will continue in the Routine Immunization (RI) Program to cover the new cohort. The summary of JE vaccination coverage for 2006 – 2009 is given below in table 2

Table 2. - Summary of JE vaccination coverage for 2006 – 2009

	Year	No. of Districts covered till date	Total Population	Target population- 1-15 years	Total JE vaccination campaign coverage	JE vaccination campaign Reported coverage %
1	2006	11	29420139	9708646	9308688	88.30%
2	2007	27	65934009	21758223	18431087	85%
3	2008	22	57772199	20040262	16881941	84.20%
4	2009*	30	45032191	27161011	17441254	64.21%
		90	**198158538**	**78668142**	**62062970**	**78.89%**

Table 3 .District wise JE vaccination coverage reported from 2006, 2007, 2008, 2009**:**

JE Vaccination Coverage 2006					
SNo.	**State**	**District**	**Target Children (1-15 yr)**	**Children Covered**	**% Coverage**
1	West Bengal	Burdwan	2190690	1229404	56.12
2	Assam	Dibrugarh	409611	370653	90.49
3	Assam	Sibsagar	372356	276487	74.25
4	Karnatka	Bellary	720517	595648	82.67
5	Uttar Pradesh	Gorakhpur	1390307	1349047	97.03
6	Uttar Pradesh	Deoria	1074219	1072683	99.86
7	Uttar Pradesh	Kushinagar	1095877	1085055	99.01
8	Uttar Pradesh	Maharajganj	776500	806996	103.93
9	Uttar Pradesh	Lakhimpur Kheri	1183481	1218364	102.95
10	Uttar Pradesh	Sidhartnagar	775934	792944	102.19
11	Uttar Pradesh	Saint Kabir Nagar	542062	511417	94.35
		Total 2006	**10531554**	**9308698**	**88.39**

JE Vaccination Coverage 2007					
1	Haryana	Karnal	464098	417751	90.01
2	Haryana	Kurukshetra	290463	244789	84.28
3	Assam	Jorhat	366242	338340	92.38
4	Assam	Golaghat	316831	293535	92.65
5	West Bengal	Birbhum	1063726	792872	74.54
6	Uttar Pradesh	Ambedkar Nagar	764068	741354	97.03
7	Uttar Pradesh	Behraich	990327	992254	100.19
8	Uttar Pradesh	Balrampur	623020	622963	99.99
9	Uttar Pradesh	Barabanki	1074154	1063815	99.04
10	Uttar Pradesh	Basti	774322	750262	96.89
11	Uttar Pradesh	Gonda	1040501	1045957	100.52
12	Uttar Pradesh	Mau	719800	691341	96.05
13	Uttar Pradesh	Raibareilly	1058987	1029154	97.18
14	Uttar Pradesh	Saharanpur	1056185	923246	87.41
15	Uttar Pradesh	Sitapur	1385606	1312326	94.71
16	Uttar Pradesh	Sravasti	331903	326485	98.37
17	Andhra Pradesh	Warangal	984176	792061	80.48
18	Maharashtra	Amravati	895167	387784	43.32
19	Maharashtra	Nagpur Rural	736728	506479	68.75
20	Maharashtra	Bhandara	381981	259748	68.00
21	Karnatka	Kolar	798392	696722	87.27
22	Karnatka	Raichur	595975	516387	86.65
23	Tamil Nadu	Villupuram	1000347	770833	77.06
24	Tamil Nadu	Virudhnagar	508861	412905	81.14
25	Tamil Nadu	Cuddalore	810812	595627	73.46
		Total 2007	**19032672**	**16524990**	**86.82**

JE Vaccination Coverage 2008					
1	Andhra Pradesh	Kurnool	1303289	979106	75.13
2	Assam	Dhemaji	212360	187772	88.42
3	Assam	Tinsukia	419965	387608	92.30
4	Haryana	Ambala	362572	345457	95.28
5	Karnataka	Koppal	425241	296730	69.78
6	Karnataka	Mandya	582414	412501	70.83
7	Kerala	Alleppy	722259	306817	42.48
8	Maharashtra	Yeotmal	879519	645011	73.34
9	Tamil Nadu	Madurai	887979	566968	63.85
10	Tamil Nadu	Perambulur	220659	167536	75.93
11	Tamil Nadu	Tiruchirapalli	865718	533426	61.62
12	Tamil Nadu	Thiruvarur	409650	252944	61.75
13	Uttar Pradesh	Azamgarh	1400000	1329471	94.96
14	Uttar Pradesh	Ballia	1067337	1040948	97.53
15	Uttar Pradesh	Bareily	1337392	1399552	104.65
16	Uttar Pradesh	Faizabad	649634	641736	98.78
17	Uttar Pradesh	Hardoi	1270372	1296593	102.06
18	Uttar Pradesh	Lucknow	1506695	1477852	98.09
19	Uttar Pradesh	Muzafarnagar	1340232	1243694	92.80
20	Uttar Pradesh	Sultanpur	1234068	1229295	99.61
21	Uttar Pradesh	Unnao	1030843	1049252	101.79
22	West Bengal	Paschim Midnapur	1912064	1091672	57.09
		Total 2008	**20040262**	**16881941**	**84.24**

JE Vaccination Coverage 2009					
1	**Andhra Pradesh**	Krishna	1385667	1002000	72.31
2	**Andhra Pradesh**	Nellore	877689	749732	85.42
3	**Andhra Pradesh**	Medak	928450	788574	84.93
4	**Andhra Pradesh**	Adilabad	942266	529413	56.19
5	**Assam**	Lakhimpur	330555	315731	95.52
6	**Assam**	Sonitpur	650156	431387	66.35
7	**Assam**	Kamrup	501318	351040	70.02
8	**Bihar**	Gaya	1362508	1118579	82.10
9	**Goa**	Goa North	263736	70399	26.69
10	**Goa**	Goa South	209870	92173	43.92
11	**Haryana**	Panipat	362312	333424	92.03
12	**Haryana**	Yamunanagar	351532	285231	81.14
13	**Karnataka**	Dharwad	546352	474521	86.85
14	**Karnataka**	Bijapur	651610	464147	71.23
15	**Kerala**	Trivandrum	856885	340623	39.75
16	**Maharashtra**	Beed	581815	367886	63.23
17	**Maharashtra**	Latur	797452	220179	27.61
18	**Maharashtra**	Gadchiroli	1160086	202969	17.50
19	**Maharashtra**	Washim	370485	194921	52.61
20	**Tamil Nadu**	Thanjavur	780275	523404	67.08
21	**Tamil Nadu**	Thiruvannamalai	772111	567286	73.47
22	**Uttar Pradesh**	Allahbad	1953904	1673687	85.66
23	**Uttar Pradesh**	Pratapgarh	1028331	984230	95.71
24	**Uttar Pradesh**	Kanpur Nagar	1660800	1227209	73.89
25	**Uttar Pradesh**	Shahjahanpur	953078	887267	93.09
26	**Uttar Pradesh**	Fatehpur	913749	681420	74.57
27	**Uttar Pradesh**	Jaunpur	1546931	1370141	88.57
28	**Uttar Pradesh**	Ghazipur	1202355	1007125	83.76
29	**West Bengal**	Hoogly	1693989	379295	22.39
30	**West Bengal**	Howrah	1524744	440379	28.88
Total India			**27161011**	**18074372**	**66.55**

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.

There are 3 strategies for prevention and control of JE

1. Surveillance for cases of encephalitis
2. Vector control
3. Vaccination

1. 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 Annexure - H, on pages 81 and 82.

2. 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.

3. 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

4. Vaccination:

- Vaccination is the most cost effective and the best means of preventing and controlling JE.

Table 3 below has the list of JE vaccines which are available in the market internationally and nationally.

Table 4: Summary of JE vaccines available or under development

Vaccine type	Strain & substrate	Producer	Remarks on licensure & marketing
Inactivated, Purified	Nakayama strain *Mouse-brain*	Biken – Japan Green Cross – Korea Vabiotech - Vietnam GPO - Thailand	International, Local & regional, Local, Local & regional
	Beijing 1 strain *Mouse-brain*	Kaketsuken, Biken, Kitasota – Japan	Production stopped, bulk storage.
	P3 strain *PHK or Vero cells*	Several – China	Domestic only.
Live, attenuated	SA14-14-2 strain on *PHK*	Chengdu - 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 *PHK*	Wuhan, Lanzhou – China	Marketed for domestic use in China only.
Under development	SA 14-14-2 strain *Vero cells*	Intercell, Biological Evans – India	Under various stages of development and licensing.
	Beijing 1 strain *Vero cells*	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, Panecea – India	Under various stages of development and licensing,

5. JE vaccination in India – Strategy

To control JE, the Government of India has decided to introduce and expand JE vaccination to the JE endemic districts of the country in a phased manner taking into consideration the following factors:

- 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.

5.1 Strategy

Based on the recommendations of the Bi-Regional Consultation on Japanese Encephalitis (WHO SEA/WPR and PATH, Thailand, March-April 2005), Government of India has decided on the following strategy for the introduction of the JE vaccine in the endemic districts in India:

- A one time mass campaign targeting all children in the age group of 1-15 years in the districts.
- Followed by integration of the JE vaccine into the Routine Immunization Program 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 between 1-2 years of age along with the DPT booster dose, under the Routine Immunization Programme.
- A special campaign has been planned for 2010 in selected districts in the country to cover left outs and new cohorts.
- Age distribution pattern of the lab confirmed JE cases will be reviewed to further inform strategy.

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 has been 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 epidemiological data in India in 2005, the Government of India made the decision to control JE by introducing a mass vaccination program in 104 endemic districts in 11 States of India in a phased manner for 5 years from 2006 – 2011 by using the live attenuated SA 14-14-2 JE vaccine manufactured in Chengdu Institute of Biological Products (CDIBP), China. The JE campaign was to be a one time mass immunization campaign targeting all the children in the 1-15 years age group in the high-risk districts. Following the campaigns the vaccine was to be integrated into the Universal

Immunization Program (UIP) of the same districts to cover the new cohort of children between 1-2 years of age.

Since 2006, the surveillance has improved and the data has been reviewed through the years for the cases of AES and JE. Some districts in 4 new states, Manipur, Nagaland, Arunanchal Pradesh and Uttarakhand have shown evidence of ongoing JE transmission. A decision has been made to include these districts for the JE campaigns in 2010. Hence, 15 states (109 districts) have been included in the phased plan out of which the campaigns have been held in 90 districts till date.

The various criteria used to identify these districts are:

- 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.

6. Macroplanning

Macroplanning should begin at least 2-3 months prior to the date of the JE campaign.

6.1 Macroplanning plan

At the National level

The planning at the National level should be done way in advance and the following should be included in the plan:

1. Obtaining approval from the policy makers
2. Soliciting high level political commitment
3. Involving the UIP division, Vector Borne diseases and partner agencies in the planning process for the campaigns
4. Inter-sectoral coordination with Health and Education and ICDS
5. Ensuring that the latest demographic data - target population, target area is available to plan for calculating the vaccine requirement and the budget Calculation of logistics
6. Timely procurement of vaccine & other logistics
7. Review of guidelines and training material
8. Social mobilization and advocacy plans
9. Organizing National/ state/ district level trainings for the JE vaccination program
10. Plan for distribution of vaccine, logistic supplies and funds to the state
11. Monitoring and Supervision plans- Pre and Post Campaign
12. Post campaign Evaluation of coverage
13. Plans for introduction of vaccine in routine immunization following campaign.

At the State level

The state should ensure that the district has the following plan in place.

1 The updated target population

2 Funds allocated from the Government of India for the JE campaigns – If not then a letter from the Ministry of Health should be reach the state stating that the funds from the NRHM utilized flexipool should be utilized.

3 Plan for training at the state level with the GoI and partners to discuss the guidelines for macro and microplan for the JE campaign

4 District level orientation meeting for Medical Officers

5 Training/ sensitization of vaccinators on the JE vaccination program,

6 Timelines for Microplanning

7 Sensitization of ICDS and Education department

8 Planning for DTFs

9 Plan for a meeting with community leaders and politicians to sensitize them about the JE program

10 Plan for sensitization meetings for JE campaigns for media, medical fraternity, (IMA, IPA etc) and community leaders

11 Plan for DTFs

12 Monitoring and Supervision plans- Pre and Post Campaign

13 Plans for introduction of vaccine in routine immunization following campaign.

6.2 Coordination

1. The plan specifying date of the campaign in each village should be made available to the DTF well ahead of the program.
2. 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

6.3 Timelines for starting activities:

The timeframe required for commencing the key activities are enlisted in table 5 below.

Table 5:

Activity	Time frame
Orientation of MOs	8 weeks before the campaign
Identification of manpower & Completion of Micro plan	6 weeks before the campaign
Completion of Micro plan	6 weeks before the campaign
Release of Funds to Districts	3- 4 weeks before the campaign
Training of vaccinators & supervisors	1 week before the campaign

6.4 Draft work plan development

A draft work plan should be made and the timelines should be decided for each activity which is planned. Table 6.

The Block Medical officer / Urban Health Officer will ensure a clear, complete, action oriented micro plan. He will report the completeness of the same to the DTF well in advance of the activity.

Time line	Activity	Participants	Responsible person	Expected out come
10 weeks before	DTF-1	Existing Member of DTF	CMO&DIO	Inter sectoral Co ordination & roles & responsibility
9 week before	Process for Procurement of printing materials and IEC	NA	CMO/DIO	Materials for IEC and Forms available before activity
8 weeks before	Orientation of Medical officers/ District trainers		CMO/DIO	Medical Officers are trained to generate micro plans
7 weeks before	Micro plan		PHC MO/ BMO/DIO	Requirement of manpower , vaccines, logistics assessed. Vaccination site identified
4 weeks before	DTF-2	Existing Member of DTF	CMO & DIO	Approval of the Micro plan & Identification of manpower
4 weeks before	Identification and process for relocation of vaccinators from other districts		Secretary Health/ Director Health/DM	Orders for relocation issued from the State/District
2 weeks before	Meeting with Community/ Religious leaders		DIO/CMO/BMO/MO PHC	Awareness of the program among the community
1- 2 weeks before	Training of Vaccinators+ Supervisors	Vaccinators + Supervisors	MO PHC/BMO	All vaccinators and supervisors trained
1 week before	Orientation of other team members	ASHA, AWW, Teachers	MO PHC/BMO	Other team members oriented of their role in the program
2 weeks before	Release of fund to PHC/Block		CMO/DIO	Funds available at PHC level
2 weeks before	DTF-3		CMO/DIO	Instruction issued by DM to other depts. for their involvement
Week before	Distribution of vaccine and logistics to the PHC/BPHC		DIO	Vaccines and logistics are available at the PHC/BPHC
3 days before	Miking, drum beating		MO PHC/ BMO	Community aware of vaccination campaign
3- 4 days before	DTF - 4		CMO/DIO	Review progress and solve last minute problem
Day before	Reporting of relocated Vaccinators to PHC MO		DIO	All vaccinators are in place
Day before	Meeting of teams with respective supervisor		MO/BMO/Supervisor	All supervisors are aware of the team and plan of activity

7. Micro planning for the JE Vaccination Program

7.1 Key components of a Micro Plan for the JE Vaccination campaign

1. Planning for immunization site at village/ urban level.
2. Estimation of beneficiaries
3. Planning for manpower
4. Planning for supervision
5. Planning for orientation training of vaccinators and supervisors
6. Planning for vaccine, logistics and cold chain maintenance including contingency plans
7. Route chart for distribution of vaccines and logistics
8. Planning for IEC
9. Planning for recording and reporting
10. Planning for referral in case of AEFI
11. Waste disposal plans

A time line may be prepared for the above mentioned activities, so that the implementation is smooth. States should ensure that the schedule of routine immunization services are not hampered during the campaign days.

7.2 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 enrollment 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 enrollment 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 eg. Angan Wadi center, 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 Center. 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 centers in the villages/urban areas.

7.3 Composition of vaccination teams:

1. There should be around four to five functionaries assigned to each vaccination center.
2. 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.
3. One of the vaccinators should be the ANM of the local Sub center.
4. The other vaccinator should be deputed by the district / block / PHC health administration from adjoining area.
5. 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 center.
6. 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)
7. One team shall be assigned only one village at a time.
8. Two or more villages should not be clubbed together for one immunization center
9. The activity should always be carried out from within a room designated as the "vaccination center"
10. MO (Medical Officer) PHC (Primary Health Centre) shall be responsible for overall team selection
11. Team supervisor will assist the MO, PHC in identifying team members where possible

Model Vaccination Team Composition:

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

7.4 Roles and responsibilities of Vaccination team:

1. Vaccinator – (2 per team)

During the planning stage -

- Develop micro plan for activity in her sub center area (local sub center ANM)
- Ensure completeness of micro plan
- Vaccination site selection in the village
- Identify the third and fourth and fifth member of the team
- Orientation of the third and fourth member
- IEC and IPC before campaign in her assigned area (through ASHA/AWW/PRI)
- Assist in vaccine and logistic transportation planning for her sub center area

On the day of the JE Campaign-

- Vaccinate children after due screening for any contraindication for vaccination
- Give specific instructions to parents on any reactions/ AEFI (Adverse events following immunization
- Take appropriate measures in case of any AEFIs.
- Ensure completeness and reporting of day's activity in the designated format
- Overall responsible and accountable for planning, training and conducting the activity in the center

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.

2. **AWW / ASHA / Link person**

Before Activity:

- Social Mobilization – parent's meeting, IPC etc. in village as awareness campaign
- Coordinate with school personnel in preparing the vaccination center

On day of activity

- Manage queue
- Provide logistic support to vaccinators
- Repeat instructions of the vaccinator to parents before they leave the center

After- Activity

- Mobilize absentee children to the PHC for vaccination

3. Teacher

Before Activity:

- Ensure that all staff and children of school know about the activity
- Make arrangements in vaccination site for activity

On day of activity

- Mobilizing and controlling the flow of children.
- Assist team for screening children for any contraindication for vaccination
- Fill up the tally sheets and vaccination cards
- Instruct Parents to retain cards
- Mobilize the absentee children from the village and send them to the school for immunization.
- *Assist the team to manage AEFI and allay fears/misconceptions about the vaccination*

After Activity

- Mobilize absentee children to the PHC for vaccination

4. Role of Volunteers

- Mobilize children from the village to the vaccination center
- Assist in identification of absentee children
- Incase 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.
- Instruct Parents to retain cards

7.5 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
- It is recommended that a name based listing is done prior to the vaccination campaigns.
- It is estimated that the above age group will constitute about 33 % of the population.
- **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.**

7.6. Estimation of number of days of activity in the village

- It has been planned that 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.***

Illustration 1. Example 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 x 33 % = 495

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

Estimated number of children vaccinated by 2 vaccinators per day = 125x2 = 250

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

- The total number of days required for vaccinating all the target children in the village or specified urban area will depend upon the number of beneficiaries in the village/area. (Illustration 1)

7.7 . Vaccination center management and logistics

Each team should have the following:

- One vaccine carrier with 4 conditioned ice packs.
- Adequate quantity of JE Vaccine vials along with diluents supplied by the manufacturer. [1]
- Adequate number of 0.5ml AD syringes.[2]
- Adequate number of 5ml syringes for reconstitution. [3]
- Adequate cotton swabs.
- Adequate number of vaccination record cards.[4]
- 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.
- Emergency medicine kits.

7.8 Functioning of vaccination centers

1. The booth should begin functioning early (no later than 9 am) and should run for at least 8 hours.
2. The center should be located in the shade. Vaccine vials and vaccine carriers should not be exposed to sunlight.
3. **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.**

[1] Total number of JE vials that should be carried to the vaccination site = (Total number of estimated beneficiaries x 1.11) / 5 considering that the total number of doses per vial = 5 and the wastage would be 10 %

[2] Total number of AD syringes that should be carried to the vaccination site = (Total number of estimated beneficiaries x 1.11) considering the wastage to be 10%.

[3] Total number of reconstitution syringes = Total number of vials.

[4] Total number of vaccination record cards = Total number of beneficiaries in the village x 1.11 considering the wastage to be 10%.

4. **Do not pre-fill syringes.**
5. Ice packs should not be removed from the vaccine carrier containing the JE vaccine vials.
6. 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.
7. 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.
8. The tally sheet should be filled in by a member of the team other than the vaccinator (ideally the teacher from the school).
9. The vaccinator should inform parents about the signs and symptoms of AEFI 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.
10. After vaccination, the children should be observed for half an hour in the center for signs of AEFI.
11. 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.
12. The team members, other than the vaccinators, should organize the vaccination center for effective catering to beneficiaries. See Appendix F for Site Plan.
13. Any AEFI related information including the AEFI Form (Form 3) should be filled up by the vaccinator only.
14. 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 center.
15. 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.
16. 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
17. For Micro planning, use **Form 6**.
18. For Logistics planning, use **Form 7**. Computerization of Forms 6 and 7 should be done in the Excel sheet provided during the district workshops.
19. The microplan booklets should be made after computerization at the planning units and districts.

20. The microplan booklets should contain all other formats of planning (District Profile, Vaccine delivery route chart, teams & supervisory maps, IEC plan and logistic planning).
21. 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.

Vaccination Team with model Role and Responsibilities:

1. ANM from local HSC – Vaccinating the Beneficiaries - observation of children for AEFI
2. 2nd 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)

8. Activities for the JE vaccination campaign at the District/ Block level

At the National level an orientation planning & consultation workshop should be conducted to plan for the JE campaigns. At the State level – State orientation and JE campaign planning meetings should be held for the districts undertaking the JE vaccination campaign.

At the District/ Block level –

1. District Task Force (DTF existing for NIDs /SNIDs) meetings should be held The objectives of these meetings should be

- For orientation and to set timelines.
- Inter-sectoral coordination (Health, Education, ICDS etc).
- To review broad district plans and to conduct district microplanning meeting for both rural and urban areas to review preparedness, microplanning and progress in IEC/social mobilization, trainings, etc and to review the progress and solve last minute problems.
- To meet before and after and as and when required to take corrective actions.

2. During the JE campaign - to review the activity and make further plans for the introduction of the JE vaccine in the routine immunization program.
3. Orientation of district and block level trainers/medical officers.
4. Identify one media spokes person at the State and the District level.
5. Initiate preparation of block-wise microplans, procurement of logistic materials and printing of stationary like immunization cards, supervisory and vaccinators instructions, checklists and tally sheets etc.
6. Review microplans prepared at Blocks/PHCs/urban areas.
7. Identify ice factories/cold storages for procurement of ice or freezing of ice packs.
8. Verify functioning and availability of cold chain equipments, like deep freezers, ILRs, vaccine carriers, adequate icepacks and cold boxes.
9. Blocks/ PHCs /urban areas to submit micro plans to the district.
10. Organize orientation meeting of community /religious leaders at district headquarters.
11. Finalize and release funds to blocks/urban areas.
12. Start orientation of supervisors, vaccinators and cold chain handlers.
13. Human Resource Deployment.
14. 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
15. M O to organize meetings/panch sammelans with community and religious leaders.
16. Continue orientation of supervisors and vaccinators and cold chain handlers.

17. Distribute vaccines and logistics to PHCs.

18. Intensify social mobilization; begin with display of IEC materials, rallies, *prabhat pheri*s.

19. Start miking and public announcements from fixed sites like temples and markets three days prior to activity.

20. Implement immunization activities.

21. Daily evening meetings at block/PHC to get feedback from supervisors and plan for mid round corrective actions.

22. Send Block reports to district headquarters in the evening or the next day.

23. Consolidate immunization figures for the district and report to SEPIO & AC (Imm.), MOH&FW, GoI.

9. District Task Force: Roles and Responsibilities

The District Task Force (DTF) constituted for the Pulse Polio Programme will also be the responsible body for implementation of the JE vaccination programme in the district. The composition of the DTF is as follows:

Members:

1. District Collector / Magistrate / Chief Development Officer (Chair Person)
2. ADM
3. CMO
4. DIO (Convener)
5. Dy. CMOH (Public Health)
6. District Malaria Officer
7. SMO & RIO (NPSP)
8. UNICEF- District Representative
9. District Education Officer
10. CDPO
11. BDOs
12. DPRO (District Panchayati Raj Officer)
13. District Mass media/health education officer
14. Chairperson of district AEFI committee
15. RTO (Regional Transport Officer)
16. IAP/IMA representative
17. Prominent NGO representatives
18. Representatives from Medical Colleges
19. BMO s and Urban Health Officers
20. Any other officer suggested by DM

Roles of the DTF

a. The role of the DTF is to plan, coordinate, support, monitor and ensure the highest quality of JE vaccination campaigns in the district.

b. These meetings should be used as a platform to clear obstacles for the planning and implementation of the program.

c. DTF should ensure that all arrangements for the management of serious AEFIs in the district are in place.

d. Members of the DTF should be actively involved in supervising and monitoring before and during the campaigns and the DTF should meet before and after and as and when required.,

e. In a similar plan Block level Task Force (BTF) should be constituted under the chairmanship of the Block Development Officer. The BMO will act as the convener of the BTF.

The DTF should be responsible and accountable for the implementation of the quality of the JE vaccination campaign in the district.

10. Roles and Responsibilities of the Government Officials/Departments and other sectors in JE vaccination campaigns

10.1 Role of District magistrates/ District Collector/ Municipal Commissioner

1. District Magistrates (DMs) are responsible for monitoring the planning and implementation of the JE vaccination campaigns in the district with a weekly review of the progress and problem solving.
2. They shall ensure the involvement and inter-sectoral coordination of all other departments in the district for mobilization of manpower, transport and social mobilization thereby ensuring that all departments function to their full potential.
3. Review adequate preparedness to manage Adverse Events Following Immunization (AEFI).
4. Depute senior officials from the administration and other sectors to supervise preparations and implementation of the campaigns in various blocks and urban areas of the district. *These senior officials may be assigned specific Blocks and will be held accountable for the quality of the activity in their assigned area.*

10.2 Role of Chief Medical Officer of Health / Civil Surgeon

1. Shall support the District Magistrate and the District Task Force in their roles outlined above for the timely implementation of the campaign activity.
2. Shall ensure review and finalization of microplans of all PHCs and urban areas before the start the of activity.
3. Shall ensure all vaccinators and supervisors have undergone orientation before the onset of the campaign.
4. Make supervisory visits to review preparedness and monitor implementation.
5. PHC wise allocation of vaccines and other logistics.
6. Timely release of funds to Blocks / PHCs.
7. Concurrent evaluation and feedback to Blocks/PHCs to take corrective actions on a day to day basis.
8. Ensure adequate arrangements to treat AEFIs.
9. Assign specific blocks to senior health officials to review the microplans of the activity in the Block. While the Chief Medical Officer will be responsible for the overall development of the microplans of the entire district, the senior district health official will be responsible for the quality of the training and the microplan of the block assigned to him.

10. 3 Role of District Immunization Officer/ District Malaria Officer

1. Shall support the Chief Medical officer in the role outlined above.
2. Shall convene the DTF.
3. Shall be responsible for ensuring that the quality of trainings are maintained and are conducted as per the prescribed timelines in the Blocks/Districts
4. Shall collect, compile and transmit data to State/GOI.
5. Shall analyze feedback / data and present it to the DTF and at the District review meetings for corrective actions.

10.4 Role of MO Block/PHC/urban areas

1. Overall responsibility of preparing micro plans.

2. Review and finalize microplans before the activity and report its completion to the Block Task Force (BTF) and DTF.

3. Convene the BTF meetings.

4. Coordinate with other Block level officers for the implementation of the activity.

5. Identify supervisors and assist them in the identification of the vaccinators. Calculate shortfall and intimate the same to the District Medical officer/ DM.

6. Ensure that the orientation / training of vaccinators and supervisors is done before the campaigns.

7. Conduct meetings with community leaders for promote propaganda and awareness of the program.

8. Plan and ensure that IEC materials are utilized in a timely for effective propaganda and awareness.

9. Take stock of cold chain equipments available in the Block. Identify additional support required for the cold chain in the Block. Intimate CMO, DIO and SIO of any shortfall and ensure remedial measures. Plan and ensure adequate cold chain support to the vaccinators, daily.

10. Arrange transport for the delivery of vaccine and other logistics to the teams.

11. Supervise the activity at the village level on a day to day basis.

12. Collect and compile reports from supervisors.

13. Analyze and review feedback data from the teams, supervisors, monitors, medical officers and take corrective actions, if needed.

14. Ensure adequate referral capacity if AEFIs occur. They will be responsible for the overall activity in their area.

11. Supervision

High quality supervision is essential for the success of the campaign. Additional Medical Officers at PHCs should be involved in supervision. Incase 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 3)** 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. Use the Supervisory checklist at the time of the visit to the vaccination sites.

i. Assist the Medical officer to identify and replace poor performing vaccinators.

j. Collect, compile and analyze data from vaccination teams and submit them to the BMO/PHC.

k. Attend all the evening meetings at Blocks and provide a proper feedback to the Medical Officer.

12. Estimation of Vaccines, Cold Chain and other Logistics

12.1 Vaccines Estimation and storage

1. Vaccine should be calculated taking a wastage multiplication factor of 1.11 for the campaign.
2. Total JE vaccine doses required for the campaigns = Total Population x 33% x 1.11
3. Total JE vials required = (Total Population x 33% x 1.11) / 5.

Illustration 2: 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 1.11 = 550 doses

JE Vaccine vials required for the village =550 545/5= 10910 vials

4. The Block or urban areas should take into account the number of cold boxes/ ILRs
5. Deep freezers that are required and available for the storage.
6. The requirement for Cold boxes/ vaccine carriers for transportation of the required JE vials should also be calculated for the freezing and transportation ice packs.
7. 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.
8. 2000 vials of vaccine along with 2000 vials of diluents can be stored in one small ILR (10000 doses of vaccine). 20000 doses including diluents can be stored in a Large ILR. 30-35 vaccine vials and 30-35 diluent vials can be kept in one vaccine carrier in a polythene packet (ie. a total of 60 to70 vials or 150 to 175 doses). In case of heavier workload, 2 independent teams should be employed with equals sets of tools. Micro plans should have logistics distribution points and plans.
9. Each center should have a vaccine carrier with conditioned ice packs. Vaccinators and supervisors should know the source of the ice, ice packs and vaccine for replenishment.
10. Supervisors should carry vaccine carriers with conditioned ice/ice packs and enough vaccines and diluents for replenishment if necessary.
11. Strategy for timely replenishment and supply of ice, ice packs and vaccines to the village immunization centers should be a key component of the micro plan
12. Other logistics- such as AD syringes, disposable syringes and red/black bags, hub cutters etc should also be carried to the session site

12.2 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.

12.3 Vaccine handling guidelines in the vaccination centers:

Some general instructions for vaccinators for handling vaccines:
Protect the vaccine carrier and the vaccine from sunlight. Open only one vial at a time for use and keep it outside the vaccine carrier.

- 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.
- **The reconstituted vaccine should not be used after 2 hours of reconstitution.**

Suggested Planning: For Example

Block population (PHC): 150000

- **Target (33%): 49500**
- **Vaccine requirement: 49500*1.11=54945 doses i.e.10989 vials of vaccine and 10989 vials of diluents**
- **Duration of campaign: 10 days**
- **Estimated Vaccine requirement/day: 54945/10=5495doses i.e.1099 vials of vaccine and 1099 vials of diluents**
- **ILR capacity: 2 ILRs of 140 L: In one ILR 2000 vials each i.e. in two ILRs, 4000 vials each of vaccine and diluents can be stored (20000 doses)**
- **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.**

- 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.

- Both the Vaccine vial and the diluents are to be stored at a temperature of 2 - 8 ^{o}C. The diluents can be kept at room temperature **but REMEMBER - 48 HOURS PRIOR TO THE COMMENCEMENT OF THE JE CAMPAIGN IN THE DISTRICT, the required amount diluents should be kept in 2-8 ^{o}C along with the vaccine vials**
- Reconstitute vaccine with diluent at same temperature only.
- Never use any other diluent for reconstitution

13. Transport

1. The number and type of vehicles required for the transport of vaccines and logistics should be determined from the microplans.
2. Every vehicle that is used must have a route chart clearly indicating the places to be visited along the route and approximate time of visit. The team should be aware of the vaccine arrival time.
3. The vehicles should be responsible for distributing and collecting back vaccine and other logistics, immunization waste and reports from session sites
4. All efforts should be made to use the existing vehicles. Additional vehicle requirement should be notified to the Block/district task force so that they can be arranged from other government departments for the duration of the program.

Route chart of vehicles is a key component of the microplan

14. 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 subcenter. 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 Assistant Commissioner (I) , 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 Vaccinator's training module's Appendix G for the forms**

15. 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 center for JE immunization.

16. Microplanning Guidelines

In order to ensure that all children in the age group of 1-15 years are given the JE vaccination, it is essential to develop microplans. The microplans should be developed at the block level under the supervision of the Medical Officer. The following items should be considered while preparing a micro plan for the JE vaccination campaign:

1. Listing of all villages under each sub center along with maps.
2. Estimate children in the age group of 1-15 years of age in each village.
3. Listing all school and ICDS centers in the area. Selection of the vaccination sites.
4. Identifying and listing of vaccinators.
5. Identifying and listing of other team members.
6. Identifying of social mobilizer namely AWWs, ASHAs, Panchayat Members, School Teachers etc.
7. Estimating vaccination team days.
8. Vaccine vials required for the session/team days.
9. Requirement of AD syringes and reconstitution syringes.
10. Vaccine delivery plan / identifying of alternate vaccine delivery.

16. 1 Development of a Micro Plan template at the PHC level

The following estimates need to be taken into account for the preparation of the micro plan:

1. Listing all Sub Centers at the PHCs – assistance may be taken from the following groups
    (i) Anganwadi workers
    (ii) Health workers
    (iii) Panchayat
    (iv) Civil society organizations, self-help groups, workers' unions
    (v) School teachers and students
    (vi) IMA and IAP
    (vii) Youth organizations like NYK, NSS, NCC, Scouts
2. Listing all villages, schools and ICDS centers in each Sub Center Area
3. Population of each village in the Sub Center Area
    (i) For the campaign: estimate the population of 1-15 year olds
    (ii) For Routine Immunization – estimate the population between 1- 2 years

4. Vaccines and logistics requirement.
    (i) Estimate for the campaigns and for RI based on target group
5. Manpower requirement
    (i) Required
    (ii) Available
    (iii) Shortfall
6. Vehicle requirement
    (i) Number
    (ii) Type
7. Requirement of Forms:
    (i) Form 1. Vaccination Card
    (ii) Form 2. Tally Sheet
    (iii) Form 3. Supervisor reporting format
    (iv) Form 4. Block reporting format
    (v) Form 5. District reporting format
    (vi) Form 6. Micro planning format
    (vii) Form 7. Logistic Planning format
    (viii) Form 8. Adverse Event Following Immunization Form FIR Form
    (ix) Form 9. Adverse Event Following Immunization Form PIR Form
    (x) Form 10. Adverse Event Following Immunization Form DIR Form
    (xi) Form 11. Lab Request form for serious AEFI cases sample collection
    (xii) Form 12. Line list Format for AEFI Cases
    (xiii) Form 13. Supervisory Checklist
    (xiv) Form 14. Monitoring format
8. Soft copies for Computerization
    (i) Micro Planning Tool for computerization of Form 6 & 7.
    (ii) Coverage Data Compilation Tool for daily coverage data compilation.

17. 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:

16.1 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 programmes. 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
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.

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
- Both-or multiple-sides of the story

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.

16.2 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.
- Use your organization's name, never "we" or "I".

16.3 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

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.

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.

- 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.

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?

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 rumors about vaccine 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 rumor, 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.

1. 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.

2. 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.

3. 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 though a press release or hard copy document.

4. 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.
- 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.

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.
- Take time to clarify or elaborate.
- Offer to followup with additional information.
- Supply photos if possible.

- 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.

16.4. 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 pubic 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

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?

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
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.

1. *Building Trust and Responding to Adverse Events Following Immunization in South Asia: Sing Strategic Communication.* Unicef, Regional Office for South Asia, 2005
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 Centers for Disease Control and Prevention **(**CDC**)**

18. Details for Administration of JE Vaccine

Type of vaccine	Live attenuated SA-14-14-2 JE vaccine
Presentation	Multi-dose vials with 5 doses as a lyophilized powder that looks like a milky-white crisp cake Diluent vial of 2.5 ml
Reconstitution	The vaccine should be reconstituted with the supplied diluent only After reconstitution it turns into a transparent orange red or light pink **The reconstituted vaccine should not be used beyond two hours of reconstitution**
Schedule	One dose (0.5 ml) containing not less than 5.4 log PFU of live JE virus)
Administration of Vaccine	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.
Vaccine vial and diluent storage	Stored and transported between 2^0C to 8^0C and should protected from sunlight. (Remember the diluent should also be kept at 2-8 degrees 48 hours prior to the commencement of the JE campaigns

19. 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.
- The left outs should be encouraged to take the vaccine
- Immediately after the campaign, the left outs and drop outs should be covered
- Any child attaining 16 months – 15 years of age will be eligible to receive the JE vaccine

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 – Same as mentioned in module 18- Page 56

Do's and Dont's

- 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 Government of India 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.
- **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.

- 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

- Assessment of the total population of infants between 1-2 years should be done after the JE Campaign.
- 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 maintenance and logistics for storage of vaccines should be prepared well in advance.

Estimated population in the age group 1-2years = Number of surviving infants at the end of the year (estimation for coverage under routine immunization)

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

Product Information Sheet – Multiple dose vial

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.

Ingredients

1 vial contains : live attenuated JE virus [Virus Strain: SA-14-14-2]. One dose of 0.5 ml contains 5.4 log PFU.

Indication and Usage

Immunization against Japanese Encephalitis

Dosage and Administration

0.5 ml of vaccine should be given subcutaneously to children between 1 – 15 years of age.

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 ^{o}C), nausea , rashes, local inflammation at the site of Injection

Precautions

1. The health care provider should question 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.
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 given , 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

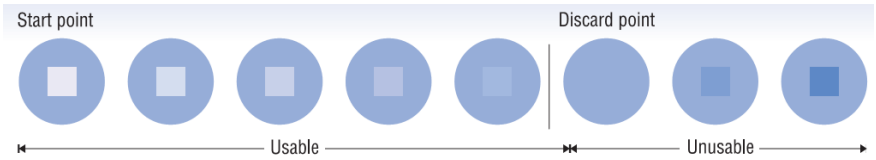
How is the vaccine Supplied?

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 ^{o}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.

Appendix B: Cold Chain Management guidelines

Storage of Japanese Encephalitis Vaccines

Japanese Encephalitis (JE) Vaccines are to be stored at a temperature of 2 - 8 ^{o}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 ^{o}C along with the vaccine vials**

VVM (Vaccine Vial Monitor) Guidelines:

The JE vaccine vials are supplied with VVMs which 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.**

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 ^{o}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 ^{o}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 the cold chain. The temperatures at these Cold Storages must be maintained between 2 to 8 ^{o}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 ^{o}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 Owner / Manager of the Cold storage is to be briefed of the importance of maintaining the Temperature of the cold storage **between 2-8 ^{o}C only.**
- The Owner / 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.
- Vaccines and diluents should be preferably kept at the first floor of the Cold storage. Vaccines and Diluents should never be kept 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 Deg 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) is kept ready for storage of the vaccines and diluents *(The ILR should be connected with the Voltage stabilizer).*
2. One deep freezer is available to freeze ice packs. Generator is in proper working condition.
3. Adequate vaccine carriers are available along with ice packs.
4. 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. Storage capacity is given below:

Type of equipment	Make	Capacity	Storage capacity	Color of pack	Doses
ILR	Haier Vestfrost	70 litres 140 litres	2000 JE vaccine vials & 2000 JE diluents	Dark green Light green	10,000 Doses
ILR	Vestfrost	300 litres	4000 JE vaccine vials & 4000 JE diluents	Dark green Light green	20,000 Doses

- The temperature of 2-8 ^{o}C should be maintained in the ILR and this should be monitored at least twice a day.

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

Storage in vaccine carriers

Type of equipment	Make/Color of box	Storage capacity	Doses
Vaccine Carrier	Yellow / Blue	40 JE vaccine vials & 40 JE Diluents	200 Doses
Vaccine Carrier	Grey (New supply)	30 JE vaccine vials & 30 JE Diluents	150 Doses

- 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 the original packs (Ten in each pack) in the vaccine carrier. It has been observed that vaccine vials are 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".

Vaccine handling at the site

Vaccinators require taking the following action at the site:

- The vaccine carrier and vaccines are protected from sunlight.
- One vaccine vial and one diluent vial are to be open at one time and kept outside the vaccine carrier for use.
- The expiry of the vaccine and diluent should be checked before usage,
- The VVM should also be checked on the cap of the vial before opening the vial and only if the vial is in usable stage of VVM should the vaccinator continue to open it. If the vial is in unusable VVM stage, them the vial should be **NOT BE USED.**
- Once the cap of the vial is removed, the role of the VVM will cease to exist.
- After reconstitution of the vaccine, the time of reconstitution should be noted on the vial.
- **The lid of the vaccine carrier should be opened only to take the vaccine out.** Immediately after taking the vaccine vial and diluent out of the vaccine carrier, the lid should be shut properly and tightly.
- **The reconstituted vaccine should not be used after 2 hours of reconstitution**.

Facts to remember

- ***The lid of the vaccine carrier should be opened only to take the vaccine out.***
- ***It should not be opened unnecessarily.***
- ***Ensure that the lid is shut tightly.***
- ***VVMs usability should be determined before proceeding to open the vial.***
- ***Time of reconstitution should be written on the vial and the reconstituted vaccine should not be used after 2 hours of reconstitution***.

In general follow all guidelines for cold chain maintenance for vaccine in the field

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
- 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:

An AEFI Committee under the chairmanship of the Chief Medical Officer of Health will be set up 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

Roles and responsibilities of the District AEFI Committee:

1. Before the campaigns, the Committee will ensure and review preparedness of the Medical College, District Hospital and other possible sites of AEFI case referral.
2. The Committee will hold one orientation meeting of all Medical officers from PHCs, District Hospital and Medical College.
3. The Committee will identify one nodal person for AEFI investigation and reporting in each of these institutions. Following should preferably be identified as the nodal person:

a. PHC: Medical officer
b. District Hospital: Pediatrician
c. Medical College: Pediatrician

4. Each and every case reported as a serious AEFI (hospitalized cases or serious events of unexplained cause occurring within 15 days after vaccination and/or deaths) will be investigated at the earliest (within 24 hours) by at least one member of the AEFI committee. This investigation will include a visit to the facility where the case is admitted or the community if the child has died before hospitalization. The committee member will also ensure that each case has been diagnosed provisionally pending final diagnosis.
5. Detail protocol as prescribed in the "Operational Guidelines Japanese Encephalitis Vaccination in India: as issued by the Immunization Division, Department of Family Welfare, Ministry of

Health and Family Welfare, Government of India, should be followed in investigation of the AEFI cases

6. The committee will also identify and prepare a local laboratory (e.g.: District Laboratory) for preliminary testing (cytology, grams stain and biochemistry) of CSF samples. The committee will also define the process of transfer of specimens to NIV, Pune/Gorakhpur for further testing of CSF.

Forms to be filled up in AEFI:

1. First Information Report (FIR) – To be reported in the first 24 hours.
2. Preliminary Investigation Report (PIR) – To be reported within 7 days
3. Detailed Investigation Report (DIR) - To be reported within 90 days of submitting the FIR.

1. FIR: 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:

- 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 AC-I MOHFW, GoI within next 24 hours **(Fax Number: 011-23062728)** .

Steps for completing the FIR.

Role of health facility MO

1. Ensure that the notified adverse event fulfills the criteria of a serious AEFI.
2. Medical officer (MO) should examine the patient and immediately submit the FIR **(within 24 hours of notification)** to the DIO.

Role of DIO

1. Within the **next 24 hours**, the DIO should review the FIR sent by the MO and provide district specific information like the EPID number, contact details, initiate sample collection and a tentative plan for further investigation and forward this copy to the State immunization officer and Assistant Commissioner (UIP), MoHFW, GoI **(Fax Number: 011-23062728**

Specimens for testing must be collected as soon as possible as outlined in the chapter "AEFI - laboratory aspects". The collected samples may be sent only if specified by the district AEFI committee.

2. **)**The DIO should convene a meeting of the district AEFI committee and determine the need for conducting a time bound investigation and deciding the further course of action.
3. Copies of the FIR should be shared with the
    - district AEFI committee
    - drug inspector (who is also a part of the AEFI committee)
    - in case a post mortem (autopsy) is planned, a copy should be provided to the concerned officer
    - the testing laboratory along with LRF (Laboratory Record form) and other documents (as outlined in chapter "Laboratory aspects of AEFI"), in case the district AEFI committee decides to send the samples of implicated vaccine/ diluents/ logistics or biological products for testing.

Role of State immunization officer (SEPIO)

On receipt of FIR at state level, the SEPIO should decide on the gravity of the AEFI case and can take a decision to involve state/ regional AEFI committee at this stage or wait for the report of the PIR and involve the State/ Regional AEFI committee (including State drug controller) and chalk out further course of action.

Role of AC (UIP) MoHFW, GoI

At the national level, the Assistant Commissioner (UIP) , MoHFW, GoI should decide on the gravity of the AEFI case and can take a decision to involve DCG(I) at this stage or wait for the report of the PIR and involve the DCG(I) (National AEFI committee if required) and chalk out further course of action.

Preliminary Investigation Report (Annex) The purpose of the PIR is to act as a guide for the investigating team to collect important information required for final categorization of the adverse event.

Routing and Reporting Timeline

The Routing and reporting of the FIR should be done from the DIO to the SEPIO and AC (UIP) MOHFW, GoI, as early as possible or within 7 days of submitting the FIR

Responsibility:

DIO should be assisted by the district AEFI committee and the area medical officer / staff.

Steps for completing the PIR.

Role of the DIO

The DIO should discuss and coordinate with the district AEFI committee to plan the preliminary investigation using the PIR. The DIO should first ensure that he/ she has the relevant documents which should include

- Complete FIR
- Vaccine, cold chain, logistic distribution and utilization (including batch number, lot number etc)
- Other AEFI in the area

- Other details such as preexisting health, medical and environmental conditions both in the case(s) as well as the area
- Should organize an AEFI investigation in the field
- Once the preliminary investigation is completed, the district AEFI committee should review the findings and attempt to confirm the AEFI as per definition and categorize the type of the adverse event.
- The completed PIR along with copies of supporting documents should be sent to the SEPIO and Assistant Commissioner (UIP), MoHFW, GoI. Copies of the same should be shared with member of the district AEFI committee, the autopsy team (only in case of death) and laboratories to which implicated samples sent.

It is essential that the DIO should periodically update the SEPIO on the status of the investigation and seek assistance if required

Role of SEPIO

The state AEFI committee including the state drug controller should review the PIR and copies of the supporting documents, categorize the AEFI and decide the further course of action. Deaths and clusters should be taken up as a priority for review. The state AEFI committee should attempt to undertake a preliminary causality assessment for the event taking into consideration the state experience with the vaccine(s) and if necessary request for additional information such as laboratory tests, field level information etc.

Role of AC (UIP) MoHFW, GoI

At the national level, the Assistant Commissioner (UIP), MoHFW, GoI should share the available information in the PIR with the DCG (I) and other senior officers in the ministry of health and family welfare. The DCG (I) will inform the drug manufacturers and review GMP.

Detailed Investigation Report (Annex): 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.

Routing and Reporting Timeline

- Section A to be completed by the DIO with help of the district AEFI committee and forwarded with copies of supporting documents to SEPIO within 90 days of submitting the FIR.
- The SEPIO should convene a state AEFI committee meeting and conduct a causality assessment

and complete the final documentation (section B) and forward the completed DIR with (causality) assessment and copies of documents to the AC (UIP), MoHFW, GoI within 30 days of receipt of DIR at the state level.

Responsibility

- DIO
- SEPIO

Steps for completing DIR.

- The DIO should compile all the relevant documents including
    - Complete FIR and PIR
    - District reports, health centre reports, field reports, hospital records, laboratory results, post mortem reports and results of tests conducted) as relevant
- The DIO should complete the DIR with assistance of the district AEFI committee, obtain the committee's endorsement and forward the same with a case summary report to the SEPIO within 90 days of submitting the FIR.
- The SEPIO should ensure that the final (causality) assessment is conducted by the state AEFI committee and results incorporated in the DIR within 30 days of receipt of the DIR at the state level. A copy of this along with the completed case summary should be sent to AC (UIP) as indicated above. The final report should include the diagnosis, type of adverse event and the key remarks/inputs of the district and state AEFI committee.
- Timely submission of completed DIR is a good indicator of AEFI surveillance.

- ✓ 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 Government of India. Reporting of an AEFI 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.

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

Steps to encourage reporting

Staff should be encouraged to report AEFI without fear of penalty. Reporting can be enhanced by

- Training.
- Positive feedback.
- Ensuring there are enough support available at all levels
- Sharing results of the investigation and any corrective action taken.

<u>Illustration of investigation of a case of AEFI admitted in a hospital:</u>

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 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 etiology)
3. Brain tissue should be collected and transported in cold chain to District Immunization officer for further histo-pathological investigation.

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

Submission of Investigation report

The completed investigation reports (FIR, PIR and DIR) and other relevant records need to be submitted by the Ttate 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 can not be collected, paired blood samples must be collected. Blood samples will be collected on the day of admission and on the 10^{th} day or at discharge or death, which ever 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 hemolysis 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 021Maharashtra
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)	• District AEFI committee that includes local drug inspector. If required consult state AEFI committee
2	Decision to temporarily suspend the use of implicated batch of the vaccine/diluent/logistics	• MoH&FW Govt of India. • The local drug authority representative after discussion with the AEFI committee.
3	Collection and sending of samples	• The Drug Inspector & DIO
4	Decision on type of samples that need to be collected	• Based on recommendations of the District AEFI committee. • The Drug Inspector may also collect additional samples as he considers appropriate.
5	Packaging & Cold Chain of samples	• Drug Inspector and DIO
6	Sealing of specimen using "official lac seal"	• Preferably by Drug Inspector; in case the drug inspector is not available, then by DIO using the CMO's seal
7	Transportation of samples to laboratories	• Preferably DIO and/ or Drug inspector
8	Laboratory for sending specimen	• Identified laboratories as described in this chapter
9	Funding	• 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. • All expenses towards testing of vaccines in CDL Kasauli and Kolkata will be borne by the respective

		laboratories. • NIV Pune will bear the expenses related to testing of samples for adverse events occurring following JE vaccination.
10	Reporting of laboratory results/ reports	• The laboratory as a rule will forward a copy of the report to CDSCO, AC (UIP) MoHFW, State immunization officer, State Cold chain officer and State drug authority. • 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.
11	Sharing Laboratory results	• DIO to share with - District cold chain officer, - Drug Inspector - Block Medical officer reporting the case - Private health facility reporting the case.

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

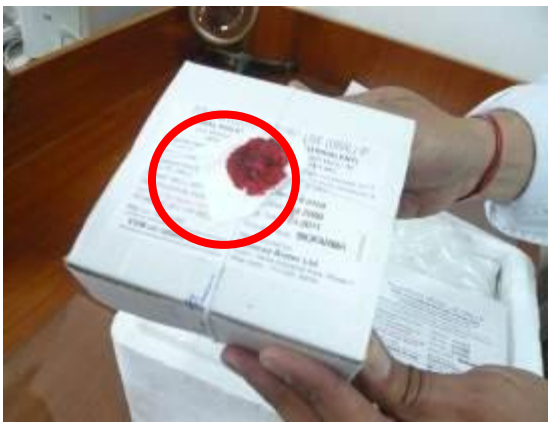
- Separate plastic zipper bags should be used for packing different vaccine and diluents.
- The name, age, date of collection, AEFI epid number and point of collection of vaccines/ diluents should be mentioned only on the label of each plastic zipper bag.
- All the packed zipper bags (separate for vaccines 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

Head,

Central Drugs Laboratory,
Central Research Institute,
Kasauli – 173 204.
Himachal Pradesh.
Email : nclkasauli@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.

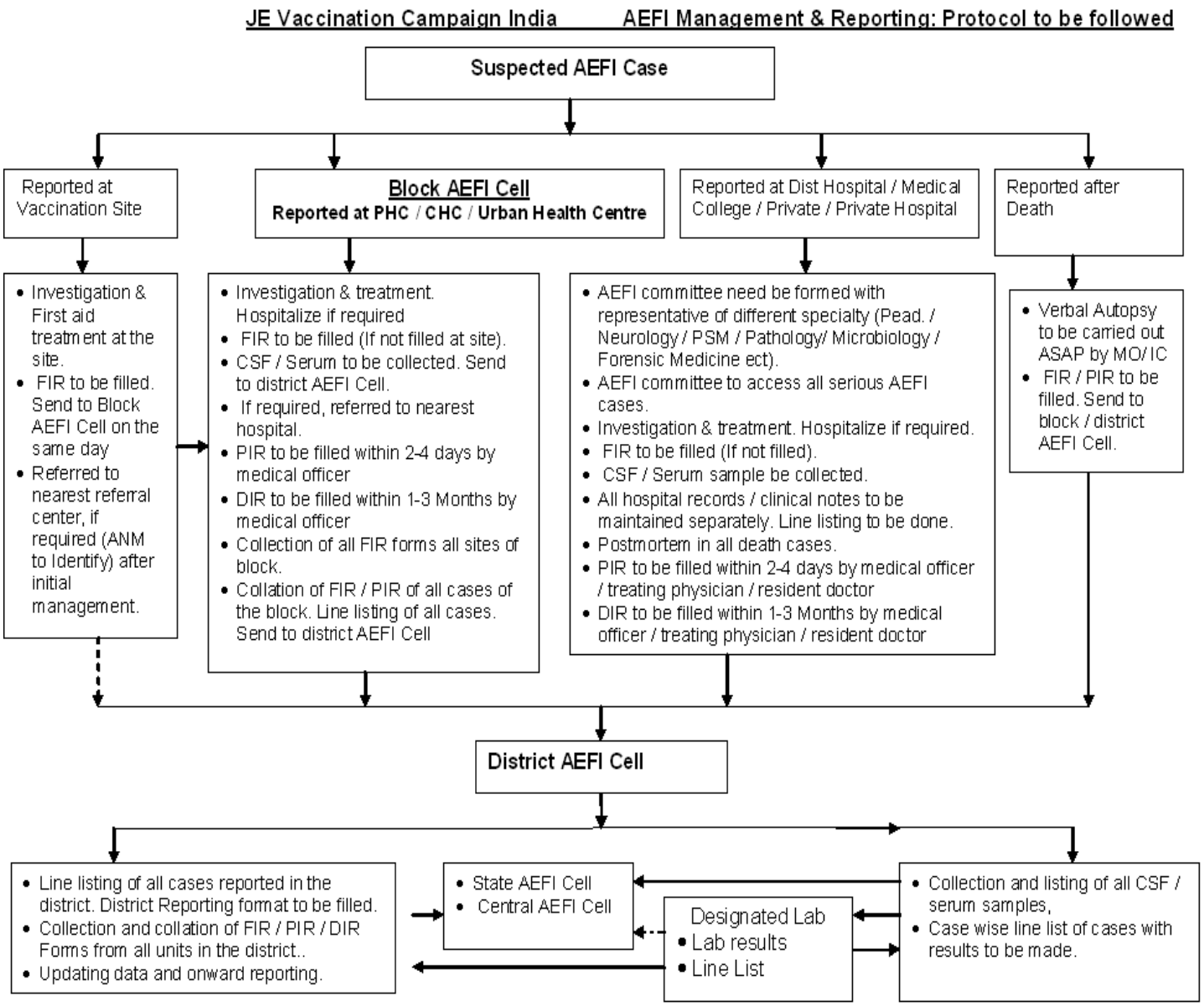
- CDL laboratory Kasauli accepts samples received on all days of the week. The messenger carrying the samples to CDL Kasauli must insist on getting the 'sample received receipt' for official record. This receipt will also provide details on the condition of samples received in the laboratory. (issue 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.

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**.
3. Computerization of line list is to be done in the Excel sheet provided during the workshop.
4. Line list will be maintained at Block and at the District HQ.
5. Updated line list will be send to MoHFW along with daily coverage report.


JE Vaccination Campaign India AEFI Management & Reporting: Protocol to be followed
Suspected AEFI Case
Reported at Vaccination Site
Block AEFI Cell
Reported at PHC / CHC / Urban Health Centre
Reported at Dist Hospital / Medical College / Private / Private Hospital
Reported after Death
• Investigation & First aid treatment at the site.
• FIR to be filled. Send to Block AEFI Cell on the same day
• Referred to nearest referral center, if required (ANM to Identify) after initial management.
• Investigation & treatment. Hospitalize if required
• FIR to be filled (If not filled at site).
• CSF / Serum to be collected. Send to district AEFI Cell.
• If required, referred to nearest hospital.
• PIR to be filled within 2-4 days by medical officer
• DIR to be filled within 1-3 Months by medical officer
• Collection of all FIR forms all sites of block.
• Collation of FIR / PIR of all cases of the block. Line listing of all cases. Send to district AEFI Cell
• AEFI committee need be formed with representative of different specialty (Pead. / Neurology / PSM / Pathology/ Microbiology / Forensic Medicine ect).
• AEFI committee to access all serious AEFI cases.
• Investigation & treatment. Hospitalize if required.
• FIR to be filled (If not filled).
• CSF / Serum sample be collected.
• All hospital records / clinical notes to be maintained separately. Line listing to be done.
• Postmortem in all death cases.
• PIR to be filled within 2-4 days by medical officer / treating physician / resident doctor
• DIR to be filled within 1-3 Months by medical officer / treating physician / resident doctor
• Verbal Autopsy to be carried out ASAP by MO/ IC
• FIR / PIR to be filled. Send to block / district AEFI Cell.
District AEFI Cell
• Line listing of all cases reported in the district. District Reporting format to be filled.
• Collection and collation of FIR / PIR / DIR Forms from all units in the district..
• Updating data and onward reporting.
• State AEFI Cell
• Central AEFI Cell
Designated Lab
• Lab results
• Line List
• Collection and listing of all CSF / serum samples,
• Case wise line list of cases with results to be made.

GUIDELINES FOR MANAGEMENT OF ADVERSE EVENTS

(Adapted from MLM Training Module V, Annexure 5)

Adverse Event	Symptoms	Management
Anaphylaxis (very rare)	Within Minutes • Acute decompensation of circulatory system. • Hypovolemic shock • Altered sensorium • Laryngospasm/oedema • Acute respiratory distress	• Adrenaline **(1:1000)** 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. • Cardiopulmonary resuscitation • IV volume expanders • Oxygen Inhalation • Hydrocortisone injection IV
Bacterial abscess or Sciatic nerve injury May be due to contamination of vaccine or lack of sterilization	Within 72 hours fluctuant or firm abscess with or without fever	• Antibiotic • Antipyretics • Drainage (if needed)
Moderate local reaction	Non fluctuant swelling / redness 3 -10 cms at the site of injection	• Paracetamol Syr. (Dose: 10 mg / kg bd.wt per dose orally – can be repeated every 6 – 8 hrs). Paracetamol Syr has 125mg/5ml
Severe local reaction	Non fluctuant swelling / redness 10 cms in size or larger at the site of injection	• Paracetamol (dose as above)
Seizure/s with/without fever (rare) or convulsions.	By 24 - 48 hours Always generalized Simple or Complex	• Anticonvulsants e.g. Injection Diazepam (Dose: 0.3 mg/kg /dose slow IV) • Can be repeated after 30 minutes. • Antipyretics • IV fluids if need be
Hyperpyrexia	By 12-24 hours	• Antipyretics • Tepid water sponging.

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 (1/16th of a ml)
2-5 years	0.125 ml (1/8th 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 maybe used**

Recommendations of AEFI Committee:

National level committee of experts which was formed on 13th 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.

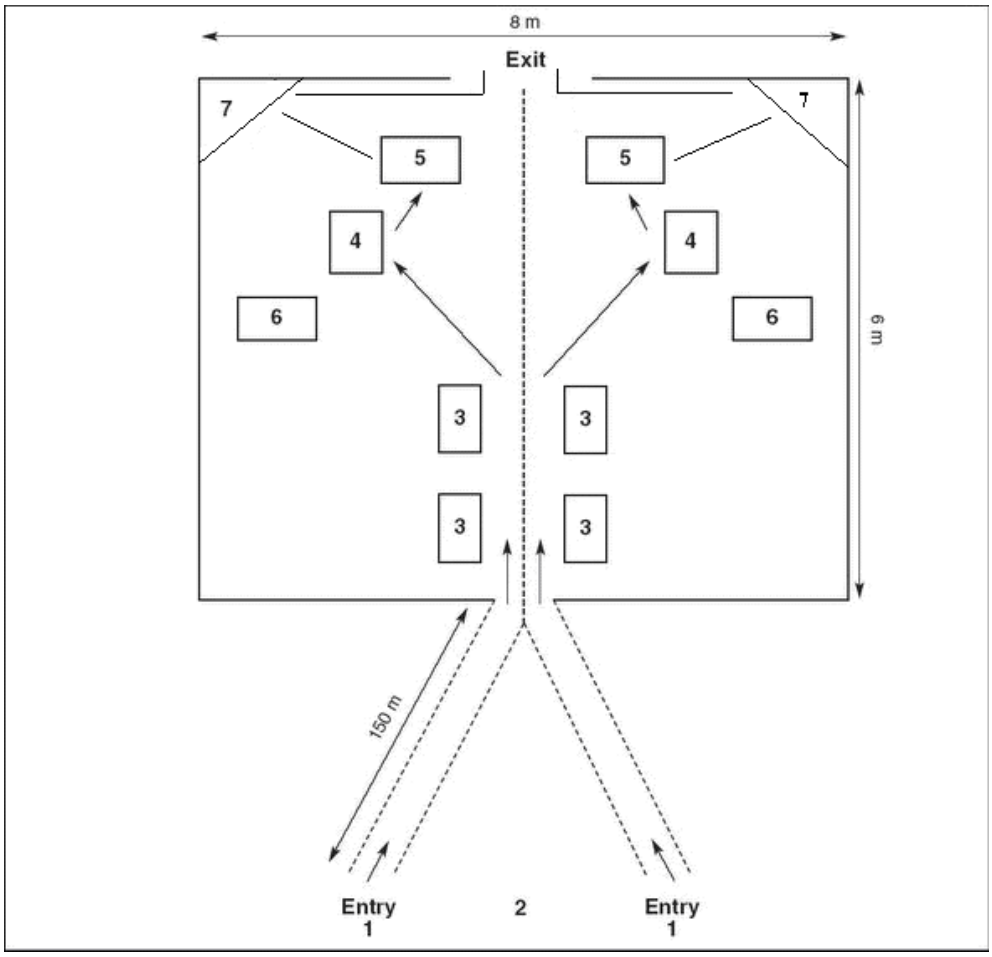
Step 2 The cut needles will get collected in the **white translucent container of the hub cutter.**

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	**Color code**	**Disinfection**	**Disposal**
Cut syringes	RED bag	Boil waste in water for at least 20 minutes OR Autoclaving OR Chemical Treatment	After disinfection :Recycle or Land fill
Used vials and Diluents	RED bag	Local autoclaving OR Chemical Treatment	After disinfection :Recycle or Land fill
Cut Needles/Sharps	Blue/White Translucent puncture proof container	Disinfect with household bleach at 0.5% chlorine solution OR Chemical Treatment	After disinfection : Dispose in Pit / Tank
General waste	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 center 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 2010

Japanese Encephalitis Vaccination Campaign

Name: _____

Age in yrs:_____

Sex:_____

Fathers Name:_____

Village:_____

Sub Center:_____

PHC:_____

District:_____

Date of vaccination:__ __ / __ __ / __ __ __ __
(Day) (Month) (Year)

Any Adverse Events:_____

[TO BE RETAINED BY VACCINATOR]
[To be retained at the Sub Center]

Form 1 Vaccination Card: JE Vaccination Campaign 2010

Japanese Encephalitis Vaccination Campaign

Name: _____

Age in yrs:_____

Sex:_____

Fathers Name:_____

Village:_____

Sub Center:_____

PHC:_____

District:_____

Date of vaccination:__ __ / __ __ / __ __ __ __
(Day) (Month) (Year)

Any Adverse Events:_____

[TO BE RETAINED BY BENEFICIARY]

Form 2 Tally Sheet: JE Vaccination Campaign 2010

Japanese Encephalitis Vaccination Campaign
Village / Urban Vaccination Site Tally Sheet

Name of Village / Urban site: _____Sub-center / Urban Outpost:_____
Name of Vaccinator:1. Resident: _____ 2. Supporting: _____

Other team members (√ as appropriate): ☐ *ASHA* ☐*ASHA like persons* ☐*Teachers* ☐*AWW* ☐*Community Volunteers* ☐*Others*

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:***

Number of children vaccinated

Age group	Male										Total	Female										Total	Grand Total
1-5 years	1	2	3	4	5	6	7	8	9	10		1	2	3	4	5	6	7	8	9	10		
	11	12	13	14	15	16	17	18	19	20		11	12	13	14	15	16	17	18	19	20		
	21	22	23	24	25	26	27	28	29	30		21	22	23	24	25	26	27	28	29	30		
	31	32	33	34	35	36	37	38	39	40		31	32	33	34	35	36	37	38	39	40		
	41	42	43	44	45	46	47	48	49	50		41	42	43	44	45	46	47	48	49	50		
5-10 years	1	2	3	4	5	6	7	8	9	10		1	2	3	4	5	6	7	8	9	10		
	11	12	13	14	15	16	17	18	19	20		11	12	13	14	15	16	17	18	19	20		
	21	22	23	24	25	26	27	28	29	30		21	22	23	24	25	26	27	28	29	30		
	31	32	33	34	35	36	37	38	39	40		31	32	33	34	35	36	37	38	39	40		
	41	42	43	44	45	46	47	48	49	50		41	42	43	44	45	46	47	48	49	50		
10-15 years	1	2	3	4	5	6	7	8	9	10		1	2	3	4	5	6	7	8	9	10		
	11	12	13	14	15	16	17	18	19	20		11	12	13	14	15	16	17	18	19	20		
	21	22	23	24	25	26	27	28	29	30		21	22	23	24	25	26	27	28	29	30		
	31	32	33	34	35	36	37	38	39	40		31	32	33	34	35	36	37	38	39	40		
	41	42	43	44	45	46	47	48	49	50		41	42	43	44	45	46	47	48	49	50		
Total children vaccinated												Total children vaccinated											

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

	Received	Used	Balance
Vaccine vials (5 doses per vial)			
AD syringes			
Syringe for reconstitution (5 ml)			

Date: __ __/ __ __/ __ __ __ __ Signature of Vaccinator_____

Form 3 Supervisor's Form: JE Vaccination Campaign 2010

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																		
TOTAL																		

_____ _____

Name Signature

Supervisor's comments:

1. How many immunization centers 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 2010

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																		
TOTAL																		

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 Signature

Form 5: District Daily Reporting Format: JE Vaccination Campaign 2010

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**
TOTAL																		

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																		
(C) Cumulative Data till Date (Today's Coverage + Cumulative Data till Previous day for District) (C=A+B)																		

Chief Medical Officer

District JE Program Officer

Form 6 : Micro Planning Format: JE Vaccination Campaign 2010

Micro Plan for J.E. Vaccination 200___: **District:**

PHC :

Ad. PHC : **Name of Nodal Officer (Superintendent / MOIC):**

Sub Centre:

Place		Beneficiaries		Date	Supervisor		Team Composition					
Village / Urban Area	Total Population	1-15 (Target)	Immunization Site	Immunization Day		Team No	ANM / Vaccinator 1	ANM / Vaccinator 2	AWW	Asha / Link Worker	Teacher	Volunteer

Name of the Nearest Referral Center for AEFI

Telephone No.

Name of Medical Officer for AEFI

Signature

Medical Officer IC PHC/CHC

Form 7: Logistic Planning Format: JE Vaccination Campaign 2010

Micro Plan for J.E. Vaccination

PHC :

Ad. PHC : **Name of Nodal Officer (Superintendent/ MOIC):**

Sub Centre:

Place		**Date**	**Beneficiaries**				**Logistic Supply**					
Village / Urban Area	**Immunization Site**	**Immunization Day**	**Total Population**	**1-15 (Target)**	**Supervisor**	**Team No**	**Vaccine Vials**	**AD Syringes**	**Reconstitution Syringe**	**Hub Cutter**	**Banner**	**Poster**

Name of the Nearest Referral Center for AEFI

Telephone No

Name of Medical Officer for AEFI

Signature

Medical Officer IC PHC/CHC

Form 8: FIR (AEFI): JE Vaccination Campaign 2010

Adverse Events Following Immunization (AEFI) Reporting Form

FIRST INFORMATION REPORT FORM
Adverse Events Following Immunization
(To be reported within 48 hrs to the GoI)

Case ID No.: IND (JE/AEFI)/_ _ /_ _ _ /_ _ / _ _ _
Use same coding as done for AFP cases, EPID number will be given by DIO / District JE Program Officer Only (ID will remain same on FIR / PIR for particular Case, Same ID should not be used for two or more Cases)

State	District
Block	Date of report
Name	
Age (DOB)	Sex: Male/Female
Mother's / Father's Name	
Complete Address of the case	
Date & time of vaccination	Date & time of onset of symptoms
Complete address of place of vaccination	
Vaccines given	
Batch Number & Expiry date of each vaccine	
Type of reaction	
Date of Death	
Any other comment[5]	

Name of person filling the report _____

Signature and Designation _____

On completion the form should be sent along with the monthly surveillance report of AEFI to Assistant Commissioner (UIP), CH division of Govt. of India (Fax No. 011-23062728 or email: (jeindia2007@yahoo.co.in)
Note: Use Form 12 for compilation and computerization of AEFI Line List.

[5] Preliminary report will follow in a week and detailed investigation report will be submitted in three months

Form 9: PIR (AEFI): JE Vaccination Campaign 2010

PRELIMINARY INVESTIGATION REPORT FORM

PRELIMINARY INVESTIGATION REPORT

Adverse Events Following Immunization

(To be reported within 7 DAYS to the GoI)

Case ID No.: IND (JE/AEFI)/_ _/_ _ _/_ _/ _ _ _

Use same coding as done for AFP cases, EPID number will be given by DIO / District JE Program Officer Only (ID will remain same as on FIR / PIR for particular Case, Same ID should not be used for two or more Cases)

State	District
Block	Date of report
Name:	
Age (DOB):	Sex: Male/ Female
Mother.s / Father.s Name	
Complete Address of the case	
Date & time of vaccination	Date & time of onset of symptoms
Vaccines given	
Complete address of place of vaccination	
Batch Number & Expiry date of each vaccine	
Type of reaction	
Date of Death	
Probable cause of death:	

Probable cause of the AEFI: Program error/ Vaccine reaction/ Coincidental/ Unknown Further action planned: Yes/ No (if Yes Details)

Any other comment:

Name of person filling the report: _____

Signature and Designation: _____

On completion the form should be sent along with the monthly surveillance report of AEFI to Assistant Commissioner (UIP), CH division of Govt. of India (Fax No. 011-23062728 or email: (jeindia2007@yahoo.co.in)

Note: Use Form 12 for compilation and computerization of AEFI Line List.

Form 10: DIR (AEFI): JE Vaccination Campaign 2010

DETAILED INVESTIGATION REPORT FORM

DETAILED INVESTIGATION REPORT Adverse Events Following Immunization (AEFI)
(To be reported within three months)
Adverse event following Immunization or Death after Immunization
Date of Investigation:

Case ID No.: IND (JE/AEFI)/_ _ /_ _ _ /_ _ / _ _ _
Use same coding as done for AFP cases, EPID number will be given by DIO / District JE Program Officer Only (ID will remain same as on FIR / PIR for particular Case, Same ID should not be used for two or more Cases)

1.	Name of child affected (In Block Letters)	
2	Name of Parents	Father's name Mother's name
3	Age and Sex	. ./. ./ . . Date of Birth Male/ Female yrs mo days (if know)
4	Full detailed address	
5	Place of immunization	Health facility/ Out reach session site/Field camp/ Hospital/ Maternity home/ Private clinic/ any other place
6	a. Date and time of immunization	
	b. Location of immunization session (Full address)	
7	No. of children immunized at the session	BCG___ DPT1___ DPT2___ DPT3___ DPT B___ OPV1___ OPV2___ OPV3___ OPV B___ HEPB 1___ HEPB 2___ HEPB 3___ MEASLES___ DT___ TT1___ TT2___ TT B___ VIT A___ OTHERS___
8	Date and time of onset of AEFI Date of Initial report	
9	Type of AEFI	
10	Was the patient admitted to hospital	Yes/ No/ Unknown

11	If Yes, date & Time of admission	
	Name of Hospital	
	Ward no	
	Centralized admission number	
	Outcome	Recovered/ still in hospital/ death/ unknown/ Residual problem
12	SYMPTOMS AND SIGNS	
	a. Time of onset	
	b. Sign of shock present/absent	
	c. Temperature	
	d. Pulse	
	e. Respiration	
	f. Convulsion	
	g. Vomiting	
	h. Diarrhoea	
	i. Altered sensorium	
	j. Rash	
	k. Any other symptoms & sign (pl specify)	
	l. Progress of symptoms and signs with brief history & chain of events (Please attach additional sheet if required or patient records if available)	
	m. Mention whether above sign and symptoms are seen by investigating officer or whether above sign and symptoms are noted from hospital record	

13	Treatment given (attach copy of case sheet, if available)	
14	GROWTH & DEVELOPMENT/PAST/ FAMILY HISTORY (please fill as relevant to case)	
	a. Type of Delivery	Normal delivery/ LSCS/ Assisted birth
	b. Gestation	Full term/Premature/Post dated
	c. Complications during birth	
	d. Birth weight (if possible)	
	e. Present Weight (if possible)	
	f. Present length/ height (if possible)	
	g. Present head circumference (if possible)	
	h. Developmental milestones	Gross motor
		Fine Motor
		Language
		Adaptive & Social
	i. Past illness like allergy, asthma, convulsion etc	
	j. Any previous history of similar event after immunization	Yes/ No/ Unknown
	k. Family history - history of epilepsy, allergy, asthma etc in the family	
	l. Any history of similar event in siblings	Yes/ No/ Unknown
	m. Was the child on any concurrent medication for any illness	Yes/ No/ Unknown If yes: Indication & Dosage

15	INFORMATION ON IMMUNIZATION (IN CASE PROGRAMME ERROR SUSPECTED)	
	a. Name of worker who administered vaccine	
	b. Designation	
	c. Length of service	
	d. Experience	
	e. When did worker receive the last training in immunization	
	f. Name of Health Assistant (Supervisor)	
	g. Designation	
	h. Length of service	
	i. Experience	
	j. When did Health Assistant (Supervisor) receive the last training in immunization	
16	k. Total number of mother and children immunized. Attached detailed list giving name/age/sex/vaccines given	
	l. Any history of similar event reported (among those vaccinated)	a. At same clinic: Yes/ No/ Unknown b. Using same vaccine type at previous clinic sessions: Yes/ No/ Unknown
	If Yes	Specify event Number Place
	m. Any history of similar event reported (among unimmunized)	a. At same clinic session: Yes/ No/ Unknown b. In the field: Yes/ No/ Unknown
	If Yes	Specify event Number Place

	n. At what stage was the index child immunized	a. Within the first few doses of the vial b. Within the last few doses of the vial c. Within the first vaccinations of the clinic session d. Within the last vaccinations of the clinic session e. Unknown
	o. Vaccination technique (observe the relevant vaccinator)	Reconstitution: Satisfactory/ Unsatisfactory/ Not observed
		Drawing of vaccine: Satisfactory/ Unsatisfactory/ Not observed
		Injection technique: Satisfactory/ Unsatisfactory/ Not observed
17	DETAILS OF VACCINE GIVEN PRIOR TO AEFI	
	a. Date of receipt of vaccine of implicated batch by	MoH/ State Regional Store District PHC/CHC/ Urban Health Center Sub center/ Out reach session site
	b. Status of maintenance of cold chain at	State
		Regional store
		District Head Quarter
		PHC/ Urban health post
		Subcenter
		Session Site
	c. Is there a suspicion of breach of cold chain as per records? (If so, when & where?)	
	d. Is there a suspicion of freezing of .T. series vaccines? (If so, when & where?)	
	e. Where are the vaccines and diluents stored	In the PHC/CHC: In the Subcenter: In the Clinic: Others (specify)
	f. How are the vaccines transported	In a vaccine flask or vaccine carrier/ In a cold box/ Others (specify)

	g. Is the packing of vaccine	Satisfactory/ Unsatisfactory/ Not observed
	h. Maintenance of cold chain for unopened/ opened vials during immunization session	Satisfactory/ Unsatisfactory/ Not observed
	i. Status of the vaccine storage in the refrigerator/s	Deep freezer: Satisfactory/ Unsatisfactory/ Not observed
		Status of the VVM: Satisfactory/ Unsatisfactory/ Not observed
		Main compartment of refrigerator: Satisfactory/ Unsatisfactory/ Not observed
	j. Are any other drugs or food stored in the refrigerator/s	Yes/ No/ Unknown If yes, specify
	k. If vaccine given by private practitioner, then	Source of vaccine: Govt supply/ procured from manufac turer/ pharmacy
		Status of cold chain at clinic: Satisfactory/ Unsatisfactory/ Not observed
		Status of cold chain at procurement site: Satisfactory/ Unsatisfactory/ Not observed
	IF VACCINE GIVEN DURING FIELD CAMP/ OUTREACH SESSION	
	l. Time of collection of vaccine from Health Post/ PHC for field camp immunization	

Time of receipt of vaccine at field camp site (immunization session site) n. Maintenance of cold chain during transit from Health Post/ PHC to field camp site o. Name of person collecting vaccine from fixed centre to field camp site p. Vaccines used q. If reconstituted, what diluent was used r. Which type of syringe was used for reconstitution? s. Practice of reconstitution t. Is the needle left in reconstituted vaccine vial u. Whether label of vial intact i) Batch No ii) Expiry date iii) Manufactured by v. Date and time when vial opened w. Date of vaccine sent for testing x. Result of sample of vaccine sent for testing y. Is the vaccine collected by FDA or SRA i) Name of the officer ii) Date when vaccine sent for testing	BCG/ DPT/ OPV/ Measles/ Hepatitis/ Vit A/ others (specify) Reusable/ Disposable/ AD Same syringe used for multiple vials of same vaccine/ Same syringe used for reconstituting different vaccines/ Separate syringe for each vial/ Separate syringe for each vaccine Yes/ No/ Not observed

	iii) Place where vaccine sent for testing	
	iv) Result of vaccine sent for testing	

18	STERLISATION OF SYRINGE AND NEEDLE	
	a. Types of syringes used to vaccinate the child.	Reusable/ Disposable/ AD
	b. Method of sterilization if reusable syringes used	
	c. Name and Designation of person who was responsible for autoclaving/ boiling for 20 minutes	
	d. Date and time of autoclaving/ boiling started	
	e. Date and time of autoclaving/ boiling completed	
	f. Sterilization satisfaction as per records of Signolac strip register	
	g. No of syringes & needles autoclaved	
	h. No of syringes & needles used for the session.	
19	INVESTIGATIONS DONE	
	a. Whether any blood tests were done	
	b. If yes, results of blood tests	
	c. Whether CSF was examined	
	d. If yes, result of CSF tests	
	e. Any other investigation done	
	f. Results of other investigations	

20	IN CASE OF DEATH	
	a. Any post mortem done	
	b. If yes, were was it done	
	c. Post mortem findings in brief (Please attach the post mortem report)	
21	Probable cause of death/ Residual problem	
22	Probable cause of AE	Programme error: Injection Sterility/ Vaccine reconstitution/ Administration technique/ Vaccine storage/ Vaccine transportation/ Unknown/ Others (specify)_____
		Vaccine reaction: Vaccine lot problem/ Known vaccine reaction at expected rate/ others
		Coincidental: Similar events in unimmunized/ others
		Unknown
23	Remarks including recommendation (or any addition information / action taken or to be taken)	

Name/s of the person doing investigation

Signature and Designation

Please attach photocopies of relevant documents such as case records, inpatient records, lab reports etc

If certain information is not available at the time of filling report to don.t delay in sending the report, please send the form within 90 days. You can forward additional information whenever it becomes available On completion the form should be sent along with the monthly surveillance report of AEFI to Assistant Commissioner
(UIP), CH division of Govt. of India (Fax No. 011-23062728 or email: aefi@rediffmail.com
Note: Use Form 12 for compilation and computerization of AEFI Line List.

Form 11

AEFI LABORATORY REQUEST FORM

This section should accompany specimens to the laboratory and be completed by the **sender** of the specimens

State: IND (JE/AEFI) / - - / - - - / - - / - - -			
Patient's Full Name Male / Female	Age(DOB)		Sex
Complete Address of patient			
Date of onset of symptoms of AEFI	Day	Month	Year
Date of collection of specimen	Day	Month	Year
Date specimen sent	Day	Month	Year
Precise description of the samples (Batch no / Expiry date / manufacturer / Quantity sent)			
How are specimens shipped (e.g. with ice pack)			
Tests requested			
Preliminary clinical diagnosis (working hypotheses)			
Name and complete address of person to whom laboratory results should be sent			
Telephone number: Fax number:			
Type of Sample Collected: Vaccine / Diluent / AD Syringe / Disposable Syringe / Blood / Serum / CSF / Stool / Any other specify_____			

Form 13: Supervisor's Checklist

Checklist for Mass Immunization 2010

JE Campaign Supervisory Checklist

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**

	Fill in the supervisor checklist at the visited site	**Site 1**	**Site 2**	**Site 3**	**Site 4**	**Site 5**
1	Name of the vaccination site and time of the visit					
2	Are the vaccinators present as per the micro plan? (Yes/No)					
3	Are the other team members as per the micro plan? (Yes/No)					
4	How was the vaccine distributed to the vaccination site(Describe)					
5	Are the team members managing the crowd at the site? (Yes/No)					
6	Does the vaccination site have visible IEC (Banner/Poster)? (Yes/No)					
7	Do the vaccinators have sufficient number of tally sheets and reporting formats? (Yes/No)					
8	Does the vaccination site have adequate 0.5 ml AD syringes? (= no. of Beneficiariesx1.1) (Yes/No)					
9	Does the vaccination site have adequate number of 5ml reconstitution syringes? (=No of vaccine provided vials)					
10	Does the vaccination site have adequate number of JE vaccination cards? (Yes/No)					
11	Does the vaccination site have sufficient number of AEFI forms available? (Yes/No)					
12	Does the vaccination site have the AEFI medicine Kit? (Yes/No)					
13	Is there an episode of AEFI? If yes was it reported to Sector In charge/MOI/C? Give Details.					
14	Are the vaccination cards and the counterfoil being filled up for the beneficiaries? (Yes/No)					
15	During the vaccination the ice packs in the vaccine carrier are found frozen? (Yes/No)					
16	Is the vaccination been done at the correct position and is been given subcutaneously? (Yes/No)					
17	Is the vaccinator using new reconstitution syringe for diluting each vaccine vial? (Yes/No)					
18	Is the vaccinator aware that a maximum time in which a reconstituted vaccine is to be used? (Yes/No)					
19	At the time of supervision how many beneficiaries have been vaccinated?					
20	Time of leaving the vaccination site by the supervisor.					

Signature Of Supervisor

Form 14: Monitoring Format

Japanese Encephalitis Vaccination Campaign, 2010

Monitoring Format

Name:_____ Designation:_____ Organization:_____

District:_____ Block/Urban Planning Unit:_____ Date:_____/_____/

Type of Site
School (S)
Sub Center (SC)
Aganwadi Center (AW)
Outreach RI Site (RI)
Others(O)

Site	Village/Mohalla	Site Name	Sub Center (Name of ANMs sub center)	Team No
1				
2				
3				

			Mark: YES (Y) or NO (N) or Don't know (DK)		
A. SITE ORGANIZATION			**Site-1**	**Site-2**	**Site-3**
A.1	The site is well marked with IEC ***(Poster/Banner)*** and can be easily identified				
A.2	Are vaccinators present as per Micoplan?				
A.3	Adequate mobilizers are present	Aganwadi Worker/Sahayika			
		Asha/Asha like mobilizer			
		School Teacher/Children			
		Gram Pradhan			
		Others			
		None			
A.4	Crowd is well controlled and session is going on smoothly				
B. SESSION CONDUCTION & INJECTION PRACTICE					
B.1	Only one vial is reconstituted at a time				
B.2	**Only 2.5 ml of diluent is used for reconstituting a vial? (observe a reconstitution process)**				
B.3	**Is vaccinator using a new mixing syringe for each vial for reconstitution (check by counting mixing syringes & vials)**				
B.4	Has vaccinator mentioned time of reconstitution on the vial				
B.5	**Is vaccinator aware the reconstitute vaccine should not be used after 2 hour of reconstitution?**				
B.6	Vaccinators administering the vaccine at the upper outer arm				
B.7	Vaccinators administering the vaccine through subcutaneous route				

B.8	Vaccinators following 'non-touch technique' during reconstitution, drawing and administering vaccine																			
B.9	Is Tally Sheet correctly marked immediately after vaccination of each child																			
B.10	Is vaccination card / Counter foil being filled for each beneficiaries																			
B. 11	**Are the numbers of filled cards matching with consumed doses?**																			
C. WASTE MANAGEMENT																				
C.1	Have used AD Syringes / mixing syringes being kept separately after use																			
C.2	Are vaccinators aware to send/carry the used AD Syringes / mixing syringes back to PHC/CHC																			
C.3	Other wastes are kept in a separate bag/container ***(blister pack, cotton, empty diluent ampoule, used vial)***																			
D. AEFI MANAGEMENT																				
D.1	AEFI reporting form available at the site																			
D.2	Do vaccinators know what to do in case of an AEFI ***(assurance, contact no for referral purposes and reporting)***																			
D.3	Are drug for AEFI available with vaccinator	Injection/ Tablet Avil																		
		Injection Dexamethasone																		
		Tablet Paracetamol																		
D.4	Does vaccinator have knowledge to administer these drugs correctly as per guideline																			
E. SUPERVISION																				
E.1	Did a Team Supervisor visit the team today ?																			
E.2	Did any officers/monitor visit the team today/yesterday?																			
F. COLD CHAIN																				
F.1	Is JE vaccine stored in vaccine carrier with 4 ice packs																			
F.2	Are ice packs frozen/semi frozen **(if melted write 'No' otherwise 'Yes')**																			
F.3	Cold chain maintained for diluents																			
F.4	Mode of vaccine transport from PHC/vaccine distribution point to session site	ANM																		
		Team Supervisor																		
		Others																		
G. LOGISTICS																				
G.1	Adequate JE vaccine vials are present at the site. ***Adequate = (target x 1.1) / 5***																			
G.2	Adequate AD syringe (0.5 ml) is present at the site. ***Adequate = target x 1.1***																			
G.3	Adequate Reconstitution syringe is present at the site. ***Adequate = # of JE vaccine vial supplied***																			
G.4	Adequate diluents vials are present at the site. ***Adequate = # of JE vaccine vial supplied***																			
G.5	JE vaccine and diluents are made of same manufacturer																			
H. SOCIAL MOBILIZATION/COMMUNICATION			**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**			
H.1	How beneficiary came to know about the campaign *(Interview maximum 5 respondent at each site)*	Drum Beating (Munadi)																		
		Miking																		

		Radio/TV/Newspaper																	
		Poster Banner																	
		JE Hand Bill																	
		School Teacher/Student																	
		Neighbour/ Friends																	
		Others																	
H.2	Whether mobilizer visited their houses to invite for vaccination																		
H.3	Are they aware of target age for vaccination in this campaign																		
I. Visit to block/Urban vaccine distribution point and review the followings			Yes, No or Don't know																
I.1	EPI cold storage	a. Vaccines are kept in correct temperature (between +2 to +8 C)																	
		b. Proper method of ice pack freezing is followed ***(ask Cold chain handler about the method he follows)***																	
I.2	AEFI management preparedness	a. Life saving drugs for AEFI management are available in the facility (inj. Adrenaline, inj. Hydrocortisone etc.)																	
		b. Concerned persons are alert and aware of use of these drugs																	
I.3	Waste disposal sites and practice	a. Collected wastes are kept in a secured place																	
		b. Is waste disposable pit present																	

Name & Signature of Monitor

Form 15: State Daily Reporting Format: JE Vaccination Campaign 2010

Japanese Encephalitis Vaccination Campaign
Block 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*

	1 to 5 years		5-10 years		10 to 15 years		Total		Grand total (M+F)	Vaccine Vials			AD Syringes			Disposable Syringes		
District	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**		**Received**	**Used**	**Balance**	**Received**	**Used**	**Balance**	**Received**	**Used**	**Balance**
TOTAL																		
Above 15																		

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)																		
(C) Cumulative Data till Date (Today's Coverage + Cumulative Data till Previous day for State) (C=A+B)																		

SEPIO

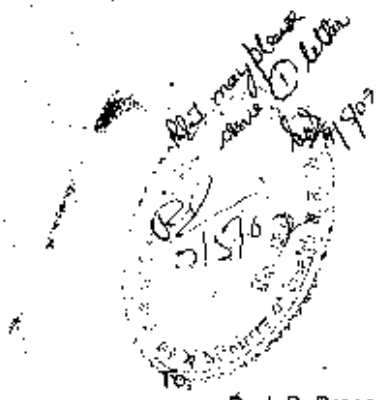
State JE Program Officer

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

Appendix H: IEC Prototypes

Prototype 1-7

Appendix I – GoI Letter



File No T-22014/11/2006 CC & V
Government of India
Ministry of Health & Family Welfare
(Department of Family Welfare)

Nirman Bhawan, New Delhi
Dated the 07th May, 2007

To,

Dr. L.B. Prasad
Director General (FW)
Swasthya Bhawan,
Lucknow, Uttar Pradesh.

Dear Sir,

Kindly refer to your letter no MAL/B/2007/883 dated the 3rd May,2007 regarding interval between administration of two live vaccine.

In this regard, the opinion of WHO was sought and WHO has informed that they do not have a position that conflicts with administration of Live attenuated JE vaccine & OPV at an interval of less that 4 weeks.

Copy of the letter is enclosed for your information.

With Regards

Yours Sincerely

(Dr. P. Biswal)
Assistant Commissioner (Immunization)

Appendix – J
States of India Reporting AES and JE Cases

1. Andhra Pradesh
2. Arunanchal Pradesh
3. Assam
4. Bihar
5. Haryana
6. Goa
7. Karnataka
8. Kerala
9. Maharashtra
10. Manipur
11. Nagaland
12. Tamil Nadu
13. Uttrakhand
14. Uttar Pradesh
15. West Bengal

List of sentinel sites for JE

Sl. No.	STATES	No. of Sentinel sites
1.	Andhra Pradesh	5
2.	Assam	5
3.	Uttar Pradesh	15
4.	Maharashtra	5
5.	Bihar	2
6.	Tamil Nadu	5
7.	Kerala	1
8.	West Bengal	2
9.	Goa	1
10.	Karnataka	3
11.	Haryana	4
13	Manipur	1
	Total	50

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