

General Circular Letter No. 02-31/2011

My No. DGHS/MR/2011/04
Department of Health Services
"Suwasiripaya"
No.385, Baddegama Wimalawarasa Thero Mawatha,
Colombo 10.

08/05/2011

All Provincial Secretaries of health
All Provincial/Regional Directors of health services
All Directors of Teaching Hospitals
All Heads of Specialized Campaigns
Medical Superintendents of Provincial Hospitals &
District Medical officers of Base Hospitals


REVISED PROTOCOL FOR ANTI RABIES POST EXPOSURE THERAPY

Herewith I am annexing Circular No. 02/31/2011 on the revised protocol for Anti Rabies Post Exposure Therapy (PET) which would help the Medical Officers to upgrade their knowledge on correct management of dog bite victims. This protocol is based on the Rabies Vaccines: WHO position paper No 32, August 2010 in the WHO weekly Epidemiological Record.

It would be essential to circulate this among all the Consultants and Medical Officers. These guide lines will help to update the knowledge on correct management of rabies PET and would also prevent wastage of anti rabies serum and vaccine in government hospitals.

It would be the responsibility of the Heads of the Institutions to ensure the usage of the serum and vaccine strictly according to the protocol so that the treatment will be uniform island wide.

Please bring the contents of this circular to all prescribers in your Province/Region and Institutions.


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Protocol for anti rabies post exposure therapy (PET)

1.0 Management of a patient following an animal bite

- 1.1 Wounds should be washed immediately with soap and water for 3-5 minutes.
- 1.2 Wounds should be cleaned thoroughly at the hospital with 70% alcohol or povidone iodine.
- 1.3 Anti tetanus immunization should be inoculated when necessary.
- 1.4 Antimicrobials should be prescribed if necessary to control bacterial infection.

It is essential to screen the patient and the animal before the decision is made regarding PET.

2.0 Screening the patient - Categorization of the exposure

2.1 Major exposures:

- a. Single or multiple bites with bleeding on head, neck, face, chest, upper arms, palms, tips of fingers & toes and genitalia.
- b. Multiple deep scratches with bleeding on the head, neck and face.
- c. Single or multiple deep bites on any part of the body.
- d. Contamination of mucous membranes with saliva.
- e. Bites of wild animals with bleeding.

2.2 Minor exposure:

- a. Single, superficial bite or scratch with bleeding on the lower limbs, upper limbs, abdomen and back.
- b. Nibbling of uncovered skin.
- c. Contamination of open wounds with saliva,
- d. Single or multiple bites or scratches without bleeding on any part of the body.
- e. Drinking raw milk of rabid cow or goat.

3.0. Screening the animal

3.1. In case of major exposure to dogs and cats:

- 3.1.1 If the animal is **apparently healthy, observable and has had a minimum of 2 rabies vaccinations given not more than 2 years apart, with the last vaccination given within 1 year** of the incident, PET can be delayed while observing the animal for 14 days.
- 3.1.2 When the animal is **suspicious or is sick, but observable** initiate PET while observing the animal. Discontinue treatment if the animal is apparently healthy after 14 days.

3.1.1 If the animal is **having rabies** (confirmed by laboratory diagnosis) or **unobservable** (animal dead, killed, missing or stray animal) initiate PET and continue the full course.

3.2. In case of **minor** exposure to **dogs and cats**:

3.2.1 If the animal is **apparently healthy, observable and has had a minimum of 1 rabies vaccination.**

- within 1 year of the incident.
- at an age above 3 months
- incident occurring at least 1 month after the vaccination

PET can be delayed while observing the animal for 14 days.

3.2.2 When the animal is **suspicious or is sick, but observable**, initiate PET while observing the animal. Discontinue PET if the animal is healthy after 14 days.

3.2.3 If the animal is **having rabies** (confirmed by laboratory diagnosis) or **unobservable** (animal dead, killed, missing or stray animal) initiate PET and continue the full course.

The patient must be clearly advised that the animal should be put in a cage or leashed during the observation period. If the animal dies, becomes sick or develop any abnormal behaviour, the patient should be advised to report to the hospital immediately. In case of death of the animal patient should be encouraged to send the head of the animal for laboratory confirmation of rabies.

The following are not considered as exposures:

- a. Contamination of intact skin with saliva of a suspected rabid animal.
- b. Petting, bathing or coming in contact with utensils of a suspected rabid animal.

4.0 **Anti Rabies PET:** When indicated:

4.1 All patients in the **major** category should be given rabies immunoglobulin (equine or human) followed by a course of anti rabies vaccine (ARV).

4.2 Patients in the **minor** category should be given only a course of ARV.

5.0 **Rabies Immunoglobulins (RIG)**

5.1 RIG available in Sri Lanka at present:

- a. Equine rabies immunoglobulin (ERIG)
- b. Human rabies immunoglobulin (HRIG)

- **Administration of RIG should be considered as an emergency. Rabies immunoglobulins should be given immediately after the incident.**
- If the patient reports late, RIG could be given up to 3 months after exposure, if the patient has not taken the anti rabies vaccine.

It is essential to test for sensitivity before administering ERIG. Method of sensitivity testing (ST) for ERIG is given in annexure I. HRIG does not require sensitivity testing prior to its administration.

Performing a repeat ST for ERIG is not a contraindication.

If a patient with a **major exposure** is **ST positive for all available products of Equine RIG, Human RIG** should be considered.

However, in a situation where HRIG is not available

- a. If the animal is **apparently healthy and observable**, the modified 4 site ID – ARV schedule could be considered.
 - b. If the animal is **suspicious of having rabies or is unobservable**, WHO recommended method of using ERIG under adrenaline and antihistamine cover in an ICU setup should be considered.
- In case of major exposure where modified 4 site ID-ARV was administered in place of RIG and the patient reports that the animal is dead, missing, sick or having abnormal behaviour within 07 days of initiation of ARV, WHO recommended method of using ERIG under adrenaline and antihistamine cover should be administered in an ICU setup. This should be followed up with a fresh course of 2 site ID-ARV.
 - If the patient reports after 07 days of initiation of ARV, continue and complete the modified 4 site ID-ARV schedule. **Rabies immunoglobulin is not indicated.** In such situations, additional doses of ARV could be considered after seeking expert opinion.

5.2 Dosage of RIG

- a. Equine rabies immunoglobulin (ERIG) 40 IU/ kg body weight.
- b. Human rabies immunoglobulin (HRIG) 20 IU/ kg body weight.

RIG should be infiltrated in and around all wounds. After infiltration of the wounds if there is any remaining RIG, it should be given IM on the thighs. Deltoids should be spared for ARV when giving RIG. Vaccines should be administered preferably on the same day after RIG, but at a different site.

6.0 **Anti Rabies vaccines (ARV)**

Following anti Rabies vaccines are available in Sri Lanka at present:

- a. Purified chick embryo cell culture vaccine (PCEC)
- b. Purified Vero cell rabies vaccine (PVRV)

6.1 Intramuscular (IM) schedules of ARV

This schedule is used in hospitals where less than 5 patients following animal bites are treated per day.

6.1.1 For major exposures: 5 dose regimen with RIG

IM-ARV one dose* each on D0, D3, D7, D14 & D30.

6.1.2 For minor exposures: 4 dose (2-1-1) regimen

2 doses* of IM-ARV one in each deltoid on D0 followed by 1 dose* each on D7 & D21.

*1 dose = PCEC 1 ml (1 vial) / PVRV 0.5 ml (1 vial)

IM injections should be given into the deltoid muscle or in small children into the anterolateral thigh muscle.

6.2 Intradermal (ID) schedules of ARV

These schedules are administered in Teaching Hospitals, General Hospitals, Base Hospitals and some District hospitals where more than 5 patients following animal bites are treated per day. WHO has recommended the use of ID schedules in developing countries, where cost of vaccines is a major limiting factor.

Intradermal schedules of ARV is not recommended for immunocompromised patients (patients on cytotoxic drugs, on long term steroids, positive for HIV/AIDS, on anti-malarials etc.)

They should be administered IM-ARV schedule after expert consultation.

The recommended ID dose is 0.1ml per site for both PCEC and PVRV

It is also recommended to use fixed needle 1mL disposable syringes for intradermal administration of ARV.

6.2.1 The 2 Site ID schedule (2-2-2-0-2 schedule)

The standard schedule used in government hospitals: One dose each (0.1 ml) is given at 2 sites, on both arms (over deltoids) on D0, D3, D7 and D30 .

6.2.2 The modified 4 site ID schedule (4-2-2-0-2 schedule)

One dose (0.1 ml) given at 4 sites on day D0 (deltoids and lateral thighs), one dose (0.1ml) given at 2 sites on D3, D7 and D30.

6.3 Precautions that should be taken when using ID - ARV schedules

All injections should be administered only **by trained staff** under supervision of a medical officer. Once the vaccine is reconstituted the contents should be used as soon as possible (preferably within 8 hours, stored at 2-8°C). Separate disposable syringes and needles should be used for each patient.

7.0 Anti rabies pre-exposure therapy

This form of therapy is indicated for persons who are at a higher risk of exposure to rabies virus i.e. laboratory staff handling live rabies virus, veterinarians and support staff, rabies control staff (vaccinators) wild life officers, employees in animal quarantine premises and zoological establishments.

The recommended schedule is IM-ARV - 1 dose each on D0, D7 & D28.

A booster dose is given 1 year after the first dose. Additional booster doses are given once every 05 years.

Administration of RIG is contraindicated in persons on pre - exposure therapy. They should only be given additional doses of IM-ARV 1 dose each on D0 and D3 as boosters even in a case of a major exposure.

8.0 Important points to be noted

- Suturing is best avoided. If necessary, should be done after infiltration with RIG.
- RIG should be administered before starting on ARV.
- Administration of RIG or ARV on the buttocks is not recommended as absorption is poor.
- In small children with multiple bites, if the volume is insufficient for infiltration in and around all wounds, dilute RIG with sterile N. Saline up to double or 3 times.
- Human to human transmission of rabies has not been reported (except through corneal or organ grafts).
- For any person who has had direct or indirect contact with a rabies patient, PET is not recommended except in special situations (Gen. Circular No: 01-22/2004 on "Guidelines for the procedure to be followed in a case of death due to human rabies and disposal of the body").
- Laboratory confirmation of rabies should always be encouraged.
- In situations where the animal is not vaccinated, encourage the owner to vaccinate the animal concerned after the observation period.
- Pregnancy is not a contra-indication for RIG and ARV therapy when indicated.
- All patients who receive rabies PET should be given a document / card, clearly stating the date, month & the year of vaccination and the type of vaccine used.
- Rabies PET is not recommended following house rat bites.

9.0 Management of patients following previous rabies PET

9.1 For both major and minor exposures: If the animal is **apparently healthy and observable**, PET could be delayed while observing the animal for 14 days.

9.2 If the animal is **proven rabid, suspicious of having rabies or unobservable**:

9.2.1 After a full course of ARV:

- a. Up to 06 months from the last dose of ARV - PET is not indicated.
- b. From 6 months - 05 years from the last dose of ARV- 2 site ID-ARV 2 doses each or IM-ARV one dose each should be given on D0 and D3. As an alternative to this regimen, the patient may be offered a single visit 4 site intradermal regimen consisting of 4 injections of 0.1ml, equally distributed over left and right deltoids or prescapular areas.
- c. Up to 05 years from the last dose of ARV, RIG is not indicated.
- d. After 5 years: full course of ARV with or without RIG (depending on the category of exposure and animal screening) is recommended.

9.2.2 After 3 doses of ARV (D0, D3, D7)

- a. Within 30 days: continue the original course of ID-ARV by giving 2 ID doses of ARV on D30.
- b. From 1 to 6 months from the last dose of ARV: ID-ARV 2 doses or IM-ARV one dose should be given on D0 (on the day the patient reports) and D3.
- c. From 6 months to 5 years from the last dose of ARV: a full course of 2 site ID-ARV or IM-ARV should be given.
- d. After 5 years: full course of ARV with or without RIG (depending on the category of exposure and animal screening) is recommended.

Please note that all health care staff managing anti Rabies PET patients, should strictly adhere to the guide lines given in this protocol. For any clarification, contact Consultant Virologist, Dept of Rabies and Vaccines, MRI. Telephone numbers: 0112698660, 011-2693532 - 4.

It is essential that all institutions using RIG and ARV should send a monthly return (Annexure I) to Consultant Virologist, Dept. of Rabies and Vaccine QC, MRI, Director, Public health Veterinary Services, 6th Floor, 555/5, Elvitigala Mw, Colombo 05 and to the Director/MSD, before collection of the next months vaccine supplies from MSD/RMSD. Any adverse reactions following rabies PET should be reported to Director/MSD, D/MT&S and Virologist/Dept. Rabies, MRI.

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Method of sensitivity testing (ST) for Equine Rabies Immunoglobulin (ERIG)

Control - Inoculate 0.1 ml of N. saline intradermally (ID) on flexor aspect of the forearm.

Test - Prepare a 1:10 dilution of rabies equine serum with sterile N. Saline and inoculate 0.1 ml intradermally (ID) on flexor aspect of the opposite forearm.

The diameter of the induration should be recorded in mm. immediately after performing the ST.

Separate fixed needle syringes should be used for each patient. Patient is kept under observation and the ST should be read after 20 minutes. Examine for itching, induration or urticaria or any systemic effects of anaphylaxis. If the initial induration is less than 6mm and after 20mins. the induration is over 10mm in diameter or any systemic reaction should be considered as positive ST.

Drug of choice in anaphylaxis is 1:1000 adrenaline 0.5ml given intramuscularly (IM) or subcutaneously (SC) immediately. Mild sensitivity reactions could be managed with antihistamine therapy and oral or parenteral steroids should be best avoided, as it could depress the immune response.

Monthly return for vaccine consumption

Name of the institution

YearMonth.....

Type of vaccination	No. of patients treated				
Serum					
ERIG					
HRIG					
	1st dose	2nd dose	3rd dose	4th dose	5th dose
Intramuscular					
5 dose schedule					
2-1-1 schedule					
Intradermal					
2 site schedule					
8 site schedule					
Balance	Serum		Vaccine		
Opening balance					
Received					
Consumption during month					

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Signature

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Designation

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Date