



**Answers to Frequently Asked Questions on Dengue and the Dengue Vaccine
Pediatric Infectious Disease Society of the Philippines
20 February 2018**

Updated 03 March 2018

The furor created by the media release on the safety of the dengue vaccine prompted the Pediatric Infectious Disease Society of the Philippines (PIDSP) to issue a response, dated 12 December 2017¹, addressing the concerns of clinicians pertinent to the use of the vaccine. As a supplement to the previously released response, PIDSP drafted this current document to provide guidance to physicians during clinic consultations where issues on dengue and the dengue vaccine are raised.

Frequently Asked Questions on Dengue:

1. How do we prevent dengue infection?

The most important step to reduce the risk of dengue infection is prevention of contact with the mosquito vector. An integrated approach for the control of the mosquito vectors and interruption of human–vector contact is crucial for dengue prevention. This includes a combination of strategies such as environmental management to prevent or minimize vector propagation and human contact, eliminating mosquito habitats in residences and in the community, correct application of insecticides or biological control agents that will target adult mosquitoes or larvae, and use of appropriate measures for individual and household protection.

The Philippine Department of Health (DOH) promotes the “4-S” for dengue prevention which includes the following strategies²

1. Search and Destroy:
Eliminate mosquito larvae breeding sites in your surroundings and cover containers with collection of stagnant water
2. Self-Protection Measures.
Use mosquito repellent and cover yourself up to avoid mosquito bites
3. Seek Early Consultation
Consult a medical specialist at once for fever and rash of 2 days duration
4. Say No to Indiscriminate Fogging
Fogging only during outbreaks

2. What is dengue vaccine (Dengvaxia)?

The dengue vaccine, (Dengvaxia®), developed by Sanofi Pasteur, is a live recombinant tetravalent dengue vaccine, based on the yellow fever 17D vaccine strain, and has 4 components, encoding for antigens of the four dengue virus strains. The vaccine is given as a 3 dose series with 6 months interval between doses³. It is the first dengue vaccine licensed, and has been approved by regulatory authorities in 19 countries for use in endemic areas in individuals 9 to 45 years of age.³ It has been introduced in two subnational programs in 2 countries, the Philippines and Brazil targeting about one million individuals. It is also available on the private market in countries where there is a marketing authorization.⁴

3. Will a child get dengue after receiving the dengue vaccine?

NO. The vaccine does not cause dengue infection. Dengue is a febrile illness caused by the bite of an Aedes mosquito carrying the dengue virus.

4. What are the present recommendations for the use of the dengue vaccine?

In the document released by the WHO on 22 December 2017, they recommended “vaccination only in individuals with a documented past dengue infection, either by a diagnostic test or by a documented medical history of past dengue illness.”³

PhilFDA Advisory 2017-318, dated 4 December 2017, directed Sanofi to suspend the sale/distribution/marketing of Dengvaxia and caused the withdrawal of the vaccine in the market pending compliance with the directives of the FDA.⁵

On 10 January 2018, the DOH created a National Expert Panel to provide technical assistance to the DOH Dengue Task Force on scientific/medical concerns related to the dengue vaccine (CYD-TDV). “In view of the sparse information from the clinical trials on the consequences of administration of less than three doses of Dengvaxia, a firm recommendation to complete the schedule of vaccination cannot be given. However, for children with incomplete doses who had been confirmed to have had dengue before Dengvaxia vaccination, completion of doses may be protective.”⁶

5. What is the stand of the World Health Organization (WHO) regarding dengue vaccine administration?

The WHO published a position paper on Dengue vaccine last July 2016. This position paper presents a conditional recommendation on the use of the vaccine in areas where dengue is highly endemic. Based on considerations of superior efficacy, safety and duration of protection, trial results and mathematical modelling suggested optimal benefits of vaccination if seroprevalence in the age group targeted was $\geq 70\%$.⁴

In 2017 Sanofi Pasteur re-analyzed the trial data in participants classified as seronegative and seropositive to estimate the long-term safety and efficacy of the vaccine by serostatus prior to vaccination using an in-house diagnostic tool. The following is the WHO interim interpretation of the data:

1. The vaccine significantly protects against hospitalized and severe dengue in seropositive subjects for dengue at time of first vaccination in all age groups studies.⁴
2. The risk for hospitalization and severe dengue is significantly increased among vaccinated subjects who were seronegative at time of first vaccination in all age groups.⁴
3. Pending full review of data, WHO recommends that Dengvaxia is only administered to subjects who are known to have been infected with dengue prior to vaccination.⁴

6. How would you know if your patient has had previous dengue infection?

Most primary dengue infections are mild and subclinical. The laboratory tests available (Dengue PCR, dengue NS1 antigen test, dengue serologic tests) are tests used to confirm dengue infection and to conduct seroprevalence studies among selected populations but are not used to check for individual dengue serostatus prior to vaccination.⁷

- Plaque reduction neutralization test (PRNT) can be used to test for serostatus but this is only done in RITM, is expensive, and turnaround time is 1 month and is not always available. This test is mainly used for research purposes.⁷
- The dengue NS1 IgG ELISA antibody assay used by Sanofi Pasteur to check for serostatus is an in-house test developed specifically for this purpose and is not commercially available.

In the absence of a reliable laboratory test to determine serostatus prior to vaccination, a documented history of previous dengue infection (e.g. hospitalizations, positive dengue tests during confinement or OPD consultation) may be used.

7. If a patient has been given one or two doses of the dengue vaccine, do we continue giving the vaccine?

Participants in the studies on dengue vaccine received 3 doses of the vaccine so there are currently no data on the efficacy or safety of the vaccine in individuals given only one or two doses, either for seronegatives or for seropositives. The long term protective effect of the vaccine in seropositive individuals who received fewer than 3 doses is unknown. It is also not known if the risk of severe disease in seronegative individuals will be determined by the number of vaccine doses they have received. Hence, we do not have sufficient data on the benefits or potential risks of completion or suspension of vaccination in those who were already given one or two doses.³

However, since the vaccine is protective in seropositive individuals, completion of the three doses may be considered in those with documented dengue infection prior to dengue vaccination, as confirmed by an appropriate laboratory test (dengue PCR, dengue NS1 antigen test, or dengue serology), or by a documented medical history of past dengue illness. Those who are known to be seronegative prior to vaccination should not receive further doses. For those with uncertain history of dengue infection or unknown serological status, it is prudent to hold further doses of the vaccine.

8. What are the possible side effects of the dengue vaccine?

Local and systemic adverse reactions following vaccination with the CYD-TDV (Dengvaxia) are comparable to those recorded for other live attenuated vaccines.⁸ In the clinical trials, these side effects usually happened within the first 2 weeks after vaccination, were generally mild to moderate and resolved rapidly. The reported side effects included the following⁹:

Very common side effects (may affect > one user in 10) Headache, muscle pain, generally feeling unwell, feeling of weakness, injection site pain, fever

Common Side effects (may affect up to one user in 10) Infection site reaction, redness, bruising (hematoma), swelling and pruritus

Uncommon (may affect up to one user in 100) Infection of the upper respiratory tract, dizziness, sore throat, runny nose, nausea, skin eruption (rash), neck pain, hardening of the skin at injection site (infection site induration)

As with any vaccine, there is a possibility of an allergic reaction. Serious allergic reaction are rare (may affect up to one in 10,000 people) and may manifest as difficulty breathing, blueness of tongue and lips, rash, swelling of face or throat, low BP causing dizziness or collapse.⁹ If such a reaction occurs, it is usually almost immediately after vaccination. This is why it is important that patients be advised to remain at the clinic for 30 minutes for observation and you should be able to provide immediate medical attention if needed.

Two 17D yellow fever vaccine associated reactions are of theoretical concern in CYD vaccine recipients because some parts of 17D YF vaccine genome had been used as backbone for CYD vaccine. These two are: (1) Yellow Fever Vaccine-Associated Neurologic Disease (YEL-AND) and (2) Yellow fever Vaccine-Associated Viscerotropic Disease (YEL-AVD). They remain theoretical risks because they have never been reported so far in any previous and ongoing dengue studies.

YEL-AVD resembles wild-type yellow fever affecting multiple visceral organs causing organ failure and death in at least 60% of cases.¹⁰ The rate of YEL-AVD is increased in the elderly.¹¹ This condition has been reported in primary vaccinees only, with an average onset of 4 days (range: 0–8 days) after vaccination. Diagnosis can be made by RT-PCR detection of the YF vaccine virus from serum or tissues.¹⁰

YEL-AND is a rarely fatal serious adverse event reported almost exclusively following primary vaccination. The onset range is 3–28 days following vaccination with the average onset on day 14. Manifestations include meningoencephalitis (most common) due to direct infection of the CNS by the vaccine virus, and GBS and ADEM, which are believed to be autoimmune mediated. CSF should be obtained to test for the presence of YF vaccine virus or YF virus-specific antibodies.¹⁰

Viral tropism, which is the affinity for a specific cell type or tissue, is known to be largely linked with the virus envelope, and in the case of the CYD vaccine viruses, the E gene is inherited from the dengue virus, not yellow fever. The CYD viruses are therefore incapable of expressing the E protein of yellow fever 17D (backbone of the vaccine) and are consequently unlikely to display the same tropism and risk for viscerotropism disease.^{12,13}

Antibody-dependent enhancement (ADE) is a phenomenon that may occur when non-neutralizing antibodies produced after a previous dengue infection or dengue vaccination results in more severe disease with a second exposure to a dengue virus of another serotype.¹⁴ In a vaccinated person, ADE may occur after exposure to wild type dengue infection if there is inadequate antibody response or waning antibody response to any of the dengue virus serotypes. Although ADE is a plausible explanation for increased severity of secondary dengue cases, it still needs definitive proof in-vivo. The role of other factors influencing severity, including T cells and dendritic cells, and mechanisms of viral entry, among others, are being investigated.^{15,16}

The risks of the study vaccine to a pregnant woman, an unborn or nursing baby are unknown at this time. Therefore pregnant or breastfeeding women (including adolescents) should not receive the dengue vaccine.⁸

9. What is an Adverse Event Following Immunization (AEFI), how is it reported and what steps are important in the assessment of a child who develop AEFI?Perhaps

Adverse Event Following Immunization (AEFI) is defined as “any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.”¹⁷

The following AEFIs should be reported by the healthcare provider:¹⁸

- Serious AEFIs (results in death, is life-threatening, requires in-patient hospitalization or prolonged hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage)
- Signals and events associated with a newly introduced vaccine
- Significant events of unexplained cause occurring within 30 days of vaccination
- Events causing significant parental or community concern

- Swelling, redness, soreness at the injection site if it lasts for more than 3 days or swelling extends beyond nearest joint.
Reporting can be done using the AEFI Case Investigation Form. (Pls refer to Appendix I).

The health provider should take a complete clinical history including all relevant medical events that occurred following vaccination, the patient's past medical history, family history, immunization history, and social and environmental history. A thorough physical examination should also be taken. This will help the health provider determine whether the side effect, or AEFI, could have been caused by the vaccine or may just be coincidental to the administration of the vaccine. The health provider may prescribe medications based on the findings or may decide to request for specific laboratory tests that will help determine the cause for the patient's symptoms. If the side effect is assessed by the health provider to be serious or severe, admission to the hospital may be warranted.

10. What do you advise the parents of patients who develop side effects post vaccination?

Patients and their parents should be advised as to what side effects may be expected after vaccination (*pls .refer to FAQ no. 8*). All patients who develop side effects post vaccination regardless of severity should consult their health provider. Immediately after vaccination, symptomatic management of local reactions such as compresses for local swelling or pain at injection site and paracetamol for fever or pain may be advised. Additional tests and medical management may be recommended based on the signs and symptoms that develop.

11. What is the definition of "severe dengue" used in the study?

IDMC (Independent data monitoring committee) classified dengue cases as severe. Severity of dengue episodes was assessed using the 1997 WHO criteria for defining dengue hemorrhagic fever (DHF)¹⁹ since clinicians are more familiar with this definition:

The following must be present:

- Fever, or history of acute fever lasting 2-7 days occasionally biphasic
- Hemorrhagic tendencies, evidenced by at least one of the following:
 - Positive tourniquet test
 - Petechiae, ecchymosis, or purpura
 - Bleeding from mucosa, gastrointestinal tract, injection sites or other locations
 - Hematemesis or melena
- Thrombocytopenia ($100,000/\text{mm}^3$ or less)

- Evidence of plasma leakage due to increased vascular permeability manifest by at least one of the following:
 - A rise in haematocrit \geq 20% above average for age, sex and population
 - A drop in haematocrit following volume-replacement treatment \geq 20% of baseline
 - Signs of plasma leakage i.e. pleural effusion, ascites, and hypoproteinemia

Dengue Shock Syndrome(DSS)¹⁹: for a case of DSS, all four criteria for DHF must be met, in addition to evidence of circulatory failure manifested by:

Rapid and weak pulse and
Narrow pulse pressure (<20 mm Hg or 2.7 kPa)

Or manifested by

Hypotension for age and
Cold clammy skin and restlessness

- In the clinical trials, for those aged 9 years and above, the cases of severe dengue that occurred in initially seronegative vaccine recipients were categorized by the company as Dengue Hemorrhagic Fever Grades I and II and did not lead to shock, severe bleeding or death.³

12. What is the absolute risk of severe dengue in the vaccinated and unvaccinated trial populations by serostatus?

The risk depends on the yearly incidence of dengue. Based on the incidence in the epidemiological settings of the trials, for persons aged 9 years and above, the new analysis indicates that the 5-year risk of severe dengue in vaccinated seronegative persons is 4 per 1,000 seronegative persons vaccinated. This means that there are about 2 additional severe dengue cases per 1000 seronegative persons compared to the unvaccinated seronegative persons where the risk is 1.7 per 1,000 seronegative persons. However, the risk of severe dengue in vaccinated seronegative persons is similar to the risk of severe dengue in unvaccinated seropositive persons (4.8 per 1,000 seropositive persons unvaccinated). In addition, there is no evidence that clinical manifestations of disease were more severe in vaccinated seronegative persons compared to unvaccinated seropositive persons. The risk of severe dengue in vaccinated seropositive persons is the lowest where it is less than 1 per 1,000 seropositive persons vaccinated. In high-burden countries where majority of vaccine recipients are expected to be seropositive at vaccination, the risk of severe dengue may be reduced for the entire vaccinated population, overall, compared to a non-vaccinated population.³



13. How do you report patients who develop adverse events following dengue vaccination?

Any suspected adverse reaction following the use of dengvaxia should be reported in accordance with the national spontaneous reporting system to the Philippine Food and Drug Administration:²⁰

email address: adr@fda.gov.ph

FDA trunkline +632-165-332

Or to

Sanofi Philippines Pharmacovigilance Unit

Telephone: +632 859555 / email: PV.Philippines@sanofi.com

21F One World Place Corporate Offices

32nd Street, Bonifacio Global City

Taguig City 1634, Philippines

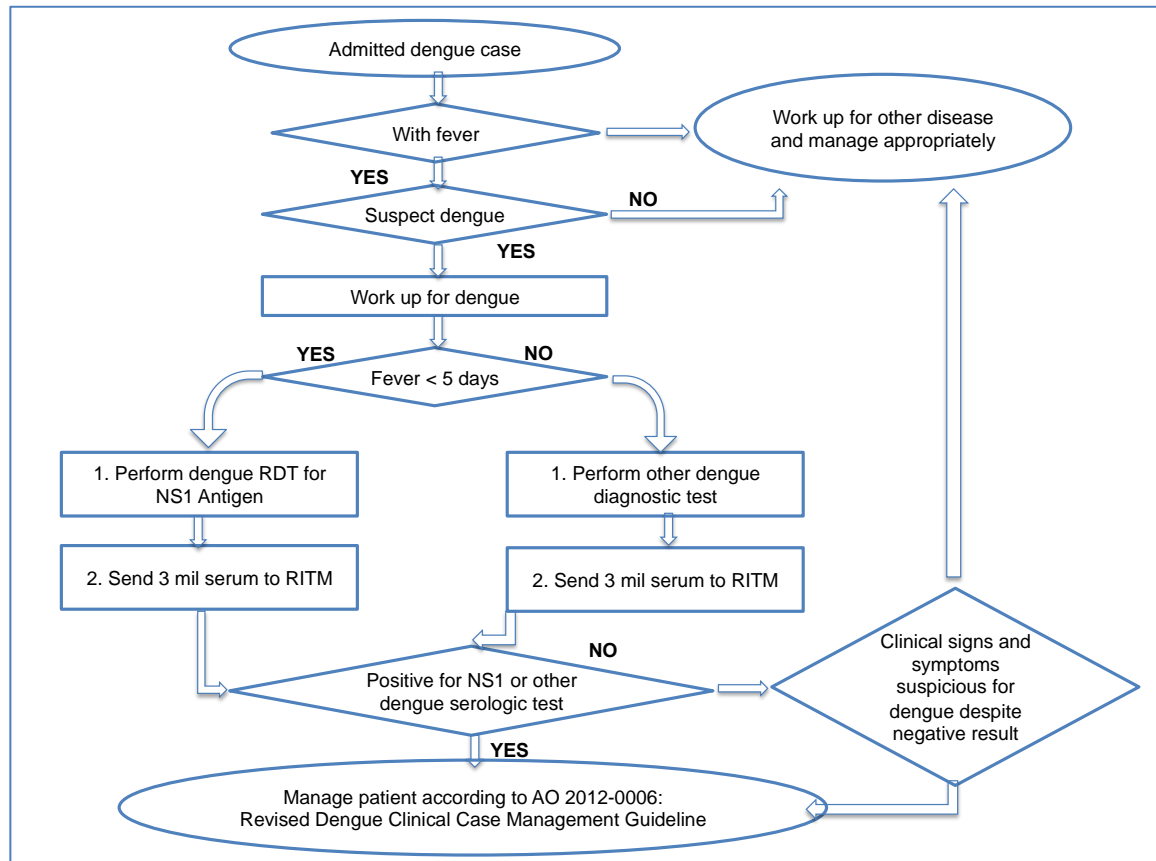
When reporting, it is important to provide as much information as possible, including information about medical history, any concomitant medication, onset of symptoms and treatment dates, product name and batch details.

14. What do you do with patients who were vaccinated with at least 1 dose of Dengue vaccine who develop fever?

The DOH-Epidemiology Bureau launched an Enhanced Dengvaxia Surveillance²¹ following the release of the new findings on the dengue vaccine by Sanofi. Pertinent information contained in this surveillance is as follows:

- Establish a Dengvaxia Surveillance in all hospitals and immediately report all vaccinated cases fulfilling the Dengvaxia AE Surveillance Case Definition:
 - Case Definition:
An individual who received at least one dose of Dengvaxia who:
 - Became ill and was admitted to a health facility for any reason
or
 - Died for any reason
- Case Notification applies to the following: any patient (regardless of age or address), who is admitted (for any reason) and vaccinated with Dengvaxia.
 - For such cases, the DOH should be informed immediately (NCR: 0917-829-0007 / 535-1488)
 - Needed information are as follows: name, age, sex, municipality or city (and province), hospital where the patient is admitted, date admitted, admitting diagnosis, and status (whether still admitted, discharged alive, or died)

- The surveillance uses the following algorithm for the laboratory confirmation of dengue in admitted vaccinees with fever:





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APPENDIX I: AEFI CASE INVESTIGATION FORM

Case Investigation Form (Only for Serious AEFI - Death/ Disability/ Hospitalized/ Cluster of Minor AEFI)																																					
Version 2015																																					
Name of DRU: _____ Type: <input type="checkbox"/> RHU <input type="checkbox"/> CHO <input type="checkbox"/> Gov't Hospital <input type="checkbox"/> Private Hospital <input type="checkbox"/> Clinic Address: _____ <input type="checkbox"/> Gov't Laboratory <input type="checkbox"/> Private Laboratory <input type="checkbox"/> Airport/Seaport																																					
I. PATIENT INFORMATION	EPIID Number _____ Patient's First Name _____ Middle Name _____ Last Name _____ Complete Address: _____ District _____ ILHZ _____ Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female Date of Birth: MM/DD/YYYY Age _____ <input type="checkbox"/> Days <input type="checkbox"/> Months <input type="checkbox"/> Years Height: _____ cm Weight: _____ kg Date Admitted/Seen/Consult: MM/DD/YYYY Name of hospital/health facility: _____ Address: _____ Admitted? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Date onset of AEFI/ present illness: MM/DD/YYYY TIME (hh:min:sec) _____ Date next higher level notified: ____/____/____ Date of Investigation: ____/____/____ Name & Designation of Reporter: _____ Institution: _____ Contact #/email: _____ Name & Designation of Investigator: _____ Institution: _____ Contact #/email: _____																																				
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AEFI Case Investigation Form

Version 2015

2/4

IV. EXAMINATION** DETAILS						
Source of Information	<input type="checkbox"/> Attending physician <input type="checkbox"/> Nurse <input type="checkbox"/> Midwife <input type="checkbox"/> Parent/Guardian <input type="checkbox"/> Other _____					
Mode of examination	<input type="checkbox"/> Interview <input type="checkbox"/> Medical records <input type="checkbox"/> Physical Examination <input type="checkbox"/> Verbal autopsy <input type="checkbox"/> Laboratory Result <input type="checkbox"/> Other _____					
If from Verbal autopsy, please mention the source: _____						
Name & Designation of person who first examined the patient:	Date & time:					
Signs & Symptoms in Chronological Order: **Instructions – Attach copies of ALL available documents (including case sheet, discharge summary, case notes, lab and autopsy reports) and then complete additional information NOT AVAILABLE in existing documents. <i>If patient has taken medical care - Attach copies of all available documents (including case sheet, discharge summary, laboratory reports and post mortem reports - if available) and write only information unavailable in the attached documents below.</i> <i>If patient has not taken medical care – examine the patient and write down your findings below (use additional sheets if necessary)</i>						
Working/Final Diagnosis:						
Condition at Investigation: <input type="checkbox"/> Alive : <input type="checkbox"/> Recovering <input type="checkbox"/> Fully recovered <input type="checkbox"/> With Permanent Disability, Specify: _____ <input type="checkbox"/> Died, Date: ____/____/____						
V. Relevant patient information prior to immunization	YES/NO	Remarks				
History of allergy						
Pre-existing illness / congenital disorder						
History of hospitalization in last 30 days (indicate the cause)						
Recent history of trauma (indicate date, time and site)						
For adult women • Currently pregnant? (If YES, indicate AOG) • Currently breastfeeding?						
For infants • Natal History • Delivery	<input type="checkbox"/> Full term <input type="checkbox"/> Premature <input type="checkbox"/> Postdated <input type="checkbox"/> Normal <input type="checkbox"/> Caesarian Section <input type="checkbox"/> Assisted birth <input type="checkbox"/> Any complication, specify					
Was the patient on any concurrent medication for any illness? (If YES, indicate name of drug, indication, doses & date in the remarks)						
Family History of similar event						
Did the patient receive any previous vaccination and experienced the similar event? <input type="checkbox"/> NO <input type="checkbox"/> YES (If YES, complete the table below)						
Vaccine	Date of Vaccination	Time of Vaccination	Batch/ Lot No.	Name of Manufacturer	Expiry Date	Name of Vaccinator



PEDIATRIC INFECTIOUS DISEASE SOCIETY OF THE PHILIPPINES, INC.

A Subspecialty Society Accredited by PMA and PPS

AEFI Case Investigation Form

Version 2015
3/4

IV. IMMUNIZATION PRACTICES <i>(Fill up this section by asking and observing immunization practices at the place (s) where concerned vaccine was used)</i>		
Syringes and Needles Used	YES/NO/NA*	Remarks
Are auto-disable syringes used for immunization?		
If NO, specify the type: <input type="checkbox"/> Glass <input type="checkbox"/> Disposable <input type="checkbox"/> Recycled disposable <input type="checkbox"/> Pre-filled syringes <input type="checkbox"/> Other _____		
Specific key findings/additional observations and comments:		
Reconstitution procedure (complete only if applicable) * Not applicable		
Same reconstitution syringe used for multiple vials of same vaccine?		
Same reconstitution syringe used for reconstituting different vaccines?		
Separate reconstitution syringe for each vaccine vial?		
Separate reconstitution syringe for each vaccination?		
Are the vaccines and diluents used as recommended by the manufacturer		
Specific key findings/additional observations and comments:		
Injection technique of vaccinator (s): (Observe another session in the same locality –same or different place)		
Correct dose and route?		
Time of reconstitution mentioned on the vial (in case of freeze dried vaccines)?		
Non-touch technique followed?		
Contraindication screened prior to vaccination?		
How many AEFI reported from the center that distributed the vaccine in the last 30 days?		
Training received by the vaccinator: (Title)		If YES, specify date of last training ____/____/____
Specific key findings/additional observations and comments:		
V. COLD CHAIN AND TRANSPORT <i>(Fill up this section by asking and observing practice)</i>		
Last vaccine storage point:	YES/NO	Remarks
Type of vaccine storage: <input type="checkbox"/> Freezer <input type="checkbox"/> Refrigerator <input type="checkbox"/> Dry Store <input type="checkbox"/> Other, specify:		
Temperature: Body of refrigerator _____ °C Freezer: _____ °C		
Correct procedure of storing vaccines, diluents and syringes followed?		
Any other item (other than vaccines and diluents) in the refrigerator or freezer?		
Partially used reconstituted vaccines in the refrigerator?		
Unusable vaccines in the refrigerator?		
If YES, check all that apply: <input type="checkbox"/> expired <input type="checkbox"/> no label <input type="checkbox"/> VVM Stage 3/4 <input type="checkbox"/> Frozen		
Unusable diluents in the storage area?		
If YES, check all that apply: <input type="checkbox"/> expired <input type="checkbox"/> manufacturer not matched <input type="checkbox"/> cracked <input type="checkbox"/> dirty ampule		
Specific key findings/additional observations and comments:		
Vaccine transportation:		
Vaccine carrier used: <input type="checkbox"/> Polyurethane Foam Insulation <input type="checkbox"/> Insulated Plastic Container <input type="checkbox"/> Styrofoam <input type="checkbox"/> Other, specify		
Vaccine carrier sent to the site on the same day of vaccination?		
Vaccination carrier returned from the site on the same day of vaccination?		
Condition of the vaccine carrier: Was ice-pack used?		
Specific key findings/additional observations and comments:		



AEFI Case Investigation Form

VI. VACCINE DETAILS (Indicate vaccines provided at the site linked to AEFI on the corresponding day)									
Number of recipients immunized for each antigen at the session site. Attach record (s) if available	Vaccine Name								
	Total Doses Given								
NOTE: Provide explanation for each YES answers on the following:									YES/NO/#
a) When was the patient immunized? (Tick box below)									
<input type="checkbox"/> Within the first vaccinations of the session <input type="checkbox"/> Within the last vaccinations of the session <input type="checkbox"/> Unknown <input type="checkbox"/> Within the first few doses of the vial administered <input type="checkbox"/> Within the last doses of the vial administered <input type="checkbox"/> Unknown									
b) Was the recommendation for use of this vaccine not followed?									
c) Based on the investigation, does the vaccine (ingredients) administered could have been unsterile?									
d) Based on the investigation, does the vaccine's physical condition (e.g. color, turbidity, foreign substances etc.) was abnormal at the time of administration?									
e) Based on the investigation was there an error in vaccine reconstitution/preparation by the vaccinator (e.g., wrong product, wrong diluent, improper mixing, improper syringe filling etc.)?									
f) Based on the investigation, was there an error in vaccine handling? (e.g. Break in cold chain during transport, storage and/or immunization session etc.)?									
g) Based on the investigation, was the vaccine administered incorrectly (e.g. wrong dose, site or route of administration, wrong needle size, not following good injection practice etc.)?									
h) Number of OTHER recipients immunized from the concerned vaccine vial/ampule									
i) Number of OTHER recipients immunized with the concerned vaccine in the same session:									
j) Number of OTHER recipients immunized with the concerned vaccine having the same batch number in other locations: _____ Specify locations: _____									
k) Is this case a part of a cluster?									
If yes, how many other cases have been detected in the cluster?									
a. Did all the cases in the cluster receive vaccine from the same vial?									
b. If No, Number of vials used in the cluster (enter details separately)									
VII. COMMUNITY INVESTIGATION									
Any known similar events reported recently in the locality/community? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNK									
a. If YES, Describe:									
b. How many events/episodes?									
Of those affected, how many are: Vaccinated _____ Not vaccinated _____ <input type="checkbox"/> Unknown									
Other significant findings in the community									
VIII. CAUSALITY ASSESSMENT									
<input type="checkbox"/> NAEFIC			<input type="checkbox"/> RAEFIC			Date Classified: _____			
<input type="checkbox"/> [A1] Vaccine product-related reaction			<input type="checkbox"/> [A4] Immunization anxiety-related reaction						
<input type="checkbox"/> [A2] Vaccine quality defect-related reaction			<input type="checkbox"/> [B1] Consistent temporal relationship but insufficient evidence						
<input type="checkbox"/> [A3] Immunization error-related reaction			<input type="checkbox"/> [B2] Conflicting trends of consistency and inconsistency with causality						
<input type="checkbox"/> error in vaccine handling			<input type="checkbox"/> [C1] Co-incident - Underlying emerging condition (s) or exposure to external factors/something other than vaccine						
<input type="checkbox"/> error in vaccine prescribing or non-adherence to recommendations for use			<input type="checkbox"/> [D] Unclassifiable/Inadequate information						
<input type="checkbox"/> error in administration									
<input type="checkbox"/> Other, specify _____									