NATIONAL GUIDELINES FOR MANAGEMENT OF RABIES AND ANTI-RABIES PROPHYLAXIS

Zoonotic Disease Control Unit
Health Emergencies Programme
Communicable Diseases Division
Department of Public Health
Ministry of Health, Thimphu, Bhutan

3rd Edition 2023
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CONTENTS

FOREWORD

Rabies is an important zoonosis that continues to be one of the major public health problems in the country. Regular rabies outbreaks are reported annually in animals in Bhutan, which pose a constant risk of transmission of the deadly virus to humans. The country continues to witness 1 or 2 sporadic human rabies deaths with the last death recorded in 2023.

This virtually 100% fatal nature of the disease is preventable through timely and appropriate post-exposure treatment. Modern, safe, and effective anti-rabies Cell Culture Vaccines (CCVs) are being used for post-exposure prophylaxis which is provided free of cost in all health facilities across the country. However, with increasing awareness among people about rabies and animal bite cases seeking rabies PEP in health centers, it is important for health workers to conduct a risk assessment and to ensure that prophylaxis is administered appropriately. To overcome the rising costs of anti-rabies PEP and to ensure wider and uninterrupted accessibility to anti-rabies vaccines, the Ministry of Health recommended the intra-dermal route of vaccine administration (IDRV) in 2013. The IDRV should now be the routine route of ARV administration in all health facilities as recommended in this guideline unless when its administration is not possible or in unavoidable circumstances.

This is the 3rd edition of the national guideline on human rabies case management and antirabies prophylaxis developed jointly by experts from the human and animal health sectors. This national guideline was reviewed and revised in the light of new recommendations of the WHO Expert Consultation on Rabies in 2018 by the Technical Advisory Group and experts in 2020, and all the relevant health workers at all levels of health care settings in August 2023 to achieve and maintain zero human death from rabies. The guidelines should help to improve in making rational use of rabies vaccine and immunoglobulin. The guideline is an outcome of consensus deliberations of the expert group which is brought out for publication, wider circulation, and compliance by health workers and other relevant health officials in Bhutan.

I hope this publication will be of immense use to our health workers in managing animal bite cases and in making appropriate decisions for prescribing anti-rabies prophylaxis.

Karma Jamtsho
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Abbreviations and acronyms

CSF	Cerebrospinal Fluid
FAVN	Fluorescent Antibody Viral Neutralization
FAT	Fluorescent Antibody Test
DRIT	Direct Rapid Immunohistochemical Test
RABV	Rabies Virus
PEP	Post Exposure Prophylaxis
PrEP	Pre-Exposure prophylaxis
ID	Intra-Dermal
IM	Intra-Muscular
SC	Subcutaneous
IDRV	Intra-dermal route of Vaccination
CCVs	Cell Culture Vaccines
NCAH	National Centre for Animal Health
NEWARS	National Early Warning, Alert and Response Surveillance
NASBA	Nucleic Acid Sequence-based Amplification
RCDC	Royal Centre for Disease Control
PCECV	Purified Chick Embryo Cell culture Vaccine
PVRV	Purified Vero Rabies Vaccine
RFFIT	Rapid Fluorescent Foci Inhibition Test
RT-PCR	Reverse Transcriptase Polymerase Chain Reaction
HDCV	Human Diploid Cell Vaccine
PDCV	Purified Duck Cell Vaccine
eRIG	Equine Rabies Immunoglobulin
hRIG	Human Rabies Immunoglobulin

1. INTRODUCTION

Rabies is a neglected zoonotic disease caused by the RNA virus belonging to the genus Lyssavirus and family Rhabdoviridae. It has the highest documented case-fatality rate, approaching close to 100%. The estimated number of human rabies deaths globally is 59,000 annually. The vast majority of these deaths occur in Asia (59.6%) and Africa (36.4%) and 99% are dog-mediated rabies. The overall economic costs of dog-mediated rabies were estimated to be US$ 8.6 billion. In 2015, the World Health Organization (WHO) and World Organization for Animal Health (OIE), in collaboration with the Food and Agriculture Organization (FAO) and the Global Alliance for Rabies Control (GARC) launched the global framework for the elimination of dog-mediated human rabies to achieve a global goal of zero human rabies deaths by 2030. Bhutan has committed to prioritize rabies elimination in its national plans and the human and animal health stakeholders are collaborating and working closely to achieve zero dog-mediated human rabies death elimination by 2030.

In Bhutan, rabies is commonly reported in the southern districts of the country that share a direct and porous border with India. However, sporadic outbreaks are reported in some interior districts (Tashigang, Tashi Yangtse, Haa) as a result of the incursion of disease from the bordering areas which poses a risk of establishing endemic transmission (Figure 1). Based on the Annual Health Bulletin published by the Ministry of Health, an annual average of 7000 dog bites (1026 bites per 100,000 people annually) occur in the country and 18 human rabies deaths had been recorded between 2006 - 2022, equivalent to a cumulative incidence of 2.38 per 100,000 population. The annual public health expenditure incurred for providing human PEP is approximately Nu. 9.3 million (USD 142,000).

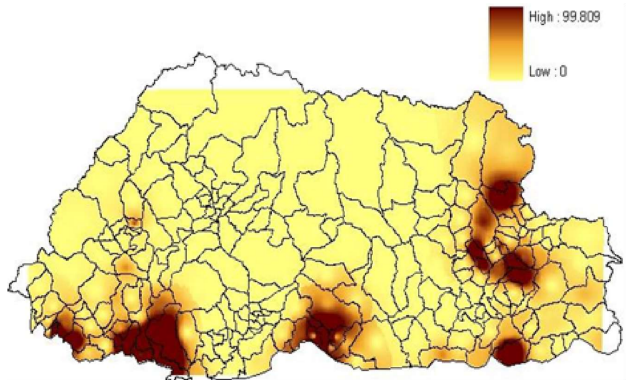

Figure 1: Map of Bhutan showing the risk of rabies transmission

2. The virus, source, transmission and pathogenesis

2.1 Rabies virus

- The rabies virus (RABV) is a single-stranded, enveloped RNA virus, and belongs to the genus Lyssavirus in the family Rhabdoviridae and order Mononegaviral.
- RABV is neurotropic and it is widely distributed in the nervous systems, saliva, and secretions once the clinical manifestations start in animals or humans.
- The highest concentration of virus occurs in the nervous system and the salivary glands.
- The Rabies virus is fragile and easily inactivated by sunlight, heat, and commonly used disinfectants.

2.2 Reservoirs and source of infections

- Rabies transmission is maintained by two transmission cycles: the urban cycle transmission which is perpetuated by dogs and the sylvatic cycle by wild carnivores e.g. foxes, jackals, wolves, and mongooses.
- The saliva of the rabid animals is the main source of infection for humans.
- The saliva can be infective about three days before the onset of clinical symptoms and during the course of the illness till the death of the rabid animal.
- The dog transmitted rabies is responsible for 99% of human rabies deaths.

2.3 Routes of transmission

- All warm-blooded mammals are susceptible to rabies virus infection.
- Rabies is transmitted through direct contact with the virus present in the saliva of infected animals, typically via bite wounds or exposure to mucous membranes.
- Human infection commonly occurs following transdermal bites and scratches from an infected animal or licks on mucous membranes.
- RABV has not been isolated from the milk of rabid cows and no human cases have been attributed to consumption of raw milk but drinking raw milk from a rabid animal is not advised. As per WHO, PEP is generally not indicated in these situations.

- In rare instances, rabies has been contracted by inhalation of virus-containing aerosol (caves inhabited by bats).
- Human-to-human transmission of the rabies virus has never been confirmed, with the exception of organ transplant from rabid patients.

2.4 Pathogenesis

- After inoculation, RABV replicates in muscles or other local tissues and gains access to motor endplates and motor axons before reaching the central nervous system. The virus can also enter motor axons in peripheral nerves directly during a penetrating injury.
- The incubation period is variable and varies from five days to several years (usually 2–3 months; rarely more than 1 year) depending on the amount of virus in the inoculum, the density of motor endplates at the wound site, and proximity of virus entry to the central nervous system.
- By the time of clinical onset of rabies, the virus is widely disseminated throughout the central nervous system and probably to extra-neural organs.
- Without intensive care, death usually occurs within 7-10 days of the manifestation of clinical symptoms.

3. Rabies in dogs

The incubation period of rabies in dogs ranges from 3−8 weeks but may vary from 10 days to as long as 6 months. In general, rabid animals of all species commonly exhibit typical signs of central nervous system disturbances with behavioral changes. A rabid dog may show either a furious or paralytic (dumb) form of rabies with signs and symptoms as described in Table 1. Furious form of rabies is the typical mad dog syndrome characterized by a change in normal behavior. The animal usually dies in about 3 -5 days after it develops clinical symptoms.

Table 1: Signs and symptoms of furious and dumb rabies in dog

Furious rabies	Dumb Rabies
• Easy irritability • Unprovoked attacks on humans and animals and biting inanimate objects, • Running aimlessly for no apparent reason • A change in voice, e.g. barking and growling in a hoarse voice or inability to make a sound • Excessive salivation or foaming at the angles of the mouth • Gasping for breath towards the later stages of illness	• The dog withdraws itself from being seen or disturbed • Hanging of jaws • Increased salivation • It lapses into a state of sleepiness • In-coordinated movement

4. Rabies in human

The consequence of exposure to the rabies virus depends on several factors including the severity of the wound, the location of the bite on the body, the inoculum of the virus, and the time of post-exposure prophylaxis (PEP) administration after exposure. As the virus spreads through the central nervous system, a progressive and acute fatal encephalomyelitis develops. Early symptoms of rabies in humans are nonspecific, consisting of fever, headache, general malaise, tingling sensation, and paresthesia at the site of the bite. As the disease progresses, neurological symptoms appear and may include insomnia, anxiety, confusion, slight or partial paralysis, excitation, hallucinations, agitation, hypersalivation, difficulty swallowing, and hydrophobia (fear of water). Human rabies can manifest clinically in two forms as shown in Table 2.

Table 2: Clinical manifestations of furious and paralytic rabies

Furious rabies ~ 80%	Dumb Rabies ~ 20%
• Tingling / numbness at bite site • Non-specific symptoms (Fever, malaise, headache, etc.) • Hydrophobia, aerophobia, photophobia • Death (cardio-respiratory failure) • Survival: 3 – 5 Days	• Tingling / numbness at bite site • Nonspecific symptoms (Fever, malaise, headache etc.) • Ascending Paralysis • Coma • Death (cardio-respiratory failure) • Survival : 7 – 21 Days

4.1 Clinical diagnosis

Clinical diagnosis of encephalitis can be difficult, particularly in the dumb form of the disease, and laboratory methods should be used to confirm a diagnosis when possible. The clinical picture of rabies is often variable and may represent a continuum of signs and symptoms. The differential diagnoses to be considered are:

- Cerebral malaria
- Organophosphate poisoning
- Herpes simplex encephalitis
- Post-vaccinal encephalitis
- Scorpion and snake envenomation
- Illicit drug use
- Psychiatric disorders
- Guillain–Barré syndrome (in paralytic form)

4.2 Laboratory diagnosis

Diagnosis of rabies is usually based on clinical features and a history of exposure to a suspected rabid animal (Annexure 1). Confirmation is challenging as brain sample collection is difficult given sociocultural reasons. Laboratory confirmation of rabies must be done wherever feasible. Laboratory diagnosis is important to confirm or rule out rabies in suspected paralytic or encephalitis cases. Details of possible laboratory diagnoses are given in Annexure 2.

4.3 Case definitions of human rabies

The human rabies case can be classified as per the standard WHO case definitions provided in Table 3 and this should be used for surveillance and reporting purposes.

Table 3: Human rabies case definitions (WHO, 2018)

Case	Definition
Suspected	• A person presenting with an acute neurological syndrome (i.e. encephalitis) dominated by form of hyperactivity (furious rabies) or a paralytic syndrome (paralytic rabies) that progresses towards coma and death usually due to cardiac or respiratory failure typically within 7-10 days of the first sign if no intensive care is instituted. • The syndrome may include any of the following signs: aerophobia, hydrophobia, paresthesia or localized pain, dysphagia, localized weakness, nausea or vomiting
Probable	• A suspect case plus a reliable history of contact with a suspected, probable or confirmed rabid animal (As per definition in Annexure 3)
Confirmed	• A suspected or probable case that is confirmed by laboratory tests

4.4 Case management

There is no effective treatment to cure rabies once the clinical signs have appeared. Hospital care for patients with clinical rabies is advisable, when possible, to reduce their suffering and ensure that they receive adequate, respectful palliative care. The focus of the management is on comfort, with heavy sedation (barbiturates, morphine) and avoidance of intubation or life-support measures, especially once the diagnosis is certain and it should be discussed with the family as soon as possible after the diagnosis is suspected. General treatment rules include

- Isolate the patient in a quiet room with subdued light and protect from drafts of air or stimuli likely to precipitate spasms and convulsions.
- Rabies patients tend to be talkative, so avoid disturbing them unnecessarily.
- Sedation with diazepam, supplemented by chlorpromazine, if necessary, will help to control muscular spasms and excitability. Phenobarbitone or morphine should be considered if required.

- Feeding orally is usually impossible. Nutrition and fluids should be given intravenously or NG tubes.
- Once the clinical diagnosis of rabies is confirmed, referral to a higher center is not recommended.

4.5 Precautions during patient management

Patients with rabies do not pose a risk to healthcare staff if routine precautions are taken. However, the staff should be reminded of the importance of adhering to barrier nursing and wearing personal protective equipment (standard precautions, including wearing gloves, glasses, and masks in case of a procedure that will generate splashes), as recommended for all infectious diseases. The procedures and precautions to be followed in the management of dead bodies are provided in Annexure 4.

5. Prevention of human rabies

5.1 Anti-rabies vaccines (ARV)

- Rabies is almost always fatal but it is preventable by vaccination before and/or after suspected exposure to the virus.
- The modern concentrated, purified cell culture and embryonated egg-based rabies vaccines have been proven to be safe and effective in preventing rabies (PCECV, PVRV, HDCV, and PDCV).
- WHO recommends intradermal administration of these vaccines as a safe, immunogenic, and dose-sparing alternative to intramuscular administration as only one or two vials of vaccine are required to complete a full course of PEP (Annexure 5).
- The ARV recommended for use and supplied in public health facilities in Bhutan is PVRV via ID route unless ID is not possible.

5.1.1 Contraindication and precautions

- There is no absolute contraindication to the administration of ARV. It can be safely given to infants, pregnant women, and immune-compromised individuals, including children with HIV/AIDS.

- However, a previous severe reaction to any component of a rabies vaccine is a contraindication for the use of the same vaccine for PrEP or PEP, and the vaccine product should be changed.
- As for all vaccinations, recipients should be kept under medical supervision for at least 15–20 min after vaccination.

5.1.2 Storage and transportation

- The vaccines should be protected from sunlight.
- As CCEEVs are available in lyophilized (freeze-dried) form, they are more tolerant to variations of temperatures, but it is recommended that these vaccines should be stored and transported at a temperature range of +2 to +8°C.
- Reconstitution: The sterile diluent supplied by the manufacturer should be used for the reconstitution of the vaccine.
- After reconstitution, the vaccine should be used immediately or within 6 to 8 hours, if kept at + 2 to 8 °C.
- The off-label* use of anti-rabies vaccines by ID route is allowed as per new WHO recommendations.

*Off-label use allows the ID route to be used for vaccine administration even if the manufacturer leaflets mention the IM route only.

5.2 Pre-exposure prophylaxis (PrEP)

In Bhutan, PrEP is recommended for the following high-risk category of people:

- Laboratory staff working with rabies virus and rabies virus-infected materials.
- Occupational groups working with animals - veterinarians, para-veterinarians, animal handlers, dog catchers, wildlife and quarantine workers.
- Travelers to endemic countries with limited access to PEP. The pre-travel advice on precautionary measures should be provided.
- The recommended route of administration should be ID.
- The PrEP session should be arranged in a group so vaccine wastage is minimized. One dose each (0.1 ml) is given at 2 sites, on both arms (over deltoids) on D0 and D7.

Table 4: Recommended regimen of PrEP

Regimen	Dosage per injection/ site	No. of injection sites/visit (Day 0,3,7,14/21/28)	Course duration	Injection sites
ID regimen	0.1ml	2-0-2-0-0	7 days (Day 0, 7)	Deltoids, anterolateral thighs, or suprascapular areas
IM regimen (Only when ID is not possible)	0.5ml	1-0-1-0-0	7 days (Day 0,7)	Deltoid area or anterolateral thigh

Note:

1. Administration of the third dose of vaccine on days 21/28 is recommended in immunodeficient patients by either ID or IM route.
2. ARV should not be given in the gluteal area.
3. Booster doses: as an additional precaution for people whose occupation puts them at continual or frequent risk of exposure, the annual booster can be provided which is a single injection by ID/IM.

5.3 Post-exposure prophylaxis (PEP)

PEP comprises of administration of wound care and immunization after a potential exposure to the rabies virus. The indication and procedure for PEP depends on the type of contact with the suspected rabid animal and the immunization status of the patient. Every animal bite should be suspected to be a potentially rabid animal bite, and treatment should be started as soon as possible, after exposure. People exposed to animals that conform to the definitions of animals as suspected, probable, or confirmed to be rabid should initiate PEP immediately (Annexure 3). However, the decision on PEP should be made after making a rational decision based on risk assessment. The algorithm to guide PEP decisions is provided in Annexure 6.

PEP always includes:

- Thorough washing and flushing of the wound for approximately 15 minutes, with soap or detergent and copious amounts of water and anti-septic application.

- A complete schedule of rabies vaccine injections administered immediately after an exposure.
- Administration of rabies immunoglobulin (RIG) in severe category III exposure.

5.3.1 Risk assessment

In any person with potential exposure to rabies virus, the following factors need to be considered:

- Epidemiology of rabies in the country (currently Bhutan is considered rabies endemic although the risk of rabies transmission is high in southern Bhutan)
- Types and severity of exposure (Table 5)
- Species and clinical features of the animal (Animal rabies case definition Annexure 3)
- Vaccination status of the animal (dogs and cats)
- Animal's availability for observation (only in dogs and cats)
- Results of laboratory testing in animals, if available

Table 5. WHO recommended PEP according to the type of exposure to rabies suspected, probable, or confirmed animals

Category	Type of exposure to animal or animal unavailable for testing	Risk	Recommended PEP
I	• Licks on intact skin, touching or feeding of animals • Petting, bathing, or coming in contact with utensils of a suspected rabid animal • Consumption of milk or milk products	None	None, if reliable case history is available

Category	Type of exposure to animal or animal unavailable for testing	Risk	Recommended PEP
II	• Nibbling of uncovered skin • Minor scratches or abrasions without bleeding • Consumption of raw meat* • Handling meat or carcasses of rabid animals	Minor	1. Wound management 2. Provide anti-rabies vaccine immediately
III	• Single or multiple transdermal bites or scratches • Licks on broken skin • Contamination with mucous membrane with saliva	Severe	1. Wound management 2. Provide ARV immediately 3. Provide RIG**

*It is important to inform the public that milk or meat from rabid or suspected animals must not be consumed.
**When RIG is limited, it should be prioritized for category 3 exposure to probable or confirmed rabid animals.

5.3.2 Management of animal bite wound

- All bite wounds and scratches should be attended to as soon as possible after exposure.
- Perform thorough washing and flushing of the wounds for approximately 15
- minutes with soap or detergent and plenty of water.
- If soap and detergent are not immediately available, wash with running water for 15 minutes.
- Wound toilet must be performed even if the patient reports late if the wounds are not healed (Since the rabies virus can persist and even multiply at the site of the bite for a long time).
- After wounds have been washed, local antiseptics like Povidone Iodine/Spirit should be applied to the wounds.

- Application of local remedies such as herbal extracts, butter, salt, and other substances on the wound should be strongly discouraged.
- Suturing of the wound is not recommended and if unavoidable, it should be done after infiltration with RIG.
- Suturing should be delayed by a few hours to allow diffusion of the immunoglobulin into the tissues.
- Whenever necessary tetanus prophylaxis should be provided and antibiotics as indicated.

5.3.3 Anti-Rabies Vaccination (ARV)

The current WHO-approved regimen for the ID route, 1-week, 2-site Institute Pasteur Cambodia - IPC regimen (2-2-2-0-0) is the recommended schedule in this guideline. The ARV should be provided to all animal bite victims of category II and III exposures and irrespective of age and body weight, require the same number of injections and dose per injection as per the schedule recommended below.

Table 6: Regimen for post exposure anti-rabies vaccination (ARV)

Regimen	Dosage per injection/site	No. of injection	Recommended PEP	Injection sites
ID	0.1ml	2-2-2-0-0	7 days (Day 0, 3, 7)	Deltoids, anterolateral thighs or suprascapular areas
IM (Only when ID is not possible)	0.5ml	1-1-1-1-0	14 days (Day 0, 3, 7, 14)	Deltoid area or anterolateral thigh

5.3.3.1 Dose and sites of vaccine administration

- One intradermal dose is 0.1 ml of reconstituted vaccine administered per ID site while one IM dose is an entire vial of vaccine, irrespective of the vial size (0.5 ml. or 1 ml).

- Day 0 is the date of administration of the first dose vaccine.
- As far as possible, vaccination schedules should be completed in the stipulated time.

5.3.3.2 PEP in immune-compromised individual

- • PEP both by ID and IM route is safe and immunogenic in such individuals
- • Thorough washing of the wound should be emphasized
- • Administer a full course of rabies vaccine
- • RIG is indicated in both Category II and III exposures, even if previously immunized

5.3.3.3 Important points to remember

- Only when ID administration is not possible, the IM regimen using 0.5ml of PVRV can be administered on Days 0, 3, 7, and day 14 or 21 or 28.
- For adults and children aged ≥2 years, the vaccine should always be administered in the deltoid area of the arm; for children aged <2 years, the anterolateral area of the thigh is recommended.
- Rabies vaccine should not be administered in the gluteal area, as the induction of an adequate immune response may be less reliable.
- Healthcare personnel should be careful not to inject less than 0.1 mL intradermal dose due to the dead space in the syringe or needle mount (insulin syringes may be used).
- Changes in rabies vaccine product and/or the route of administration during the same PEP course are acceptable, if unavoidable, to ensure PEP course completion.
- Should a vaccine dose be delayed for any reason, the PEP regimen should be resumed (not restarted). The use can be delayed up to 7 days from the date of the first vaccine doses.
- Rabies transmission has not been documented after rats and rodents bite exposure and as such, PEP after rat/rodent is not indicated.
- In areas enzootic for (canine and wildlife) rabies, PEP should be instituted immediately unless adequate laboratory surveillance and data indicate that the species involved is not a vector of rabies.

- Routine booster vaccine doses after primary rabies vaccination are not required for the general public living in areas of risk.

5.3.4 Rabies Immunoglobulin (RIG)

- RIG administration when indicated is a life-saving measure. There are two types of RIGs available- equine origin RIG (ERIG) and human origin RIG (HRIG). ERIG is much cheaper than HRIG and both have shown similar clinical outcomes in preventing rabies in humans. As ERIG products are now highly purified, skin testing before administration is not necessary and is abandoned as per WHO. This guideline recommends the use of ERIG in health centers in Bhutan.

5.3.4.1 Storage and dose of RIGs

- RIGs should be stored and transported at a temperature of +2 to 8ºC and should not be frozen.
- The RIG dose is calculated based on the patient's body weight.
- The maximum dose of ERIG is 40 IU/kg and HRIG is 20 IU/kg of body weight.
- The maximum calculated dose of RIG should not be exceeded.

5.3.4.2 Precaution in RIG administration (For RIG administration procedure Annexure 7)

- RIG should be infiltrated locally at the site of exposure as a priority when indicated.
- RIG is administered only once, preferably at or as soon as possible after initiation of PEP.
- RIG should be given with the first dose of vaccine into and around the wound site.
- RIG is administered without the use of anesthesia to prevent AEFI and anaphylaxis. The topical use of 2% lignocaine can reduce the pain during the procedure.
- If RIG is not available on the first visit, use can be delayed by up to 7 days from the date of the first vaccine dose. It is not indicated beyond the 7th day after the first dose of rabies vaccine

- Where RIG is limited or unavailable, scrupulous wound cleaning and deep irrigation, with the application of a potent antiseptic agent, and timely administration of the first vaccine dose should be performed immediately
- If a limited amount of RIG is available, RIG allocation should be prioritized based on the following criteria (Such as during outbreaks):
  - » Multiple bites
  - » Deep wounds
  - » Bites to highly innervated parts of the body, such as the head, neck, hands, genitals
  - » Immune-compromised patients with an unmanaged condition
  - » History of biting animal indicative of confirmed or probable rabies
  - » A bite or scratch or exposure of a mucous membrane by a bat can be ascertained

6. Re-exposure cases

In persons who are re-exposed with documented previous complete PrEP/PEP or who have received at least two doses of rabies vaccine, the following should be applied:

- 1-site ID/IM vaccine administration on days 0 and 3 (Recommended)
- No RIG is indicated
- People who cannot document previous PEP equivalent to PrEP or complete PrEP should receive a full PEP, including RIG if indicated.
- All health centers should print and issue PrEP/PEP vaccination cards to animal bite victims after vaccination (Annexure 8).
- REMEMBER, if an individual has a repeat exposure less than 3 months after a previous exposure, and has already received a complete PEP, only wound treatment is required; neither vaccine nor RIG is needed.

Table 7: Regimen for re-exposure cases

Regimen	Dosage per injection/site	No. of injection sites/visit (Day 0,3,7,14/21/28)	Course duration	Injection sites
ID	0.1ml	1-1-0-0-0	3 days (Day 0, 3)	Deltoids, anterolateral thighs or suprascapular areas
IM (Only when ID is not possible)	0.5ml	1-1-0-0-0	3 days (Day 0, 3)	Deltoid area or anterolateral thigh

7. Management of anaphylaxis

Prompt treatment of anaphylaxis is critical. The treatment protocol for anaphylaxis management includes:

- Place the patient in the recumbent position and elevate the lower extremities.
- Monitor vital signs frequently (every two to five minutes) and stay with the patient.
- Administer epinephrine 1:1,000 (weight-based) (adults: 0.01 mL per kg, up to a maximum of 0.2 to 0.5 ml every 10 to 15 minutes as needed; children: 0.01 ml per kg, up to a maximum dose of 0.2 to 0.5 ml) by SC or IM route and, if necessary, repeat every 15 minutes, up to two doses).
- Administer oxygen, usually 8 to 10 L per minute; lower concentrations may be appropriate for patients with chronic obstructive pulmonary disease.
- Treat hypotension with IV fluids or colloid replacement.
- Treat bronchospasm, preferably with a salbutamol nebulization.
- Give hydrocortisone, 5 mg/kg, or approximately 250 mg intravenously (prednisone, 20 mg orally, can be given in mild cases). These doses can be repeated every six hours, as required.

8. Surveillance of rabies

Effective control and elimination of human dog-mediated rabies require an effective surveillance system to monitor the progress of elimination and effectiveness of control measures.

8.1 Human rabies case notification

- Human rabies is one of the notifiable diseases in the National Early Warning Alert and Response Surveillance (NEWARS).
- The suspected human rabies cases compatible with the clinical case definition (Table 3) should be notified immediately in the web-based "Immediately Notifiable Reporting" platform in NEWARS (Refer NEWARS guideline, 3rd Edition 2019).
- The case investigation should be launched within 24 hours by the concerned health professional using the case investigation form (Annexure 9).
- A contact investigation should be conducted to find out additional people who may have had contact with the case.
- If there is no case, zero reporting should be done every week in the NEWARS web-based reporting system

8.2 Routine surveillance:

- All cases with animal exposures including animal bites visiting health centers should be categorized based on risk assessment and provide PEP as per risk category. The information on the number and types of animal exposure cases and PEP details should be collected and maintained.
- The District Health Office should collate and submit the report to the Zoonotic Disease Control program every quarterly as per the reporting form (Annexure 10).
- The health center should immediately notify the livestock official/sector for any patients reporting with history of exposure to probable rabid animal (Annexure 11).

8.3 Surveillance during rabies outbreak in animals

- When an outbreak is confirmed in animal (single or multiple cases with epidemiological link to the first animal case in a locality), all persons exposed to the animal should be listed as per the exposure categorization and PEP should be administrated (Annexure 12).
- In case, there is another outbreak confirmed in animals in the same locality but has no epidemiological link and temporal relation, the outbreak should be documented and separate line-listing should be maintained.
- The healthcare workers should proactively ensure completion of the full PEP course particularly in category II and III exposure cases.
- The line-listing form should be submitted to the Zoonotic Disease Control program within one month from the date of the outbreak in animals.
- All animal bite cases visiting health centers should be provided treatment if indicated as per the category of exposure and recorded in the registry (Annexure 13).
- During the outbreak response, the Rapid Response Team should adhere to the SOP for disinfection and decontamination of contaminated premises and materials as given in Annexure 14.

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ANNEXURES

Annexure 1: WHO human rabies exposure definitions

Exposure type	Definitions
Possible	A Person who had close contact (usually a bite or scratch) with a rabies-susceptible animal in (or originating from) a rabies-infected area.
Probable	A person who had close contact (usually a bite or scratch) with an animal displaying clinical signs consistent with rabies at time of the exposure, or within 10 days following exposure in a rabies-infected area.
Confirmed	A person who has had close contact (usually a bite or scratch) with a laboratory-confirmed rabid animal.

Annexure 2: Laboratory diagnosis of rabies

Antemortem diagnosis tests

The sensitivity of these tests depends on the

- Clinical presentation
- Stage of the disease
- Immunological status of the patient and
- Intermittent viral excretion

Detection of viral nucleic acid: Studies have demonstrated that testing at least 3 samples of saliva, taken at 3 to 6-hour intervals, together with a nuchal skin biopsy will help in almost 100% confirmation of an encephalitic case of Rabies. The tests done are for the detection of viral nucleic acid, viz., reverse transcriptase and polymerase chain reaction (RT-PCR) or nucleic acid amplification and detection methods (NASBA). However, a negative test result does not rule out a diagnosis of Rabies.

Detection of anti-rabies antibodies: Detection of anti-rabies antibodies in serum (in unvaccinated individuals) and CSF is also useful especially when the survival is prolonged beyond a week. RFFIT (Rapid fluorescent Focus Inhibition Test) and FAVN (Fluorescent antibody virus neutralization test) are used to detect the neutralizing antibodies and ELISA is used for detection of specific anti-rabies

antibodies. A combination of tests conducted on different samples in a serial order is helpful in antemortem diagnosis of Rabies.

Postmortem diagnosis tests

When brain tissue is available for testing, the commonly used test is FAT (Direct Fluorescent Antibody Test) which detects the rabies virus nucleoprotein antigens in the brain tissue. Postmortem brain tissue can be obtained by craniotomy. However, brain biopsy is the preferred postmortem sampling technique. This can be done via the orbital or trans-nasal route (samples are obtained from the orbitofrontal cortex) using biopsy needles or through the occipital route through the foramen magnum (samples from the cerebellum and brain stem) using lumbar puncture needles. The direct rapid immunochemistry test (DRIT) for the detection of viral antigens in the brain tissue is useful for the diagnosis of animal rabies and can be done in field conditions. There is no need for a fluorescent microscope for doing this test. Similarly, RDIT (Rapid Immunochromatographic diagnostic test) is available for the diagnosis of animal rabies in field conditions. These tests are not adequately validated for diagnosis of human rabies. When brain tissue is not available for post-mortem testing, the presence of viral RNA can be tested by nucleic acid amplification techniques from samples obtained by nuchal skin biopsy. However, the sensitivity is less when compared to samples obtained from brain tissue.

Annexure 3: Animal rabies case definition

Case	Definition
Suspected	A case that is compatible with a clinical case definition of animal rabies Clinical case definition: An animal that presents with any of the following signs: • hypersalivation, • paralysis, • lethargy, • unprovoked abnormal aggression (biting two or more people or animals and/or inanimate objects), • abnormal vocalization and • diurnal activity of nocturnal species
Probable	A suspected case plus a reliable history of contact with a suspected, probably or confirmed rabid animal and/or An animal with suspected rabies that is killed, died or disappears within 4–5 days of observation of illness
Confirmed	A suspected or probable animal case confirmed in a laboratory
Not a case	A suspected or probable case that is ruled out by laboratory tests or epidemiological investigation (i.e. appropriate quarantine period in eligible animals).

Annexure 4: Precautions in handling of dead bodies

- The body of a patient suspected to have died of rabies should be labeled as infectious but not as “contagious” (Not airborne or droplet transmission).
- The risk of transmission to others is extremely low if standard precautions are observed.
- Blood does not contain RABV, but the virus is present in many other tissues and fluids, such as those of the central nervous system and salivary glands.
- If embalming or autopsy is performed, it should be undertaken carefully, with appropriate precautions and personal protective equipment.
- Tissues and body fluids should be disposed of in the same manner as for other infectious diseases.

- The body of the deceased should be allowed to be buried or cremated, depending on their religious practice.

Annexure 5: Technique for ID administration of rabies vaccine

Equipment required

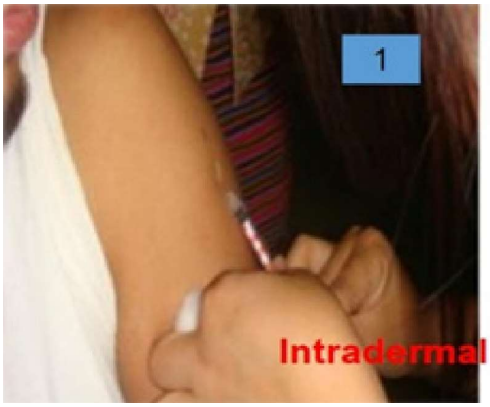
1. A vial of freeze-dried rabies vaccine and diluents
2. 2 ml. disposable syringe with needle for reconstitution of vaccine
3. Disposable 1 ml syringe. Preferably an insulin syringe with a fixed needle (28 or more gauge) should be used
4. Disinfectant swabs (e.g.70% ethanol) for cleaning the top of the vial and the patient's skin

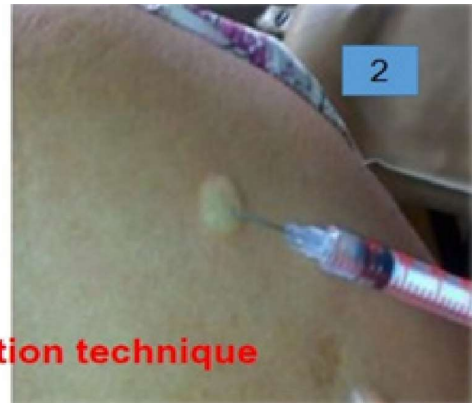
Procedure

1. Make the patient to sit comfortably and ensure adequate privacy. Patient must be reassured and their anxiety must be alleviated by briefly explaining the procedure that will be performed.
2. Both deltoids must be adequately exposed.
3. Using aseptic techniques, reconstitute the vial of freeze-dried vaccine with the diluents and syringe supplied by the manufacturer.
4. Roll the reconstituted vaccine vials between your hands and do not shake.
5. Using 1ml syringe, draw 0.2ml of reconstituted vaccine i.e. upto 20 units if using 100 iu or 8 units if using 40 iu syringe.
6. Remove any air bubbles carefully from the syringe to remove any dead space.
7. Clean the site and stretch the surface of the skin.
8. Insert the tip of the needle with the bevel upwards and keeping it almost parallel to the skin, an inch above the insertion of the deltoid, inject 4 units (0.1ml) intradermal vaccine which forms a "bleb".
9. If the needle is correctly placed in the dermis, considerable resistance is felt while injecting the vaccine.
10. Do not rub the site of injection.

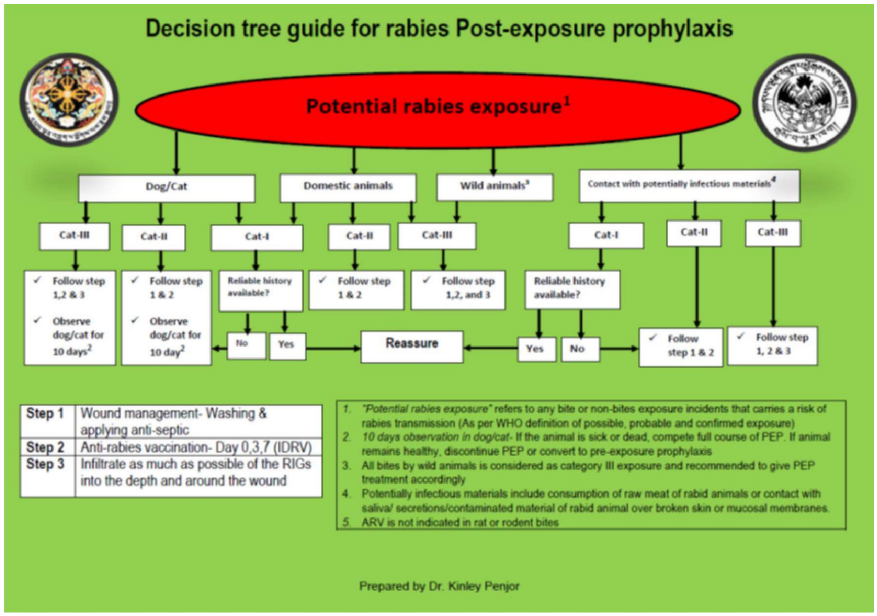
11. Inject the remaining half (0.1ml) of vaccine into the opposite deltoid.
12. If the vaccine is injected subcutaneously, the papule is not seen. Then the needle should be withdrawn and re-injected (0.1ml) at the adjacent site once more.
13. Once all doses of vaccine have been injected into the patient, discard the needle and syringe in appropriate infectious disposal bins.

Note: Some difficulty may arise with elderly patients who have thin, inelastic skin, and with infants who are crying.





Annexure 6: Rabies PEP decision algorithm



Annexure 7: Methods for RIG infiltration

Precautions

- The old practice of administering remaining immunoglobulin dose by IM should not be followed but importance must be given to local infiltration of the wounds.
- If, however, there is a high likelihood that there are additional small wounds or exposure was through other than through a bite, injection of the remaining RIG volume intramuscularly as close as possible to the presumed exposure site, to the degree that is anatomically feasible, is indicated. The same applies for mucosal exposure with no wound and rinsing with RIG can be considered.
- In the case of suspected exposure to RABV in aerosols, an intramuscular injection of RIG is nevertheless recommended.
- Infected bite wounds are not a contraindication to the administration of rabies immunoglobulin
- RIGs should be carefully infiltrated, without excessive pressure, in areas such as the tip of fingers and toes, ear lobe, nose, or around the eye, to avoid compartment syndrome.

Steps

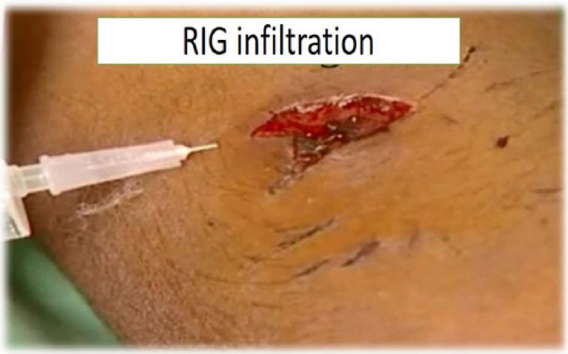
1. Rabies Immunoglobulin stored in refrigerator should be brought to room temperature (25ºC to 30ºC), before administration to the patient.
2. There is no need for skin test prior to administration of eRIG, as such tests poorly predict severe adverse events and their results should not be the basis for not giving equine immunoglobulin when indicated.
3. RIG must not be administered in the same syringe or site as the vaccine.
4. The patient should not be on an empty stomach.

Example for the calculation of the dose of eRIG

A patient weighing 60 kg, with dog bite wounds on the right forearm and elbow came for treatment to the clinic.

Body weight	60kg
Dose (maximum) of eRIG to be administered	40iu/kg BW i.e. 60 x 40 = 2400 IU
Each ml. of eRIG contains	200iu
Volume of eRIG to be used for infiltration of wounds	2400/200= 12ml

5. The entire calculated immunoglobulin dose, or as much as anatomically possible, should be infiltrated carefully into or as close as possible to the wound(s) or exposure sites. Multiple needle injections into the wound/s should be avoided.
6. If the calculated dose of the rabies immunoglobulin is not sufficient to infiltrate all the wounds, the calculated volume of RIG should be diluted in sterile physiological saline to a volume sufficient to infiltrate all the wounds.
7. If eyes are exposed, RIGs can be instilled as eye drops, after dilution (1:1) with sterile normal saline.
8. The unused portion of the RIG can be used for another patient if it is aseptically stored.
9. Keep patients under observation for at least 30 minutes after RIG administration



Annexure 8: Anti-rabies card (To be issued to animal bite victims administered PEP)

Sl no	Day	Route of vaccination (IM/ ID)	Date of administration	Due date	Remarks: (Pre/post-exposurepost exposure, booster)
1	D0				
2	D3				
3	D7				
4	D14				
5	D28				

Annexure 9: Verbal autopsy questionnaire (To be used for investigating suspected/ confirmed rabies death)

Name of interviewer: _____ Date of interview: – – /– – /– – – –

Name of the health facility:_____ Name of deceased: _____

Village_____ Gewog:_____ District:_____

GPS coordinate:_____/_____

I. Information about respondent

1.1 Name of main respondent_____

1.2 Contact information _____

1.3 What was your relationship with the deceased? (Tick)

- Parent
- Spouse
- Sibling
- Child
- Son-in-law or daughter-in-law
- Friend or neighbor
- Community leader
- Health care worker (facility name):
- Others (specify)

II. Information of the deceased 2. Demographics

2. Demographics

2.1 Nationality

2.2 Sex

2.3 Age (years)

2.3.1 For infants, record the most appropriate: Month(s) __Week(s)___ Days___

2.6 Occupation

2.7 Level of education (Tick highest level of education attained)

- Illiterate
- Below primary
- Primary or middle
- Secondary or high
- Graduate
- Postgraduate
- Other (specify)

III. Exposure (during previous 12 months)

3.1 Did any family pets or livestock die during the 12 months before the patient's illness? (Tick)

- Yes (Date of death: – – / – – / – – – –)
- No
- Unknown

3.2 Did the deceased have any contact with animals (bite, scratch, lick) within the 12 months before the illness that led to death? (Tick)

- Yes
- No
- Unknown

3.3 If yes, please describe the animal contact events

3.3.1 On what date did [deceased] have contact with the animal? *(If there are more than one animal contact events, provide specific date of the event and types of animal)*	– – / – – / – – – –
3.3.2 What type of animal? (Circle)	• Dog • Cat • Bat • Livestock • Other:_____
3.3.3 Was the animal owned?	• Owned • Not owned • Wild • Unknown
3.3.4 Did the animal have any signs of disease (Describe)?	☐ Yes ☐ No ☐ Unknown • Aggression • Paralysis • Biting • Hypersalivation • Lethargy • Other:_____
3.3.5 Is the animal alive today? (If no, estimate date of death?)	☐ Yes ☐ No ☐ Unknown – – / – – / – – – –

3.3.6 Was the animal observed for at least 10 days after the exposure?	• Yes, alive after 10 days • Yes, died during observation • No • Unknown
3.3.7 Was the animal tested for rabies?	• Yes, rabies positive • Yes, rabies negative • No • Unknown
3.3.8 Was the deceased bitten by the animal?	☐ Yes ☐ No ☐ Unknown • Location of bite: • Head • Trunk • Upper limb • Hands • Lower limb • Genitalia • Other:_____
3.3.9 Did the deceased have other contact with the animal i.e. licked, scratched.	• Scratch • Saliva contact with open wound or mucous membrane • Neural tissue contact with open wound or mucous • Membrane • Other:_____

3.3.10 What treatment did the patient receive for this contact?	• Washed the wound • Sought medical care • Received rabies vaccination

Additional Notes (Use additional page if required):

IV. Rabies treatment

4.1 Did the deceased receive treatment for any of the animal exposures above?

- Yes
- No
- Don’t know

4.2 Was any of this treatment received at home?

- Wound washing
- Over-the-counter medications
- Traditional medicines
- Other:
- None
- Unknown

4.3 Where did the deceased go for medical care for any of the exposures listed above?

	Traditional healer	Medical practitioner	Other: _____
Facility name and location			
Date(s) visited	1: – – / – – / – – – – 2: – – / – – / – – – – 3: – – / – – / – – – –	1: – – / – – / – – – – 2: – – / – – / – – – – 3: – – / – – / – – – –	1: – – / – – / – – – – 2: – – / – – / – – – – 3: – – / – – / – – – –
	• Antibiotics	• Antibiotics	• Antibiotics
	• Tetanus	• Tetanus	• Tetanus
	• Wound washing	• Wound washing	• Wound washing
	• Rabies postexposure prophylaxis or treatment	• Rabies postexposure prophylaxis or treatment	• Rabies postexposure prophylaxis or treatment
	• Traditional medicine	• Traditional medicine	• Traditional medicine
	• Other (specify)	• Other (specify)	• Other (specify)

4.4 If the patient received rabies vaccination, please record schedule of vaccine and dates received:

CCV	RIG	D0	D3	D7	D14	D28
Dose received?	• Yes • No • Unknown	• Yes • No • Unknown	• Yes • No • Unknown	• Yes • No • Unknown	• Yes • No • Unknown	• Yes • No • Unknown
Date received?						

4.5 Had the patient ever been vaccinated against rabies prior to this exposure?

- Yes: Year of vaccination: – – / – – / – – – –
- No
- Unknown

V. Signs and symptoms

5.1 Time of symptom onset and death

5.1.1 When did the illness that led to death begin?

Day_____ Month_____ Year_____ Unknown_____

5.1.2 If you don't remember the exact date, approximately how long ago did the illness begin?

Day_____ Month_____ Year_____ Unknown_____

5.1.3 How many days after illness did the deceased die? Number (estimate if needed):

5.2 During the illness did the deceased seek medical assistance?

- Yes: (Date): – – / – – / – – – –
- No
- Unknown

5.3 During the illness was the deceased admitted to a hospital?

- Yes: (Date): – – / – – / – – – –
- No
- Unknown

5.4 Characteristics of illness that led to death_____

_____

_____

5.5 Was any relevant diagnostic testing performed?

Disease	Test performed	Date	Result	Comment
Encephalitis				
Rabies				
Mosquito-borne encephalitis				
Herpes simplex virus				
Measles virus, Malaria				
Others				

5.5.1 What was the date of deceased's death?
Day ____/Month _____/Year_____

5.5.2 Where did the deceased die?

- Home
- Hospital (specify)
- Other health facility (specify)
- Other (specify)

5.5.3 Did anyone else in the community develop similar illness within the past 12 months? (If "Yes", collect contact information for other suspected cases to initiate verbal autopsy of additional cases)

- Yes
- No
- Unknown

If yes, describe:_____
_____

VI. Postmortem information

6.1 Postmortem report available (if any):

- Yes
- No
- Unknown

6.2 Death certificate available?

- Yes
- No
- Unknown

6.3 Did the deceased have any evidence of recent wounds?

- Yes
- No
- Unknown

6.4 Did the deceased have any evidence of healed wounds?

- Yes
- No
- Unknown

VII. Contact investigation

- Collect the names and contact information for any family, community members or hospital workers who had contact with the suspected rabies case in the 14 days before symptom onset until death.
- Collect the names and contact information for any people who had contact with the animal suspected of transmitting rabies to the case.
- Risk assessments should be conducted with these people to rule out potential exposure.

VIII. Classification of human rabies (Please tick your inference below)

☐ Not a case: Does not meet the clinical definition
☐ Suspected: A case that is compatible with the human clinical case definition
☐ Probable: A suspected case with probable or confirmed exposure to rabies
☐ Confirmed: A suspected or probable case that is confirmed in a laboratory

Names of Investigator(s), signatures of local informants and designation

1._____ _____
2. _____ _____
3. _____ _____
4. _____ _____

Additional enclosures (description) as evidence of rabies

1. _____ (Pages_____)
2. _____ (Pages_____)

Annexure 10: Quarterly reporting form

Name of the reporting district:												
Quarter (Please tick) Year.....			Q1 (Jan-Mar)		Q2 (April-June)				Q3 (July-Sept)	Q4 (Oct-Dec)		
			No. of animal exposures						Post-exposure Prophylaxis (PEP)		No. of Human Rabies Cases	
			Dog bites	Other animal bites	Cat I	Cat II	Cat III	Unknown	No. of people received ARV	No. of people received RIG		
Age	<15 years	M										
		F										
	≥15 years	M										
		F										
Total												

Annexure 11: Reporting form from the health center to livestock official for potential rabies exposure

(For any patients reporting to health center with history of exposure to probable rabid animals)

Sl. no	Particulars	Details
1	Reporting Health Centre	
2	Reporting date	
3	Dzongkhag	
4	Name of reporting person	
5	**Initial information by:**	
	• Name	
	• Telephone number	
	• Email	
6	**Patient details:**	
	• Name	
	• Address	
	• Contact number	
7	**Source of exposure (✓):**	
	• Own dog	
	• Owned cat	
	• Stray dog	
	• Stray cat	
	• Wild animal (specify)	
	• Other animal (specify)	

Annexure 12: Rabies outbreak line-listing form

Name of the health center:																					
Name of the health worker reporting:																					
	Patient information				Exposure details								Post exposure Prophylaxis (PEP)						Outbreak Response			
Sl. no.	Name	Present Address	Age	Sex	Mobile number	Date of Exposure (dd/mm/yy)	*Site of Exposure	**Exposure Type	***Animal Species	Category of exposure (as per the guideline)	Wound management (yes/no)	ARV given (yes/no)	D0	D3	D7	D14 (IM)	D28	RIG given (yes/no)	If HRIG not given, why no?	Animal health counterpart informed (yes/no)	IEC provided (yes/no)	Any other interventions taken

Note: To be submitted to the Program within one month after the confirmation of outbreak in animals

*Mention the site of the bite (leg, arm, face etc)

**Specify the Exposure type (bite by dog, cat scratch, dog lick one open wound, cared for rabies patient etc)

***Animal Species (Dog, Cat, Domestic livestock, Wild animals, Rats/Rodents)

Annexure 13: Rabies PEP register

Sl no	Reg. No	Name	Age/ sex	Oc-cupa-tion	Address			Ex-po-sure date	Place Where exposure occurred			Ex-poure type*	An-imal spe-cies	Vacci-nation statues (dog/cat)	Site of bite	Cat of expo-sure**	Vacci-nation route	Date of ARV pro-vided (indicate by tick mark)					Pre/ PEP	RIG (Yes/ No)	Re-marks
					Dzongkhag	Geog	Village		Dzongkhag	Geog	Village							0	3	7	14	28			

Annexure 14: Standard operating procedure for disinfection and decontamination of contaminated premises and materials.

Purpose

To have a standard procedure for effective disinfection and decontamination of contaminated premises and materials

Scope

The document describes procedures for disinfection and decontamination of contaminated materials and premises.

Users:

Health care workers

Materials/equipment required

Gloves; Apron; Gum boots; Buckets; Mugs/jugs; Water; bleaching powder; calcium hypochlorite

Procedure

1. Prepare 1% calcium hypochlorite solution in a bucket.
2. Utensils: Spray and wash barn utensils, tools, and equipment with the above solution thoroughly.
3. Dry them for reusing.
4. Burry the beddings with carcasses if it is in small quantities, and burn it in a pit if in larger quantities.
5. Contaminated premises should be disinfected thoroughly with the 1% calcium hypochlorite spray @ 1-1.5 L/m2. Allow contact time of 2-3 hrs.
6. Contaminated laboratory materials can be disinfected by immersing them in 1% calcium hypochlorite solution for at least 30 minutes.
7. Disposable items, including used PPEs, must be incinerated/burnt in a pit.