Republic of the Philippines

Department of Health

OFFICE OF THE SECRETARY

June 8, 2009

ADMINISTRATIVE ORDER

No: 2009-0027

SUBJECT: **Amendment to AO 2007-0029 regarding the Revised**

Guidelines on Management of Animal Bite Patients.

I. BACKGROUND/RATIONALE

Rabies, present in all continents and endemic in most African and Asian countries, is a fatal zoonotic viral disease, transmitted to humans through contact with infected animals, both domestic and wild. Rabies is estimated to cause at least 55,000 deaths per year worldwide, about 56% of which occur in Asia and 43.6% in Africa, particularly in rural areas on both continents. In the Philippines, although rabies is not among the leading causes of morbidity and mortality, rabies is considered a significant public health problem for two reasons: 1) it is one of the most acutely fatal infections and 2) it is responsible for the death of 200-300 Filipinos annually.

The Department of Health continues to be committed to the fight against rabies and has set the goal of rabies elimination in 2020. An essential part of this strategy is the provision of post-exposure prophylaxis to bite victims and pre-exposure prophylaxis to high risk individuals as mandated by the Anti-Rabies Act of 2007. Pursuant thereto, guidelines for the appropriate as well as cost-effective management of animal bite patients have been issued.

Historically the management of animal bite cases had to be updated every five (5) years and the guidelines revised accordingly to incorporate new and better treatment modalities based on research results. The first revision was made in 1997, the second in 2002 and the 3rd in 2007.

Since the release of the latest guidelines in 2007, new recommendations related to rabies management have been released by the World Health Organization and the US Centers for Disease Control. The Anti-Rabies Act of 2007 and its Implementing Rules and Regulations provided for the provision of pre-exposure prophylaxis among school children from high-risk areas. These current guidelines are therefore amended to incorporate these crucial recommendations.

II. OBJECTIVE

To provide updated guidelines and procedures to ensure effective and efficient management of rabies exposures toward eventual reduction, if not elimination, of human rabies

III. AMENDMENTS IN AO 2007-0029

The following sections of AO 2007-0029 are hereby amended as follows:

1) Section III. COVERAGE (in page 2)

All government health workers at all levels shall adopt these treatment guidelines to ensure standardized and rational management of animal bite patients. Private practitioners in the country are strongly encouraged to adopt these treatment guidelines.

2) Section IV. DEFINITION OF TERMS (in page 2)

1. Post Exposure Prophylaxis (PEP) – formerly post exposure treatment of (PET); refers to anti-rabies treatment administered *after* an exposure (such as bite, scratch, lick, etc.) to potentially rabid animals. It includes local wound care, administration of rabies vaccine with or without Rabies Immune Globulin (RIG) depending on category of exposure.

1. Pre-exposure prophylaxis – refers to rabies vaccination administered *before* an exposure to potentially rabid animals. This is usually given to those who are at high risk of getting rabies such as veterinarians, animal handlers, staff in the rabies laboratory, hospitals handling rabies patients and
schoolchildren from high-risk areas
, etc.

3) Section VI. A.3. Rabies exposure is stratified in three categories with corresponding management guidelines as shown in Table 1. (in page 4)

Table 1. Categories of Rabies Exposure with Corresponding Management

Category of Exposure	**Management**

Category 1

a)		Feeding/touching an an
b)		Licking of intact skin (wi
c)		Exposure to patient with
d)		Casual contact (talking

1. **Wash** **exposed skin immediately with soap and w**

1. **No vaccine or RIG needed**

1. **Pre-exposure prophylaxis may be considered for high risk persons.**

CATEGORY II

a)		Nibbling of uncovered sk
b)		Minor scratches/abrasion
c)		Minor scratches/abrasion
d)		All category II exposure

1.		**Wash**
2.		**Start vac**
a.		Complete v
	i.	

	ii.	
	iii.	
	iv.	
b.		May omit c
	i.	
	ii.	
3.		RIG is no

CATEGORY III

a)		Transdermal bites (punct
b)	□□□□□	**Licks on broken skin**
c)		Exposure to rabies patien

d)		Handling of infected carc

e)		All Category II exposures

1.	□□□□□	**Wash**

2.		**Start vac**

1. Complete vaccination regimen until day 28/30 (see Table 1a) if:

	i.	

	ii.	

	iii.	

	iv.	

1. May omit day 28/30 dose if:

	i.	
	ii.	

Table 1a. Management of patients with category II and II exposure where the biting animal cannot be observed or dies within the 14 days observation period

FAT Result

Signs and Symptoms of Rabies in biting animal

Give 3 doses (Day zero(D0), Day Three(D3), Day Seven(D7)

Give 4 th Dose (Day Twenty Eight/Thirty(D28/30)

+

+

Yes

Yes

+

-

Yes

Yes

-

+

Yes

Yes

-

-

Yes

No

Not done

+

Yes

Yes

Not done

-

Yes

Ye

4) Section VI.B.1.1.2:Types of Rabies Vaccines and Dosage (in page 5)

The National Rabies Prevention and Control Program (NRPCP) provides the following

anti-rabies tissue culture vaccines (TCV) a) Purified Vero Cell Rabies Vaccine (PVRV) – 0.5ml/vial and b) Purified Chic Embryo Cell Vaccine (PCECV) – 1.0ml/vial

Table 2. List of TCV Provided by the NRPCP to Animal Bite Treatment Centers with Corresponding Preparation and Dose

Generic Name
Preparation
Dose
Purified vero cell rabies vaccine (PVRV)
0.5ml/vial
ID – 0.1ml

IM – 0.5ml
Purified chick embryo cell vaccine (PCECV)
1 ml/vial
ID – 0.1ml
IM – 1.0m

Recommendations on the intradermal administration of anti-rabies vaccines:

The NRPCP introduced the intradermal (ID) use of rabies tissue culture vaccines in the country in 1997. The Philippines was among the first countries to adopt this regimen as recommended by the World Health Organization, in order to totally discontinue the use of nerve tissue vaccine (NTV) which was associated with vaccine induced encephalopathy. To mitigate the expected increase in the cost of PEP with the shift from NTV to TCV, the ID use of these vaccines was introduced. According to WHO, the ID use of tissue culture vaccines can decrease the cost of PEP by as much as 60-80%.

However, only a limited number of commercially available rabies vaccines have been proven, to date, as safe and efficacious for PEP when administered by the ID route. Recently, local manufacturers in rabies-endemic countries have started to produce rabies vaccines. The ID use of these vaccines should be based on adherence to WHO requirements for that route and approval by national health authorities as follows, *"New vaccine manufacturers should provide clinical evidence that their products are immunogenic and safe when used intradermally. Clinical evidence should include clinical trials involving a vaccine of known immunogenicity and efficacy when used by this route as control, serological testing with rapid fluorescent focus inhibition test, and publication in internationally peer-reviewed journals".*

To ensure compliance to these recommendations and guarantee that animal bite patients seeking treatment in government Animal Bite Treatment Centers receive only TCV that have been proven to be safe and effective, the program shall utilize for its intradermal regimen only tissue culture vaccines that satisfy the following criteria:

1. The vaccine is registered with and approved by the Food and Drug Administration, formerly known as Bureau of Food and Drugs (BFAD);

1. The vaccine has been proven to be safe and efficacious for PEP when administered by the ID route using the schedule recommended by the World Health Organization. Having limited knowledge on and experience with the ID use of all available anti-rabies vaccines in the country, the program shall utilize the WHO list of approved TCV for ID use OR in the case of vaccines not included in the WHOthe WHO requirements for new rabies vaccines and must have gone through local clinical trials on safety and immunogenicity which are published in peer-reviewed journals; list for ID use, the vaccine must comply with
2. The potency of vaccines for ID use should be at least 0.5 IU/ID dose as evidenced by their lot release certificate. The potency of the vaccine batch should be provided by the manufacturer; AND
3. The product insert must contain the vaccine's approved ID dose and consistent with its Certificate of Registry (CPR) for Disease Control.

5) Section VI.B.2.a. Types of Rabies Immune Globulins (in page 6)

Table 3. List of Rabies Immune Globulins provided by the NRPCP to Animal Bite Treatment Centers

Generic Name

Preparation

Dose

Human Rabies Immune Globulin

(HRIG)

150 IU/ml at

2ml/vial

20 IU/kg

Purified Equine Rabies Immune Globulin (pERIG)

200 IU/ml at

5 ml/vial

40 IU/kg

6) Section VI.B.2.d. Administration (in page 7)

1. The total computed dose of RIG should be infiltrated around and into the wound as much as anatomically feasible, even if the lesion has healed. In case some amount of the total computed dose of RIG is left after all wounds have been infiltrated, it should be administered deep IM at a site distant from the site of vaccine injection (preferably anterolateral thigh) using another needle. The total computed dose should be administered as a **single dose.**

1. A gauge 23 or 24 needle, 1 inch length should be used for infiltration. Multiple needle injections into the same wound should be avoided.

1. A skin test must be performed prior to ERIG administration using a gauge 26 needle. For skin testing, 0.02 ml of 1:10 dilution of solution is infiltrated to raise a bleb 3 mm and read after 15 minutes. A positive skin test is an induration >6 mm surrounded by a flare/erythema. If initial skin test is positive, repeat skin test on same arm; use distilled water as control on the other arm. The skin test is considered positive if the ERIG skin test is positive but the control is negative.

1. If a finger or toe needs to be infiltrated, care must be taken not to impair blood circulation. Injection of an excessive amount may lead to cyanosis, swelling and pain.

1. RIG should not exceed the computed dose as it may reduce the efficacy of the vaccine. If the computed dose is insufficient to infiltrate all bite wounds, it may be diluted with sterile saline 2 or 3 fold for thorough infiltration of all wounds.

1. RIG should be administered at the same time as the first dose of vaccine (day 0). In case RIG is unavailable on day 0, it may still be given any time before the day 7 dose of the vaccine. However if the day 3 and/or day 7 doses of the vaccine have not been given, RIG may still be given anytime.

1. In the event that RIG and vaccine cannot be given on the same day, the vaccine should be given before RIG because the latter inhibits the level of neutralizing antibodies induced by immunization.

1. RIG is given only once during the same course of PEP.

1. Patients with Positive skin test to purified ERIG should be given HRIG.

1. HRIG is *preferred* for the following:

a. History of hypersensitivity to equine sera

b. Multiple severe exposures (especially where dog is sick or suspected of being rabid) on head and neck area

c. Symptomatic HIV infected patients

1. Patient must be observed for at least one hour after injection of ERIG for immediate allergic reactions.

7) Section VI.D.1.1.1.e. (in page 9)

Table 4. Guide to Tetanus Prophylaxis in Routine Wound Management

Indication for TT Immunization	
Vaccination History	
Unknown for	0.5 IU/ml
-1 booster if Ab titers fall	below 0.5 IU/ml
-In the absence of serologic testing, 1 booster dose every 5 years is recommended	
HCW involved in care of rabies patients; individuals involved in rabies control program; field workers,	

Recommended

None

1 booster each on Day 0 and Day 3

-1 booster dose every 5 years

General population

Not Recommended but may be considered as an option in young children and other individuals with ris

None

1 booster each on Day 0 and Day 3

-None

The following provisions shall be added to section VI (page 23):

N. Injection Safety:

A safe injection is defined by the World Health Organization as an injection that:

- Does not harm the recipient
- Does not expose the health staff to any avoidable risks
- Does not result in waste that is dangerous to the community

1. ***Injection Equipment***

a) Auto-Disable (AD) Syringes- are disposable injection devices that are especially made to prevent re-use and are therefore less likely than standard disposable syringes to cause person-to-person transmission of blood-borne diseases.

The program recommends that health workers use AD syringe in their respective ABTC.

b) Conventional Syringes- are plastic syringes with steel needles that are provided usually by the manufacturer in sterile package. The needle may either be fixed to the syringe when it is produced or attached by the health staff just before use.

1. ***Management of Sharp Waste***

Used syringes and needles should never be dumped in open areas where people might pick them up, step on them, or come in contact with them in any way.

The need to better manage used or contaminated sharps is though the use of safety boxes or sharp containers. These are puncture-resistant containers where used syringes and needles can be immediately and temporarily stored after use until its final disposal.

1. ***Waste Disposal***

Collector boxes filled with used syringes and needles should be immediately brought to its final disposal. The program recommends the following methods of disposal:

1. Use of septic vault

2. Pit burial; and

3. Waste treatment and final disposal to landfill

III. REPEALING CLAUSE

Provisions of Administrative Order No. 2007-0029 dated September 21, 2007 “Revised Guidelines on Management of Animal Bite Patients” and Administrative Order No. 2005-0022 “Amendment to A.O. 164s. 2002 dated August 25, 2005 and any other issuances inconsistent herewith are hereby rescinded.

IV. EFFECTIVITY

This order shall take effect immediately.

FRANCISCO T. DUQUE III, MD, MSc

Secretary of Health