B. SPECIFIC SYSTEMIC TREATMENT

Nature of exposure	Status of biting animal (irrespective of any earlier vaccination) at time of exposure	during next 10 days (a)	Recommended treatment
1. Contact, but no lesion : indirect contact no contact	Healthy		None
	Suspected as Rabid (b)	Healthy Rabid	
2. Licks on the skin scratches or abrasions : minor bites (on covered areas of arms, trunk, and legs	Healthy	Healthy : Rabid (c)	None Start vaccination schedule
	Suspected as Rabid (b)	Healthy	Start vaccination schedule : stop treatment if animal remains healthy for 5 days (a) (d)
		Rabid	Start vaccination schedule : upon positive diagnosis, complete the course of vaccine
	Rabid : wild animal (e) or animal unavailable for observation		Give complete course of vaccine
3. Licks on mucosa : major bites (multiple, or on face, head, finger, or neck)	Suspect (b) or confirmed rabid domestic or wild (e) animal, or animal unavailable for observation		Serum + vaccine Stop treatment only in the case of domestic animal under observation (a) which remains healthy for 5 days.

a. This observation period applies only to dogs and cats. Other domestic and wild animals suspected as rabid should be killed and examined using the fluorescent antibody technique.

b. All unprovoked bites in endemic areas should be considered suspect unless proved negative by laboratory examination of the animal's brain.

c. During the usual period of 10 days, begin treatment with vaccine at first sign of rabies in a dog or a cat that has bitten someone. The symptomatic animal should be killed immediately and examined using the fluorescent antibody technique.

d. Or if the animal's brain is found to be negative by FA examination.

e. In general, exposure to rodents, rabbits and hares seldom, if ever, requires specific antirabies treatment.

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VERORAB

INACTIVATED RABIES VACCINE PREPARED ON VERO CELLS

INACTIVATED RABIES VACCINE FOR THE PRE-EXPOSURE OR POST-EXPOSURE IMMUNIZATION. WISTAR RABIES PM/WI 38-1 503-3M STRAIN, OBTAINED BY CULTURE ON VERO CONTINUOUS CELL LINES

COMPOSITION

Freeze-dried vaccine ..... 1 immunizing dose
such that the protective activity is equal to or greater than 2.5 International Units, before and after heating for one month at + 37 °C.
Rabies virus (Wistar rabies PM/WI 38-1503-3M strain), obtained from culture on Vero continuous cell lines, inactivated with beta-propiolactone
Maltose ..... q.s. 1 immunizing dose
Human placental albumin ..... q.s. 1 immunizing dose
Diluent : Solution of, 4 ‰ sodium chloride ..... 0.5 ml

INDICATIONS

A. Rabies prevention in subjects exposed to a risk of contamination.

This vaccination is particularly recommended for :
- Professional groups exposed to frequent contamination :
  - veterinary surgeons (including students at veterinary colleges),
  - technical personnel working with veterinary surgeons,
  - laboratory personnel handling material contaminated with rabies virus,
  - personnel in abattoirs and knackers yards,
  - taxidermists, animalists,
  - farmers, gamekeepers, and forestry workers in enzootic areas and naturalists.
- Infants particularly exposed to the risk of rabies.

B. Treatment after certain or plausible rabies contamination.
- Treatment of subjects bitten by rabid animals or those suspected of being so.
- Treatment of contact subjects.

CONTRAINDICATIONS

A. Curative treatment

All contraindications are secondary in cases of suspected rabid contamination.

B. Preventive and or booster vaccination

In cases of pregnancy and acute febrile illness, the vaccination should be differed.

WARNINGS

To be used with care in cases of true allergy to streptomycin and/or neomycin (traces present in the vaccine).

In cases of serious contamination, it is recommended by the World Health Organization that a treatment of 20 I.U. per kg of specific human rabies immune globulin or 40 I.U. per kg of purified rabies serum of animal origin be started in conjunction on first day of vaccination (D0). In subjects who have received preventive vaccination using a cellular vaccine of at least 2.5 I.U. per dose within a period of one year, and who can prove it by a vaccination certificate, it is recommended that 1 to 3 immunizing doses be given, according to the severity of the bite.

DRUG INTERACTIONS

The corticosteroids and immunosuppressive treatment may lead to vaccination failure. In these cases, a titration of neutralizing antibodies should be performed.

SIDE EFFECTS

Local minor reactions : the redness and slight induration at the injection site. Rare febrile reactions.

DOSAGE AND ADMINISTRATION

Strictly by intramuscular or subcutaneous route.
Reconstitute the freeze-dried powder with accompanying diluent
Reconstituted vaccine is a homogeneous, limpid solution without any particles in suspension.
Any reconstituted vaccine must be used immediately
The syringe should be destroyed after use

A. Pre-exposure immunization :

Primary vaccination :

2 injections of 0.5 ml by the subcutaneous or intramuscular route one month apart, followed by a booster one year later.
For countries which follow the WHO recommendations, it is mentioned that the proposed schedule is of "3 injections of rabies vaccine of potency at least 2.5 I.U. given on days D0, D7 and D28 or on days D0, D28 and D56. (a few days variation is not important)".

Boosters :

Thereafter one injection every 3 years

B. Post-exposure immunization :

- In subjects unvaccinated against rabies, the treatment consists of 5 x 0.5 ml injections by the subcutaneous or intramuscular route on days D0, D3, D7, D14 and D30, after contact with an animal who is rabid or suspected of being so. A booster dose on D90 is optional.

According to the degree and severity of the risk of infection, in cases of severe bites, 20 I.U./kg body weight of specific rabies immunoglobulin of human origin (IMOGAM RABIES) should be given in conjunction on D0, which will provide protective antibodies immediately.

- In those previously immunized by complete preventive vaccination :
- within a year : 1 booster injection of 0.5 ml given subcutaneously or intramuscularly on day D0,
- more than a year earlier : 3 booster injections of 0.5 ml given subcutaneously or intramuscularly on days D0, D3 and D7.

STORAGE

Between + 2 °C and + 8 °C

Annex 1

GUIDE FOR POST-EXPOSURE TREATMENT

The recommendations given here are intended only as a guide. It is recognized that, in special situations, modifications of the procedures laid down may be warranted. Such special situations include exposure of young children and other circumstances where a reliable history cannot be obtained, particularly in areas where rabies is known to be enzootic, even though the animal is considered to be healthy at the time of exposure. Such cases justify immediate treatment, but of a modified nature, for example, local treatment of the wound, followed by administration of a single dose of serum (preferably human antirabies immunoglobulin) and an initial course of vaccine ; if the animal stays healthy for 5 days following exposure, no further vaccine need be given. Modification of the recommended procedures would also be indicated in a rabies-free area where animal bites are frequently encountered. In areas where rabies is epizootic, adequate laboratory and field experience indicating that there is no infection in the species involved may justify local health authorities in not recommending specific antirabies treatment

Practice varies concerning the volume of vaccine per dose and the number of doses recommended in a given situation. Vaccines should be given according to the schedule and dose recommended by the manufacturer.

Combined serum-vaccine treatment is considered by the Committee as the best specific systemic treatment available for the post-exposure prophylaxis of rabies in man, although experience indicates that vaccine alone is sufficient for minor exposures. Serum should be given in a single dose of 40 I.U. per kg of body weight for heterologous serum, and 20 I.U. per kg of body weight for human antirabies immunoglobulin ; the first dose of vaccine should be inoculated at the same time as the serum, but in a different part of the body. Sensitivity to heterologous serum must be determined before it is administered. The physician should be prepared to deal with anaphylactic shock reactions.

Treatment should be started as early as possible after exposure but in no case should it be denied to exposed persons whatever time interval has elapsed.

In areas where antirabies serum is not available, full vaccine therapy should be administered.

A. LOCAL TREATMENT OF WOUNDS INVOLVING POSSIBLE EXPOSURE TO RABIES - RECOMMENDED IN ALL EXPOSURES

a) First-aid treatment

Since elimination of rabies virus at the site of infection by chemical or physical means is the most effective mechanism of protection, immediate washing and flushing with soap* and water, detergent, or water alone are imperative (this procedure is recommended for all bite wounds, including those unrelated to possible exposure to rabies). Then apply either alcohol (400-700 ml/litre), tincture or aqueous solution of iodine, or quaternary ammonium compounds (1 ml/litre).*

b) Treatment by, or under direction of a physician

1) Treat as in (a) above and then :

2) apply antirabies serum by careful infiltration in the depth of the wound and by infiltration around the wound ;

3) postpone suturing the wound ; if suturing is necessary, use antiserum locally as described above ;

4) where indicated, institute antitetanus procedures and administer antibiotics and drugs to control infections other than rabies.

* Where soap has been used to clean wounds, all remaining traces should be removed before application of quaternary ammonium compounds, because soap neutralizes the activity of such compounds

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