# Guidelines for responding to dog bites in Timor-Leste including pre- and post-exposure rabies prophylaxis

# Democratic Republic of Timor-Leste Ministry of Health





#### in collaboration with



Timor-Leste

#### **Menzies School of Health Research**



#### **Australian Government Department of Foreign Affairs and Trade**



World Health Organization Country Office for Timor-Leste

#### Disclaimer

The Australian Government through the Department of Foreign Affairs and Trade has contributed to the development of this publication. The views expressed in this publication are the authors' alone and are not necessarily the views of the Australian Government.

#### **Preface**

Dog bites are a common incidence in Timor-Leste. Dog bites and suspected rabies cases are notifiable conditions according to the Integrated Disease Surveillance and Response (IDSR) guidelines – they need to be notified to Departamento Vijilansia. Suspected rabies cases need to be notified immediately (within 24 hours).

Dog bites can result in infection from oral bacteria, loss of function of limbs, scarring, permanent disability or even death. Dog bites also cause mental trauma, with most bites occurring against children. There is the additional and serious risk of rabies infection, which, as of 2023, has not been documented in Timor-Leste. Rabies is a viral zoonotic disease responsible for over 59,000 human deaths every year. Rabies is almost invariably fatal as soon as symptoms appear, as a result of acute progressive encephalitis. The neighboring Indonesian province of Nusa Tenggara Timur (NTT) experienced an outbreak of human cases of rabies in 2023.

In response to the increased threat of rabies cases in Timor-Leste, the National Institute of Public Health (INSPTL) in the Timor-Leste Ministry of Health has produced these guidelines which aim to briefly describe the key activities required when responding to dog bites.

These guidelines are intended to be used by clinicians and public health to respond to people presenting after dog bite injuries. These guidelines can also be used as a guide to follow up bites from other animals which can potentially carry the rabies virus such as monkeys and bats.

Simple clinical and public health measures can be commenced in order to avoid bad health outcomes or death. Simple measures such as washing wounds, taking a bite history, following antibiotic guidelines and administering both tetanus and rabies vaccine where appropriate. These guidelines contain the basic information required in order to respond to dog bites and provide rabies vaccine when appropriate. This document also contains references and links to further information should that be required.

Support for the development of this guideline has come from Menzies School of Health Research, Partnerships for Human Development (PHD), the Australian Government Department of Foreign Affairs and Trade (DFAT) and the World Health Organization (WHO).

We hope that this guideline can serve as a tool to enable Timorese professionals to respond to dog bites in a way that minimizes the risk of infection disability and prevents cases of human rabies in Timor-Leste.

Finally, I trust you will use this guideline to carry out your tasks as health professionals in Timor-Leste in order to serve our countrymen and women.

Obrigada Dili, November 2023



<u>Dra. Merita Antonia Armindo Monteiro, MPH</u>
Presidente do Conselho Consultivo INSP-TL

### Brief guidelines for responding to dog bites in Timor-Leste

Objective: These guidelines are intended to be used by clinicians and public health to respond to people presenting after dog bite injuries. These guidelines can also be used as a guide to follow up bites from other animals which can potentially carry the rabies virus such as **monkeys** and **bats**.

#### **Key Points**

- 1. Dog bites injuries where the skin is broken pose a high risk of infection from bacteria or from rabies virus. These should be considered to be contaminated wounds; wash thoroughly and urgently for at least 15 minutes. Even if there is a delay, wash thoroughly and urgently.
- 2. **Rabies vaccine is available and recommended in Timor-Leste**, after a dog-bite. Depending on the exposure and patient history, rabies immunoglobulin may be indicated.
- 3. **Tetanus vaccine is available and recommended in Timor-Leste**, after a dog-bite.
- 4. Rabies vaccine even after rabies exposure can protect from development of rabies disease.
- 5. Consider providing analgesia/anaesthesia/sedation to facilitate washing and wound examination.
- 6. Dog bite wounds should be assessed carefully for depth and injury to underlying structures.
- 7. Most bite injuries should be left open, without primary closure.
- 8. **Dog bites and suspected rabies cases are notifiable conditions** according to the <u>Integrated Disease Surveillance and Response (IDSR) guidelines</u> they need to be notified to Departamento Vijilansia. Suspected rabies cases need to be notified immediately (within 24 hours).

#### **Background**

- Children (particularly toddlers) are the most common victims of dog bites
- Dog bite wounds are most often crush injuries, lacerations and abrasions resulting from the high pressures generated from the dog jaw and the associated ripping and tearing motion
- Infection is the most common complication of bite injuries
- Dog bite bacterial infections are polymicrobial, with potential pathogens arising from the mouth of the biting mammal, the child's own skin flora and the environment
- There is risk of transmission of transmission of rabies viruses from dogs in Timor-Leste.

#### Dog bites are notifiable conditions in Timor-Leste

**All dog bites and all suspected cases of rabies** are notifiable in Timor-Leste. Telephone Vijilansia immediately on +670 3310948 or 991. The case definitions are below.

#### Dog bite case definition

Reporting: Confirmed cases should be reported.

Confirmed case: A bite inflicted upon a person by a dog.

#### Rabies case definition

**Reporting:** Confirmed and probable cases should be reported.

**Confirmed case**: Laboratory detection or isolation of rabies virus; or detection of rabies-neutralizing antibody in the serum or CSF of an unvaccinated person.

**Probable case**: A person with an acute encephalomyelitis (headache, fever, hydrophobia, delirium, convulsions, or paralysis) with history of bite or scratch from a suspected rabid animal.

**Suspected case**: A person with an acute encephalomyelitis (headache, fever, hydrophobia, delirium, convulsions, or paralysis) progressing to death within 10 days after the first symptom.

#### **Assessment**



#### Any life-threatening injuries should be treated as per trauma guidelines

Children presenting with bite injuries should be fasted from arrival, in case they require sedation +/- surgical intervention.

### **Process for responding to dog bites**

#### 1. Record accurate history of bite

- Timing and geographical location of injury
- Number and location of bites or scratches
- Risk of associated injuries eg if the child has fallen or been dragged
- Immunisation status (particularly tetanus), history of adverse reactions to rabies vaccines
- Other medical history: co-morbidities (eg immunosuppression), regular medications, allergies
- Was the dog exhibiting signs/symptoms of rabies?



Any dog that presents any of the following signs; hypersalivation, paralysis, lethargy, unprovoked abnormal aggression, abnormal vocalization, is considered a suspected rabid dog.

#### 2. Washout the wound

- All dog bite wounds with broken skin require washout and exploration with anaesthesia +/- sedation.
- Should be immediate, even if the person presents long after exposure.
- Immediate washing and flushing wound for 15 minutes with soap and water, or even just water.
- Disinfection with detergent, ethanol (700ml/l), iodine (tincture or aqueous solution), 0.9% sodium chloride under pressure, or other substances with virucidal activity
- Remove any foreign bodies (teeth, debris) Use enough fluid to remove all visible dirt and foreign material.

#### 3. Give tetanus and rabies vaccinations

#### **Tetanus prophylaxis**

Dog bites are considered a risk for tetanus infection – give tetanus vaccine immediately.

#### **Rabies prophylaxis**

Any person bitten by a dog should be given post-exposure prophylaxis (PEP) to protect against rabies infection (+/- human immunoglobulin), regardless of time since injury. See guide below.

Tetanus and rabies vaccines can be given at the same time as other vaccinations without risk.

People who receive rabies vaccinations should have this recorded on a vaccination card and be reminded to attend for subsequent doses to ensure prophylaxis is completed.

#### 4. Wound and injury management

- Explore the wound and assess for extent/depth, potential injury to underlying structures (nerve, vessel, muscle, tendon) or extension into joint.
- Any bite injury which involves a "special location" (face, hand, foot or genitalia), or has extensive skin loss (>1cm defect present on attempts to oppose skin edges), requires referral to relevant surgical team for assessment and management.
- If any doubt regarding extent of wound or associated injuries, or concerns regarding ability to perform adequate washout or exploration, refer to specialty surgical unit at the Municipal Referral Hospital or Hospital National Guido Valadares (HNGV).

- Location of injury
  - Areas more likely to require specialist surgical involvement are face, hands, feet, genitals
  - A clenched-fist injury involves laceration over the dorsum and MCP joints of the hand
- Associated injuries
  - C-spine/head if fall has occurred
  - Long bone/limb/spinal if child has been dragged
  - Eye injury if face is involved
- Assess depth of wound (subcutaneous, breach of muscle fascia)
  - bites and clenched-fist injuries often penetrate deep tissues
- Look for evidence of neurovascular or tendon injury prior to local anaesthetic infiltration (altered sensation, haemorrhage, loss of function)
  - If joint involved, examine the wound in a range of positions
- Assess viability/perfusion of skin edges of wound and skin distal to the injury
- Assess for signs of infection (surrounding erythema, purulence, fever)
  - Infection can be clinically evident in dog bites within 24 hours.

#### 5. Wound closure and dressing

- Most dog bite wounds should be allowed to close by secondary intention (ie left open)
- Primary closure may be considered in select wounds: try to delay a few hours after giving RIG or rabies vaccine to allow for infiltration through the tissues. low infection risk injuries which can be adequately explored and irrigated, are <12 hours old and where cosmesis is an issue ie face/neck</li>
- Elevation of affected limb for 48-72 hours is recommended.

#### 6. Dog bite infection prevention

Antibiotic prophylaxis should be considered for bite infections, as per <u>Timor-Leste Antibiotic Guidelines</u> <u>2022</u>. Antibiotic prophylaxis is recommended in clinically non-infected bite wounds with <u>high-risk features</u> for infection.

INFECTION	ANTIBIOTIC CHOICE	COMMENTS
Bites/Traumatic wounds	Thorough debridement and cleaning is essential. If mild infection present or high risk of infection after initial injury, oral antibiotic therapy MAY be useful	High risk features include: Delayed presentation >8hrs Wounds unable to be debrided adequately
Mild	Amoxicillin/Clavulanic acid 500/125mg (child: 25mg/kg) PO BID for 5 days	<ul> <li>Involvement of underlying structures [e.g. tendons]</li> <li>Wounds on the hand feet</li> </ul>
Moderate or Severe	Cloxacillin 2g (child: 50mg/kg) IV 6 hourly + Ceftriaxone 1g (child: 25mg/kg) IV OD + Metronidazole 500mg (child: 10mg/kg) PO/IV 12 hourly  Step down to oral antibiotics (see Mild) when improving to complete a total of 14 days antibiotic therapy	or face.  Ensure Tetanus vaccine updated if the patient has not been immunised in the past 5 years.

#### High risk features might include;

- Wounds undergoing primary closure
- Delayed presentation (wound > 8 hours old)
- Deep puncture wounds or lacerations
- Bite on hands (including clenched-fist injuries), face, feet or genital area
- Close proximity to bone or joint
- Associated crush injury
- Involving an open fracture
- Immunocompromised child



Ask a Specialist Physician/Doctor for advice on;

- duration of therapy,
- when considering switching from intravenous (IV) to oral dosage, and
- to interpret the results of laboratory testing, including antimicrobial susceptibility testing results.

#### 7. Human laboratory diagnostics

#### Microbiology/bacteriology

- Collect wound swabs for MCS (microbial culture and sensitivity) only where there is clinical evidence of infection.
- Collect wound swabs and blood cultures when there is evidence that wounds are infected OR the person is exhibiting fever or other signs of sepsis.
- Send the wound swab and/or blood culture to the pathology laboratory (microbiology department) for processing. Request "Microbial culture and sensitivity" and ensure to write "Dog bite" in the clinical history.
- Cultures should not be taken for wounds that are not clinically infected, as there is poor correlation between early culture results and subsequent infections

#### Rabies virus testing

The diagnosis of rabies will likely be made according to the distinctive signs and symptoms of the patient as well as epidemiological information (as per <u>Integrated Disease Surveillance and Response Guideline – IDSR</u>).

Laboratory testing is available for rabies in Timor-Leste using PCR (polymerase chain reaction).

Testing can be performed on the following samples – ideally a combination of all 3;

- Saliva at least 3 samples taken at 3-6 hour intervals
- CSF (cerebrospinal fluid)
- tissue (virus can spread from central nervous system to peripheral tissues a sample of skin including hair follicles from the nape of the neck is the ideal tissue specimen).

#### 8. Medical imaging

- Xray or ultrasound of the area may be indicated if there is suspicion of underlying bony injury, joint
  involvement or foreign body in wound.
- Further imaging: seek senior advice;
  - Ultrasound: if suspected collection associated with an infected wound
  - CT head: in children who have sustained a dog bite of uncertain depth to the scalp, or bite
    marks on opposing sides of the skull, a CT should be performed to evaluate for associated
    skull fracture or penetrating injury
  - Abdominal CT: if abdominal injuries sustained

#### 9. Report to Departamentu Vijilansia and Diresaun Nasional Veterinaria

Also report all dog bites immediately to Vijilansia focal point in municipality and alert Diresaun Nasional Vijilansia no Epidemioloji on +670 3310948.

### 10. Report to Ministry of Agriculture, Land and Fisheries

Report all dog bites immediately to Diresaun Nasional Veterinaria on +670 78367115.

# Appendix 1. Risk category exposure which determines the level of rabies vaccination response post exposure (post animal bite).

**Rabies vaccine is available and recommended in Timor-Leste**, after a dog-bite, in accordance with WHO exposure risk categories below. Any person previously vaccinated against rabies does not require immunoglobulin.

Wound category	Type of exposure	Recommended post-exposure prophylaxis
1	Touching or feeding animals  Licks on unbroken skin	None (if history is reliable)
2		Rabies vaccination Immunocompromised people should also receive RIG
3	Any wound that bleeds after exposure (regardless of amount of blood)  Any time saliva comes into contact with mucous membranes or open wounds (broken skin)  All bat exposures (regardless of the severity of the wound)	Rabies vaccination Rabies immunoglobulin  Rabies vaccination Rabies immunoglobulin

# Appendix 2. Dosage and timing of post exposure prophylactic (PEP) rabies vaccinations.

Because of the risk of developing rabies which is <u>ALWAYS</u> fatal, there is no contraindication for giving post-exposure prophylactic rabies vaccine.

This vaccine contains neomycin. The <u>only absolute contraindication</u> for receiving this vaccine is a previous anaphylactic reaction to this vaccine, or a previous anaphylactic reaction to neomycin.

The vaccine available for use in Timor-Leste is;

Name: RABIVAX-S Serum Institute of India: Rabies Vaccine Inactivated

State: Freeze-dried (lyophilized) 1.0mL

Diluent: separate diluent

Intramuscular (IM) dose: 1.0mL (single dose vials)

Intradermal dose: 0.1mL (10 doses per vial)

WHO prequalified vaccine: since 20 December 2018



RABIVAX-S should be reconstituted only with the entire contents of the diluent supplied (Sterile Water for Injections) using a sterile syringe and needle, with gentle shaking until the dried poweder is dissolved. After reconstitution the vaccine should be used immediately.

#### Post exposure rabies vaccination for those unvaccinated against rabies

RABIVAX-S dosage for post exposure vaccination is;

Route	Dose	Number of Doses	Schedule
Intramuscular*	1ml	5	Day 0, 3, 7, 14 and 28
Intradermal	0.1ml	4	Day 0, 3, 7, and 28

In Timor-Leste, EPI and NITAG recommend that the intramuscular (IM) vaccine route is preferred for post exposure prophylaxis, however intradermal is also acceptable. The preferred site of administration is in the deltoid area because VNAb (rabies virus neutralising antibody) titres may be lower if given in other sites. Infants <12 months of age are recommended to receive the rabies vaccine in the anterolateral aspect of the thigh. The ventrogluteal site is an acceptable alternative for infants.

**Do not give rabies vaccine in the buttock**, because post-exposure prophylaxis can fail when vaccine is given in this area.

The intradermal route <u>must not</u> be used in people;

- receiving long term corticosteroid or other immunosuppressive therapy; or
- receiving chloroquine for malaria treatment or prophylaxis; or
- who are immunocompromised.

These treatments can interfere with the immune response of the vaccine and lead to the failure of the vaccination. These people should receive intramuscular vaccination instead.

NEVER give rabies vaccine by intravascular route.

If anaphylaxis occurs, provide appropriate medical treatment/intervention according to the guidelines for responding to EADI (efeito adversos depois de imunizasaun). Report the event to EADI on +670 7723 7438

#### **Immunoglobulin**

In accordance with the risk category exposure, HRIG (human rabies immunoglobulin) may be required and should be dosed at **20 IU per kilogram of body mass**.

HRIG must be infiltrated in and around all wounds using as much of the calculated dose as possible.

Any remaining HRIG that cannot safely be infiltrated in and around the wound should be given **intramuscularly** at a site away from the rabies vaccine injection site. Depending on the volume, this could be in the alternative deltoid, lateral thigh or gluteal muscle.

Immunoglobulins must be administered at the different site from that of the vaccine (the **contralateral** side). Never combine rabies vaccine and immunoglobulin in the same vaccine or inject at the same body site.

Do not give HRIG if it has been more than 7 days (168 hours) since the first dose of rabies vaccine. This is because HRIG may interfere with the immune response to the vaccine.

## Post exposure vaccination for people already <u>fully vaccinated</u> against rabies

RABIVAX-S dosage for post exposure vaccination is;

Route	Dose	Number of Doses	Schedule
Intramuscular*	1ml	2	Day 0 and 3
Intradermal	0.1ml	2	Day 0 and 3

In Timor-Leste, EPI and NITAG recommend that the intramuscular (IM) vaccine route is preferred for post exposure prophylaxis, however intradermal is also acceptable. The preferred site of administration is in the deltoid area because VNAb (rabies virus neutralising antibody) titres may be lower if given in other sites. Infants <12 months of age are recommended to receive the rabies vaccine in the anterolateral aspect of the thigh. The ventrogluteal site is an acceptable alternative for infants.

**Do not give rabies vaccine in the buttock**, because post-exposure prophylaxis can fail when vaccine is given in this area.

The intradermal route <u>must not</u> be used in people;

- receiving long term corticosteroid or other immunosuppressive therapy; or
- receiving chloroquine for malaria treatment or prophylaxis; or
- who are immunocompromised.

These treatments can interfere with the immune response of the vaccine and lead to the failure of the vaccination. These people should receive intramuscular vaccination instead.

<u>NEVER</u> give rabies vaccine by intravascular route.



Human rabies immunoglobulin (HRIG) is <u>NOT</u> required for those already vaccinated against rabies.

If anaphylaxis occurs, provide appropriate medical treatment/intervention according to the guidelines for responding to EADI (efeito adversos depois de imunizasaun). Report the event to EADI on +670 7723 7438.

# Appendix 3. Dosage and timing of pre-exposure prophylactic (PrEP) rabies vaccinations.

Pre-exposure prophylactic (PrEP) rabies vaccination is recommended for those who are at increased risk of exposure to rabies, usually due to their occupation. This may include the following groups of people;

Classification	Highest risk
Risk category 1	People who work with live or concentrated rabies virus in laboratories
Risk category 2	People who frequently do at least one of the following: handle bats, have contact with bats, enter high-density bat environments like caves, or perform animal necropsies
Risk category 3	People who interact with, or are at higher risk to interact, with mammals other than bats (i.e dogs) that could be rabid, for a period longer than three years after they receive PrEP; OR most veterinarians, veterinary technicians, animal control officers, wildlife biologists, etc.

The vaccine available for use in Timor-Leste is;

Name: RABIVAX-S Serum Institute of India: Rabies Vaccine Inactivated

State: Freeze-dried (lyophilized) 1.0mL

Diluent: separate diluent

Intramuscular (IM) dose: 1.0mL (single dose vials)

Intradermal dose: 0.1mL (10 doses per vial)

WHO prequalified vaccine: since 20 December 2018





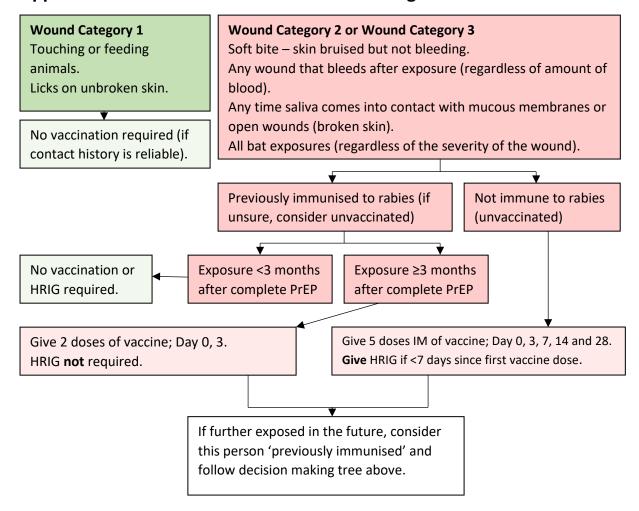
RABIVAX-S should be reconstituted only with the entire contents of the diluent supplied (Sterile Water for Injections) using a sterile syringe and needle, with gentle shaking until the dried powder is dissolved. After reconstitution the vaccine should be used immediately.

PrEP needs to be administered according to the schedule in the table below.

#### RABIVAX-S dosage for Pre-Exposure prophylaxis

Route	Dose	Number of Doses	Schedule
Intramuscular*	1ml	3	Day 0, 7 and 21 or 28
Intradermal	0.1ml	3	Day 0, 7 and 21 or 28

#### Appendix 4. Rabies vaccination decision making chart for Timor-Leste.





Any person previously vaccinated against rabies does not require immunoglobulin.

#### References.

Ministerio da Saude de Timor-Leste (2023). Grupo Assessoria Tecnica Nacional Para Imunizacao (NITAG TL). Resposta ba pedidu pareser tekniku no rekomendasaun konaba vasina anti-Rabies. Ref. 882/DGS/NITAG/VII/2023.

Ministerio da Saude de Timor-Leste (2023). Vijilansia no resposta integradu ba moras (IDSR) – matadalan ba implementasaun iha Timor-Leste. (Versaun Tetum) https://apps.ms.gov.tl/moh2/idsr.php?lan=tet&p1=001&p2=&p3=&p4=&p5=&m=

Timor-Leste Ministry of Agriculture and Livestock (2016). National Preparedness Contingency Plans on Rabies – Timor-Leste (DRAFT).

Timor-Leste Ministry of Health (2022). Timor-Leste Antimicrobial Guidelines. <a href="https://apps.ms.gov.tl/moh5/index.php?lan=eng#">https://apps.ms.gov.tl/moh5/index.php?lan=eng#</a>

Serum Institute of India PVT. LTD. Products supplied in India: RABIVAX-S. <a href="https://www.seruminstitute.com/product">https://www.seruminstitute.com/product</a> ind rabivaxs.php

World Health Organization (WHO). Who Guide for Rabies Pre and Post Exposure Prophylaxis in Humans (Updated 2014). <a href="https://www.who.int/docs/default-source/searo/india/health-topic-pdf/pep-prophylaxis-guideline-15-12-2014.pdf?sfvrsn=8619bec3">https://www.who.int/docs/default-source/searo/india/health-topic-pdf/pep-prophylaxis-guideline-15-12-2014.pdf?sfvrsn=8619bec3</a> 2

World Health Organization (WHO) (2018). WHO Expert Consultation on Rabies, third report. (WHO Technical Report Series, No. 1012). Licence: CC BY-NC-SA 3.0 IGO. <a href="https://www.who.int/publications-detail-redirect/WHO-TRS-1012">https://www.who.int/publications-detail-redirect/WHO-TRS-1012</a>

US Centers for Disease Control and Prevention (CDC) (2024). Zoonotic Exposures: Bites, Stings, Scratches & Other Hazards. CDC Yellow Book 2024.

https://wwwnc.cdc.gov/travel/yellowbook/2024/environmental-hazards-risks/zoonotic-exposures-bites-stings-scratches-and-other-

 $\frac{hazards\#: \text{``:text=Unprovoked\%20bites\%20and\%20scratches\%20increase, return\%20to\%20their\%20home\%20country.}$ 

Global Alliance for Rabies Control (2023). Wound Category Poster.

https://rabiesalliance.org/resource/wound-category-poster

Australian Government Department of Health and Aged Care (2018). Australian Immunisation Handbook. Rabies and other lyssaviruses.

 $\frac{https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/rabies-and-other-lyssaviruses \#vaccine-and-immunoglobulin-information$ 

The Royal Children's Hospital Melbourne (2023). Clinical Practice Guidelines: Animal and human bites <a href="https://www.rch.org.au/clinicalguide/guideline">https://www.rch.org.au/clinicalguide/guideline</a> index/Animal and human bites/

Dandle C. Management of mammalian bites. *Aus Fam Phys.* 2009:38(11). https://www.racgp.org.au/getattachment/6d326a0b-e2a4-433d-b691-b814e9617ccd/Mammalian-bites.aspx

## **Appendix 1. Rabies vaccination card**

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### Appendix 2. Form for reporting adverse events following immunization (AEFI).

		(	Case ID:		*Reporter's	Name:			
*Patient's full Address:					Institution:		Municipal	lity:	
Tidodoss					Designation Address:	& Department:			
Telephone: Sex: M F					Address.				
*Date of birth : (d/n				20	Telephone &		1 14		ï
OR Age at onset:   OR Age Group at or						notified event			
3 1	8 <del>-</del> 8		-		I oday's date	e: (d/m/y)	'		
Health facility (plac	e or vaccinati	on centre) nan	ne & add	ress:					
		Vaccine		10 TO 10			Diluent (i)	f applicable)	4
*Name of vaccine	*Date of vaccination	*Time of vaccination	Dose (1 <sup>st</sup> , 2 <sup>nd</sup> , etc.)	*Batch /Lo	t Expiry date	Name of diluent	*Batch /Lot number	Expiry date	Date and time of reconstitution
			11.17						
☐ Encephalopathy ☐ Toxic shock synt ☐ Thrombocytoper ☐ Anaphylaxis ☐ Fever ≥38°C ☐ Other (specify)  *Serious: Yes / No; ☐ Other important: *Outcome: ☐ Re	→ If Yes □ medical event (	Death Life specify)	threateni	ed with seque	lae Not	Recovered	 ] Unknown	ion □ Cong	genital anomaly
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Past medical history (e.g. other cases). Us  First Decision makin Investigation needed	: Yes	11	(50)		A	AEFI worldwide	unique ID:		

### Description of elements in the AEFI reporting form

#### Reporting element

#### Description

	Case ID number	Unique number assigned to the AEFI case as per the national guidelines					
	*Patient's Name	The name of the patient or initials as decided by the country					
ē	*Patient's full Address	Geographic location of the case (address), please try to provide landmarks					
Patient identifie	Telephone	Number to contact to provide or receive additional information					
t ide	Sex	Male or Female					
tien	*Date of birth	Date** patient was born					
Pa	Age at onset	If date of birth is not known, this may be considered as first alternative					
	Age Group at onset	If date of birth and age at onset is not known, this may be considered as second alternative					
	*Reporter's Name	Name of person who has reported this AEFI to the healthcare system and also completed this form					
	Institution & Municipality	The place and its municipality where the reporter is working or is affiliated to					
40	Designation & Department	Reporter's designation and his/her section of work					
details	Address	Reporters full address - Please add the name of the country here as well					
r de	Telephone	Reporter's phone number					
Reporter	E-mail	Reporter's e-mail address					
Rep							
	Date patient notified event to health system	The date** when the event was first brought to the notice of the healthcare system					
	Today's date	Date** when the report was compiled by the reporter (this can be different from the date of notification (above))					
(5,	Vaccination centre or place of vaccination -	Name and address of the place where the child received the vaccine - provide details (e.g. mobile clinic,					
uent(s	name & address	home etc.) The vaccine that is suspected to have caused the AEFI (provide brand name, if possible)					
₹	*Name of vaccine	*					
and (	Name (of other vaccines)	Other vaccines that were administered at the same time (provide brand name, if possible)					
ne(s	*Date of vaccination	Date** when the vaccine was administered					
of vaccination, vaccine(s)	*Time of vaccination	Time** when vaccine was administered - try to be as accurate as possible					
on,	*Batch/Lot number (of vaccine)	Batch number/lot number of each of the vaccines mentioned above					
inati	Dose (1st, 2nd, etc.)	Dose number of the vaccine for the vaccinee e.g. 2nd dose of DTP or 5th Dose of OPV etc.					
Vacc	Expiry date	The date** of expiry for each vaccine					
ls of	*Batch/Lot number (of diluent)	The batch/lot number of diluent (if applicable)					
Detai	Expiry date (of diluent)	The date** of expiry of the diluent					
	Time of reconstitution	Time when the vaccine was reconstituted with the diluent					
	*Adverse event(s)	The details of the events suspected to be caused by immunization. Multiple events can occur in a single patient. They need to be documented here					
	Date & Time AEFI started	Date** and time** the event was first noticed					
(5	Describe AEFI (Signs & Symptoms)	Description of the events in chronological order					
erse event(s	*Serious: Yes / No	If the case is serious, mark "Yes" and indicate one or several options: Death, Life threatening, Persistent or significant disability, Hospitalization, Congenital anomaly or Other important medical event that may jeopardize the patient or may require intervention to prevent one of the outcomes mentioned here					
Adverse	*Outcome	Outcome of the reaction(s). Indicate status of the patient at the time of reporting: Recovering, Recovered, Recovered with sequelae, Not Recovered, Unknown or Died					
	Died	Provide date of death and details of autopsy, if available					
	Past medical history	Please include history of similar reaction or other allergies, concomitant medication and other relevant information (e.g. other cases in the locality or among those vaccinated)					
	First Decision making level to complete	This section has to be completed by the decision maker for a detailed field AEFI investigation.					
	Investigation needed	Decision on detailed field AEFI investigation.					
	Date investigation planned	Date** when detailed investigation (including field investigation) is planned to start.					
use	National level to complete	This section has to be completed by the National level to decide on the next steps.					
Response	Date report received at National level	Date** this report was received at the National level					
Re	AEFI worldwide unique ID	Unique ID number (e.g. regulatory authority's case report number) for the AEFI case automatically generat for electronic transmission from National level to International level					
	Comments	Please add additional details that will help with processing this report. Please include other documents as attachments, if necessary					
	* Compulsory field	Items marked with an asterix (*) have to be completed					

<sup>\*</sup> Compulsory field Items marked with an asterix (\*) have to be completed

<sup>\*\*</sup> Please use the date format of dd/mm/yyyy e.g. 20/03/2018, for time use 12 (please indicate am/ pm correctly) or 24 hours format

# Ministério da Saúde