

A GUIDE TO INTRADERMAL RABIES VACCINATION



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2006

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FOREWORD

Human rabies is virtually 100% fatal, but is vaccine preventable. In India, every year about 20,000 persons are known to die of rabies. Recently in December 2004, following a Supreme Court order the production of sheep brain (Semple) vaccine was stopped and consequently it has to be replaced by modern rabies vaccines. But one dose of modern rabies vaccine costs about Rs 300/- and a full course of 3 or 5 doses by intramuscular route cost about Rs 900/- or Rs 1500/- which is beyond the reach of common man. The majority of animal bite victims are from the poor and low income group and are compelled to visit the Government hospitals. However, the Government hospitals which previously used Semple vaccine, now due to paucity of funds are not able to provide these modern vaccines to all patients by the intramuscular route.

During 2003-06, an Indian Council of Medical Research (ICMR) study found that intradermal rabies vaccination (IDRV) was feasible in India and the vaccines found suitable were Rabipur (PCEC), Verorab (PVRV), Abhayrab (PVRV) and Pasteur Institute of India, Coonoor (PVRV) vaccine. In this background, the Government of India, in February & May 2006 approved the administration of these vaccines by intradermal (ID) route. This leads to about one-fifth reduction in cost and volume of vaccine. This method of IDRV was approved by World Health Organization in 1992 and the same was introduced in Thailand in 1984, in Philippines in 1993 and in Sri Lanka in 1996. This has successfully reduced the number of human rabies deaths in these countries. However, some still misconstrue IDRV to be inferior or a poor cousin of intramuscular vaccination, which is a wrong notion. Besides, following the introduction of animal birth control (ABC) programme for stray dogs in municipal areas in 2001, Government of India is morally duty bound to provide ethical treatment to dog bite victims in urban areas.

Consequently, the municipal councils must now introduce this cost-effective IDRV in their hospitals with proper planning. To make IDRV successful and popular the dedication of medical profession and the support of media are very crucial. It is sincerely hoped that this guide on IDRV prepared by the Department of Community Medicine, Kempegowda Institute of Medical Sciences (KIMS), Bangalore is found useful by the health authorities and facilitates correct administration of IDRV in their hospitals.

Date: 26th September, 2006.

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LIST OF ABBREVIATIONS USED

ABC: Animal Birth Control
APCRI: Association for Prevention and Control of Rabies in India
ARC: Anti-Rabies Clinic
CRF: Case Record Form
DCGI: Drugs Controller General of India
ERIG: Equine Rabies Immunoglobulin
FAQs: Frequently Asked Questions
HDCV: Human Diploid Cell Vaccine
HRIG: Human Rabies Immunoglobulin
ICMR: Indian Council of Medical Research
ID: Intradermal
IDRV: Intradermal Rabies Vaccination
IM: Intramuscular
IU: International Unit
KIMS: Kempegowda Institute of Medical Sciences
MO: Medical Officer
PCECV: Purified Chick Embryo Cell vaccine
PDEV: Purified Duck Embryo vaccine
PEP: Post Exposure Prophylaxis
PVRV: Purified Vero cell Rabies vaccine
RFFIT: Rapid Fluorescent Focus Inhibition Test
RIA: Rabies in Asia
RIG: Rabies Immunoglobulin
RNA: Ribo-nucleic acid
TRC: Thai Red Cross
WHO: World Health Organization

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1. RABIES

Rabies is a virtually 100% fatal acute viral encephalitis caused by an RNA virus belonging to family Rhabdoviridae and genus Lyssavirus. The virus can infect all warm blooded animals; the disease is transmitted to humans by the bite / lick / scratch of an infected animal. More than 99% of all human rabies deaths occur in the developing world, the disease has not been brought under control in most of the affected countries. Although effective and economical control measures are available, their application in developing countries is hampered by a range of economic, social and political factors.

An estimated 55,000 persons die of rabies globally every year of which 31,000 are from the Asian continent. In India, the Annual Incidence of Human Rabies is 20,000 Cases. The frequency of human rabies deaths is 1 case every 30 minutes (1/2 hour) approximately. The principal animal reservoir is dog (96.3%). The Animal bite incidence rate (per 1000 population) is 17.4 and this translates to a whopping 17.4 million bites every year. The frequency of animal bites in India is 1 every 2 seconds and the annual man-days lost due to animal bite is 38 million. The annual medicinal (vaccines + other drugs) cost for animal bite treatment is Rs. 2 billion approximately (2004).

In the light of the above information it is prudent to manage exposures to rabies aggressively as otherwise the disease is invariably fatal. One should understand that the disease can easily be prevented by proper post exposure prophylaxis.

1.1 Rabies Prophylaxis

Although, rabies is a 100% practically fatal disease, it is preventable with timely & proper usage of modern immunobiologicals (vaccines and immunoglobulins). Prophylaxis against rabies is of two types. One is the post-exposure prophylaxis (PEP) i.e., initiation of treatment after exposure. This is the most common type of prophylaxis that is encountered by treating physicians. The other type is the pre-exposure vaccination in which modern anti-rabies vaccines are given even before the exposure occurs.

1.1.1 Pre Exposure Vaccination

This is recommended for use in high risk cases and vulnerable groups like those working in rabies diagnostic and research laboratories, veterinarians, animal handlers, animal rehabilitators, wildlife officers, postmen, policemen, courier boys and for people living in or traveling to high risk areas. Children under the age of 15 years are another vulnerable group, constituting about 50% of all human cases in rabies endemic areas. Pre-exposure vaccination involves administration of three doses of a cell culture or purified duck embryo vaccine (PDEV) on days 0, 7 and 21 or 28. The dose is either one standard IM dose, which may either be 1 ml or 0.5 ml according to vaccine type.

Alternatively, pre-exposure vaccination may also be given by the intradermal route which involves administration of 0.1 mL of approved vaccine intradermally over one deltoid area on days 0, 7 & 21 or 28. This ID regimen has not been tested with PDEV. If anti-malarial chemoprophylaxis (e.g. with chloroquine) is being used concurrently, IM injections are preferable, as the antibody response may be impaired if the ID method is used. Booster injections should be given only when necessary, to people at high or continuing risk of infection. Laboratory staff and others at high/continuing risk of exposure should have their rabies virus neutralizing antibody titre checked every six months. If it is less than 0.5 IU/ml a booster dose of vaccine, either by IM or ID route, should be given.

1.1.2 Post Exposure Prophylaxis

Treatment for the prevention of rabies in humans exposed to rabies should begin as soon as possible after the exposure occurs. Treatment should follow the proper categorization as per the WHO guidelines (Annexure -1).

Treatment consists of 3 important steps; i) wound cleansing, ii) administration of rabies passive immunization and iii) cell-culture or purified embryonated egg rabies vaccination.

Wound cleansing: Gentle and thorough wound cleansing for a minimum of 15 minutes using water, soap and a virucidal antiseptic (e.g. povidone iodine or ethanol).

Passive immunization: Rabies Immunoglobulins (RIGs) that are available in India are of two types viz., Human Rabies Immunoglobulin (HRIG) and Equine Rabies Immunoglobulin (ERIG). Human Rabies Immunoglobulin is administered at

the dosage of 20 IU/kg body weight (Maximum of 1500 IU). Equine Rabies Immunoglobulin is administered after skin sensitivity test at a dose of 40 IU/kg body weight (Maximum of 3000 IU). The RIGs are infiltrated into and around the wounds wherever anatomically feasible and the products are diluted with sterile normal saline if insufficient by volume. Care must be taken to ensure all wounds are infiltrated.

Vaccination

Intramuscular regimens: Five-dose intramuscular regimen (Essen regimen): This is the only regimen licensed by the authorities for use in India. In this regimen one dose of vaccine is administered intramuscularly on days 0, 3, 7, 14 and 28. Injections must be given in the upper arm (deltoid region) or, in children, into the anterolateral aspect of thigh. *Vaccine should never be administered into the gluteal region, where absorption is unpredictable.* The Day 0 is the day of administration of the 1st dose of the vaccine and not the day of Bite.

The Zagreb regimen (not approved for use in India) consists of administering 2 doses of modern vaccines intramuscularly on day 0 and one dose each on days 7 and 21.

Intradermal regimens: The National authorities have, in 2006, permitted the use of rabies vaccines by the intradermal route which will significantly bring down the cost of treatment, and this route of administration is one of the ways to ensure the provision of effective treatment to the large number of bite victims at an affordable cost. *The anti-rabies vaccines currently approved for use in India through ID route are Rabipur (PCEC), Verorab (PVRV), Abhayrab (PVRV) and Pasteur Institute of India, Coonoor (PVRV).* The vaccines Rabivax (HDCV, adsorbed, manufactured by Serum Institute of India, Pune) and Vaxirab (Purified Duck Embryo vaccine, manufactured by Zydus Alidac) are not approved for use by the ID route in India.

The guide to post-exposure prophylaxis of previously vaccinated people and of HIV infected people and HIV/AIDS patients are available in Annexure-1.

2. INTRADERMAL RABIES VACCINATION (IDRV)

The IDRV was first started in Thailand, in 1984 and found successful. In 1992, World Health Organization approved it for use in developing countries which face shortage of rabies vaccine due to paucity of funds. Consequently, Philippines in 1993 and Sri Lanka in 1996 have successfully implemented it. However, in India, as Semple (sheep brain) vaccine was widely used in Government hospitals till 2004 (till mid 2005 precisely) the shortage of rabies vaccine was not felt. But, now with the stoppage of Semple vaccine and the shortage of modern vaccines (due to budgeting constraints) is being increasingly felt over this period of time. *Consequently, it is now imperative to introduce IDRV as a safer, ethical and cost effective replacement of Semple vaccine in Government hospitals.* As this is new to India, judicious planning and proper implementation are needed for its success as it largely benefits the poor and needy who visit Government hospitals.

2.1 Mechanism of Action of IDRV

It is deposition of approved modern rabies vaccine (or antigen) in the layers of dermis of skin. Subsequently the antigen is carried by antigen presenting cells via the lymphatic drainage to the regional lymph nodes and later to the reticulo-endothelial system eliciting a prompt and highly protective antibody response. Immunity is believed to depend mainly upon the CD 4 + T- cell dependent neutralizing antibody response to the G protein. In addition, cell-mediated immunity has long been reported as an important part of the defense against rabies. Cells presenting the fragments of G protein are the targets of cytotoxic T-cells and the N protein induced T helper cells. The immune response induced by IDRV is adequate and protective against rabies.

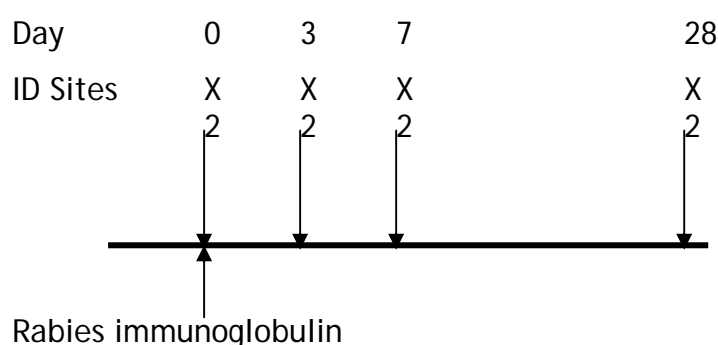
2.2 IDRV Vaccines and regimens

The following vaccines are currently approved for IDRV usage by Drugs Controller General of India (DCGI) *The anti-rabies vaccines approved for use in India through ID route are Rabipur (PCEC), Verorab (PVRV), Abhayrab (PVRV) and Pasteur Institute of India, Coonoor (PVRV).* The vaccines Rabivax (HDCV, adsorbed, manufactured by Serum Institute of India, Pune) and Vaxirab (Purified Duck Embryo vaccine, manufactured by Zydus Alidac) are not approved for use by

the ID route in India. The anti-rabies vaccines Rabipur (PCEC) and Pasteur Institute of India, Coonoor (PVRV) are 1mL vaccines whereas Verorab (PVRV) and Abhayrab (PVRV) are 0.5mL.

Regimen

As per Drugs Controller General of India (DCGI) (Annexure-2), the schedule recommended for IDRV is the updated Thai red cross schedule, which is 2-2-2-0-2. This involves injection of 0.1mL of reconstituted vaccine per ID site and on two such ID sites per visit (one on each deltoid area, an inch above the insertion of deltoid muscle) on days 0, 3, 7 and 28. The day 0 is the day of first dose administration of IDRV and may not be the day of rabies exposure / animal bite.



2.3 IDRV clinic

The following are the recommended guidelines for physical facilities and staff requirements for an anti-rabies clinic.

I. Accommodation

- 1 Clinic room 20' X 15' (minimum) and waiting hall
- 2 Toilet with tap water for washing the wound

II. Staff

- 1 Medical Officer - 1 (MBBS minimum)
- 2 Staff Nurse - 1
- 3 Attender - 1

III. Furniture

- 1 Office Table - Big - 1 (MO) and Small - 1 (Staff Nurse)
- 2 Arm chairs - 4
- 3 Revolving stools - 3
- 4 Table for examining the patient -1
- 5 Footstep stand - 1
- 6 Almirah - 1

IV. Equipments and Instruments

- 1 Refrigerator (with voltage stabilizer and thermometer) - 1
- 2 Weighing machine - 1
- 3 Vaccine carrier and ice packs (with wells) - 1
- 4 BP apparatus - 1
- 5 Oxygen cylinder with mask - 1
- 6 IV line stand - 1
- 7 Telephone - 1
- 8 Health education material - Display / Distribution (as adequate)
- 9 Fixographs (Big) - 2 with letters

V. Drugs (Injectables and Applicants)

- 1 Anti-rabies vaccines
- 2 Anti-rabies serum (Equine and Human)
- 3 Inj Adrenaline
- 4 Inj Avil
- 5 Oral anti-histamines
- 6 Inj Efcorlin
- 7 Inj Ranitidine
- 8 Surgical spirit
- 9 Povidone Iodine
- 10 Normal Saline
- 11 Glucose Saline
- 12 Tetanus Toxoid
- 13 Antibiotics, Antipyretics, Analgesics and Anti-Inflammatory drugs

VI. Other Supplies and Consumables

- 1 Cotton
- 2 Adhesive plaster
- 3 Dressing material
- 4 Detergent Soap
- 5 Surgical gloves
- 6 Insulin syringes with 26G needles
- 7 2 mL and 5mL syringes with 24 G needles
- 8 Artery forceps
- 9 Toothed forceps
- 10 Swab holder
- 11 Kidney tray
- 12 Dressing bin
- 13 Foot operated waste bin
- 14 Mattress and linen

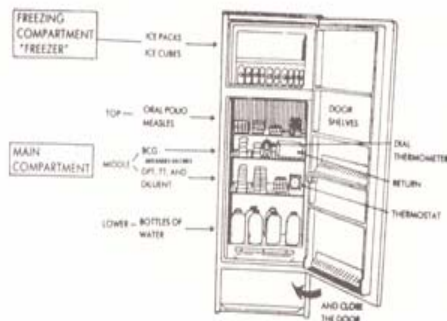
VII. Stationary and Others

- 1 Outpatient register
- 2 Temperature monitoring chart
- 3 Standard Clinical Record forms
- 4 Prescription pads
- 5 Self-addressed postcards (reply paid)for patient responses
- 6 Notice board

2.4 Vaccine Storage

Maintenance of cold chain is of utmost importance to ensure that potency of anti-rabies vaccines is retained. If great care is taken with aseptic technique, an appropriate dose of vaccine may be withdrawn from a vial and the remainder used for another patient, provided that the vial is kept cool and stored in a refrigerator at 2 °C to 8 °C (*photograph- 1*). A sterile needle and syringe must be used to draw up vaccine for each patient, to prevent cross-infection of hepatitis, HIV and other infections. Although the vaccine antigen is very stable at 4 °C, there is a high risk of contamination of multidose vials by microorganisms, especially if the vaccine does not contain a preservative. Reconstituted vaccines should be used as soon as possible and those without preservative should be used within 6 to 8 hours if kept at 2 °C to 8 °C. All unused reconstituted vaccine at the end of 6-8 hours must be discarded.

The following Dos and Don'ts must be followed for proper maintenance of cold chain equipment (refrigerator) and of vaccines.



DOs

- Keep the refrigerator in a cool room away from direct sunlight and at least 10cms away from the wall.
- Keep the refrigerator level.
- Fix the plug permanently to the socket.

Photograph -1. Storage of antirabies vaccines in the refrigerator

- Use voltage stabilizer.
- Keep the vaccines neatly with space between the stacks for circulation of air.
- Keep the refrigerator locked and open it only when necessary.
- Keep ice or ice-packs in the freezer and water bottles in the shelves not utilized for the storage of vaccines to keep the temperature down for a longer period of time in case of power failure.
- Defrost periodically.

- Check the temperature twice a day and maintain a record which should be supervised regularly.
- Tape a sheet of paper outside the refrigerator which tells anyone finding the refrigerator not working:-
 - ✓ Whom to contact; Where to check for a blown fuse; Alternate place for vaccine storage

DON'Ts

- Do not open the door unless necessary
- Do not keep vaccines in the door of the refrigerator
- Do not keep food or drinking water in the refrigerator
- Do not keep more than one month's requirements
- Do not keep "date expired" vaccines

2.5 Procedure for Intradermal Rabies Vaccination

2.5.1 Materials required

- A vial of rabies vaccine approved for IDRV and its diluent.
- 2 mL disposable syringe with 24 G needle for reconstitution of vaccine.
- Disposable 1 mL insulin syringe (with graduations upto 100 or 40 units) with a fixed (28 G) needle. (*Photograph -2*)
- Disinfectant swabs (e.g. 70% ethanol, isopropyl alcohol) for cleaning the top of the vial and the patients' skin.



Photograph -2. Insulin syringe used for administration of IDRV

2.5.2 Preparation of a Patient for IDRV

As soon as the patient is ready for IDRV administration he / she must be made to sit comfortably and ensuring adequate privacy. Patients must be reassured and their anxiety must be alleviated by briefly explaining the procedure that will be performed. A suitable poster on the ARC wall would be of great help. Both the deltoid vaccination sites must be adequately exposed and cleaned with disinfectant swabs.

2.5.3 ID injection technique

Using aseptic technique, reconstitute the vial of freeze-dried vaccine with the diluent supplied by the manufacturer. With 1 mL syringe (*photograph-2*) draw 0.2 mL (up to 20 units if a 100 units syringe is used or upto 8 units if a 40 units syringe is used) of vaccine needed for one patient (i.e. 0.1 mL per ID site X 2 sites 0.2 mL) and expel the air bubbles carefully from the syringe thereby removing any dead space in the syringe.



Using the technique of BCG inoculation, stretch the surface of the skin and insert the tip of the needle with bevel upwards, almost parallel to the skin surface (*photograph- 3*) and slowly inject half the volume of vaccine in the syringe (i.e. 0.1mL; either 10 or 4 units) into the uppermost dermal layer of skin, over the deltoid area, preferably an inch above the insertion of deltoid muscle.

Photograph -3. Position of Insulin syringe for administration of IDRV

If the needle is correctly placed inside the dermis, considerable resistance is felt while injecting the vaccine. A raised papule should begin to appear immediately causing a peau d' orange (orange peel) appearance (*photograph- 4 & 5*). Inject the remaining half the volume of vaccine (i.e. 0.1mL; either 10 or 4 units) on the opposite deltoid area.



Photograph -4 & 5. Bleb produced by correct IDRV and peau d' orange (orange peel) appearance.

Some difficulty may arise with elderly patients (thin, inelastic skin) and with squirming infants. Those inexperienced with the technique should practice

using 0.1 mL of isotonic saline until they can reliably produce a peau d' orange papule.

If the vaccine is injected too deeply into the skin (subcutaneous), papule is not seen. Then the needle should be withdrawn and reinserted at an adjacent site and the ID vaccine given once more. *If there is failure to inject intradermally in even one of the deltoid areas then the vaccine must be given intramuscularly and continued likewise thereafter to complete the full course as per schedule of IM administration.*

2.5.4 Side Effects of ID Vaccination

Throughout 20 years of use, cell culture vaccines have proved remarkably safe and free of significant adverse events. However, mild symptoms of pain, erythema



Photograph -6. Appearance on day 7 of 2-site
Id vaccine course, showing two previous
Injection sites (WHO, 1997)

(*photograph -6*), irritation or swelling at the intradermal injection sites occur in 3% to 92% of patients. The most frequent symptom is local irritation in 7% to 64% of vaccinees. Generalized symptoms reported by 3% to 14% of recipients include headache, fever and influenza- like illness. Transient maculopapular and urticarial rashes are occasionally seen. All these adverse effects are mild, transient and self limiting and rarely call for the use of anti-histamines (tablet or syrup Avil) and analgesics (tablet or syrup Paracetamol).

2.5.5 Recording

Hospital record (case record form - Annexure-3) should include the name of the patient, age, sex, type of biting animal, category of bite, RIG administration, vaccine type, batch number and treatment regimen (days of administration of vaccine). The dates of next injections must be emphasized by means of an appointment card given to each patient (Annexure-4). An ARC software for data

management is available at www.kimscommunitymedicine.org. This can also be used for data recording and analyses, wherever facilities are available.

2.6 Advice to patients

All patients who are administered IDRV should be advised about the possible side effects (commonly itching and pain at vaccination site) of vaccination and must be instructed not to scratch or rub the IDRV site. They must be advised to complete the full course of vaccination. They must also be told that there are no dietary restrictions during the course of IDRV. Wherever possible, patients must be informed to observe the biting dog / cat for 10 days for signs of rabies (Annexure-5) and wherever relevant about pet care (Annexure-6).

2.7 Laboratory testing of Sera

According to World Health Organization, serum rabies virus neutralizing antibody (RVnAb) titers above 0.5 IU / mL after day 14 is considered as protective. This can be assessed by rapid fluorescent focus inhibition test (RFFIT).

The serum sample of approximately of about 0.5 mL is required to be sent to the Laboratory for RFFIT testing. This can be obtained by drawing 5 mL of venous blood from ante cubital vein from the fore arm & transferring the contents slowly through the tip of the syringe (not through the needle as it may cause haemolysis) into a sterile, dry 10 mL test tube, allow 30 - 45 min for serum to separate & then centrifuge the vial at about 3000 RPM for 2-5 min. Collect 0.5 mL of supernatant clear serum on to the serum storage vials / aliquot. Stick the label containing patient particulars on the vial. Store the serum vial in the freezer compartment of refrigerator and arrange to send it to the laboratory in 1-2 days time. The serum vials have to be sent to the Laboratory in cold chain with an accompanying request letter (Annexure-7).

2.7.1 Addresses of RFFIT testing Laboratories

1. Head, Department of Neurovirology, National Institute of Mental Health and Neurosciences (NIMHANS) Dr M H Mari Gowda (Hosur) Road, Bangalore- 560 029; Phone: 080-26995129; Fax: 080-26564830 / 26562121
2. Director, Pasteur Institute of India, Coonoor - 643103 Nilgiris (TN)
Phone: 0423-231250 / 232602 / 231846; Fax: 0423 - 231655

3. Director, National Institute of Communicable Diseases, 22, Shamnath Marg, Delhi-110054. Phone: 011-23913148 / 23913397; Fax: 011-23922677

However, before sending the sera samples prior confirmation of testing and any further details / guidelines must be obtained from these institutions.

2.8 Disposal of clinic Waste

The waste generated in the anti-rabies clinic (ARC) during the process of vaccination must be disposed off with due care to the environment and in keeping with the guidelines of the "Biomedical Waste Management and Handling Rules - 1998"

The wastes that are generated in the ARC will include;

- Soiled waste (Cotton swabs, Bandages, Etc.) - Category 6 waste.
- Waste sharps (Needles, Syringes, Glass, etc.) - Category 4 waste.

The wastes have to be segregated at the source and care should be taken to ensure minimal human contact with the waste. The wastes have to be treated and appropriately stored pending final disposal.

The category 6 wastes are color coded RED and are to be stored in disinfected container / plastic bag and should be disposed off by autoclaving / microwaving / chemical treatment with 1% hypochlorite solution.

The category 4 wastes are coded BLUE and have to be disinfected and stored in a puncture proof container. The disinfection can be done by autoclaving / microwaving / chemical treatment with 1% hypochlorite solution and the material are disposed off after shredding or destruction so as to ensure that the material are not reused. The used vials need to be accounted for and may be disposed off as mentioned above.

2.9 Training Programme

The training program for the Medical Officers and Staff Nurses will be of 1½ days duration and will include theory and skill based (hands on) training. The training can be imparted to the Medical Officers and Staff Nurses of the ARCs in batches not exceeding 15.

Day 1:

9:00 AM - 10:00 AM

Introduction and Pretest

10:00 AM - 1:00 PM

Video Cassette / CD presentation on Rabies prevention

Introduction to IDRV, Pre requisites for IDRV clinic

IDRV - Theory aspects

Question answer session

1:00 PM - 2:00 PM

LUNCH

2:00 PM - 4:00 PM

IDRV Clinic: Hands on training (Vaccine storage, reconstitution, Administration, data entry, Etc.)

Day 2:

9:00 AM - 1:00 PM

IDRV Clinic: Hands on training (Vaccine storage, reconstitution, Administration, data entry, Etc.)

Question answer session and Post Test

Collection of feedback and concluding session

2.10 Calculation of vaccine & syringe requirements

The continuous and adequate supply of vaccine is crucial for the functioning of an IDRV clinic. The quantity of vaccine and syringes required must be calculated based on the average daily attendance at the clinic and periodicity of supply. Initially and whenever a possible delay / short supply is anticipated a buffer stock of 10% should be additionally indented. It is recommended that a wastage factor of 20% be allowed for all ID vaccinations (for possible spill over / wrong technique/ vial breakage, etc). The following example is worked out on the basis of the above recommendations for a 1mL (IM dose) anti-rabies vaccine.

E.g: If the average daily attendance at an IDRV clinic is 50 patients and the periodicity of supply is monthly then, the vaccine and syringe requirements will be as follows.

Vaccine: (1mL IM dose): $0.2\text{mL per patient per visit} \times 50 \text{ patients} = 10 \text{ mL per day}$; For 30 days $= 30 \times 10 = 300 \text{ mL}$; Wastage $= 20\% \text{ of } 300 \text{ mL} = 60 \text{ mL}$
Total $= 300 + 60 = 360 \text{ mL}$. Additional 10% buffer $= 36 \text{ mL}$; Grand total $= 396\text{mL}$.
Rounded off to 400 mL or **400 vials/month**

If the vaccine is of 0.5 mL IM dose then, the monthly requirement will be double that for the 1mL IM dose (i.e. **800 vials**) as calculated above.

Syringes: Insulin syringes $= 1 \text{ per patient per visit} = 50 \text{ per day}$
 $= 50 \times 30 = 1500 \text{ per month}$
 $+ 10\% \text{ wastage} = 150 = 1500 + 150 = 1650$
 $+ 10\% \text{ buffer} = 10\% \text{ of } 1650 = 165$
Grand total $= 1650 + 165 = \underline{\textbf{1815 syringes/month}}$

3. FREQUENTLY ASKED QUESTIONS (FAQs)

1. The IM dose of Verorab (PVRV) and Abhayrab (PVRV) is 0.5mL; that of Rabipur (PCEC) and PVRV (Coonoor) (where available) is 1mL. Still is the ID dosage of all vaccines uniformly 0.1mL?

The ID dosage of all approved vaccines is uniformly 0.1 mL per ID site irrespective of their IM dosage.

2. Can the type of vaccine be interchanged during the course of IDRV?

As far as possible, the same vaccine should be used throughout a course of IDRV.

3. Can the routes of vaccination viz., IM and ID be used interchangeably?

The route of vaccination, whether ID or IM should ideally remain the same throughout the course of vaccination in a patient.

4. What should be done if the ID vaccine administration fails? (Spills out or goes subcutaneous).

Even if the IDRV fails in any one of the deltoids, then the vaccine must be given by IM route and the remaining doses given by IM route only.

5. If for some reason, IDRV cannot be given in deltoid region, what are the alternative sites?

The alternative IDRV sites are suprascapular, anterior abdominal wall and the upper part of the thigh (where socially acceptable).

6. Are there any contraindications to IDRV?

The only contraindications to IDRV are - the patient is on chloroquine or immunocompromised or any immunosuppressant therapy viz., anticancer drugs, radiation therapy, long-term steroid usage etc. In such cases the rabies vaccines should be given by IM route.

7. Are there any dietary restrictions during IDRV?

There are no dietary restrictions during IDRV.

8. If the IDRV patients miss some days of vaccination, how should they be managed?

The first three doses of IDRV given on days 0,3 and 7 are very crucial and should be given as close to the original dates and preferably completed by day 7. About 1-2 days of variation for the fourth dose on day 28 is acceptable.

9. Is sera testing of IDRV patients necessary for checking the efficacy?

The IDRV is well tested and WHO approved and hence routine sera testing for rabies anti-bodies to know its efficacy is not required

10. Whether pregnancy and lactation are contraindications for IDRV?

Pregnancy and lactation are not contraindications for IDRV.

11. Is there a need to alter the dose or schedule of any concomitant medication during IDRV?

There is no need to alter the dose or schedule of any concomitant medication during IDRV. All prescribed medications should be taken as per instructions.

4. ANNEXURES

Annexure- 1

WHO guide for Post Exposure Prophylaxis (TRS 931, 2005)

A1.General considerations

The recommendations given here are intended as a general guide. It is understood that, in certain situations, modifications of these recommendations may be warranted. Such situations include, but are not limited to: exposure of infants or mentally disabled people to a suspect or confirmed rabid animal; and when a reliable exposure history cannot be ascertained, particularly in areas where rabies is enzootic, even when the animal is considered to be healthy at the time of exposure. A careful risk assessment should be conducted by a qualified medical professional on every patient exposed to a potentially rabid animal.

Post-exposure prophylaxis consists of local treatment of the wound, initiated as soon as possible after an exposure, followed by the administration of passive immunization, if indicated, and a potent and effective rabies vaccine that meets WHO criteria. Post-exposure prophylaxis may be discontinued if the animal involved is a dog or cat that remains healthy for an observation period of 10 days after the exposure occurred; or if the animal is humanely killed and proven to be negative for rabies by a reliable diagnostic laboratory using a prescribed test. If the animal inflicting the wound is suspected of being rabid and is not apprehended, post-exposure prophylaxis should be instituted immediately.

When animal bites occur in a rabies-free area where adequate rabies surveillance is in effect, post-exposure prophylaxis may not be required depending upon the outcome of a risk assessment conducted by a medical expert knowledgeable in the epidemiology of rabies in the area and the proper requirements for assessing the risk involved. In areas where canine or wildlife rabies is enzootic, adequate laboratory surveillance is in place, and data from laboratory and field experience indicate that there is no infection in the species involved, local health authorities may not recommend anti-rabies prophylaxis.

A2.Local treatment of wounds

Elimination of rabies virus at the site of the infection by chemical or physical means is an effective mechanism of protection. Therefore, the Consultation emphasized the importance of prompt local treatment of all bite wounds and scratches that might be contaminated with rabies virus. Recommended first-aid procedures include immediate and thorough flushing and washing of the wound for a minimum of 15 minutes with soap and water, detergent, povidone iodine or other substances of proven lethal effect on rabies virus. If soap or an antiviral agent is not available, the wound should be thoroughly and extensively washed with water. People who live in rabies-infected areas should be educated in simple local wound treatment and warned not to use

procedures that may further contaminate the wounds. Most severe bite wounds are best treated by daily dressing followed by secondary suturing where necessary. If suturing after wound cleansing cannot be avoided, the wound should first be infiltrated with passive rabies immunization products and suturing delayed for several hours. This will allow diffusion of the antibody to occur through the tissues before suturing is performed. Other treatments, such as the administration of antibiotics and tetanus prophylaxis, should be applied as appropriate for other bite wounds.

A3.Administration of rabies biologicals for passive immunization

The role of passive rabies immunization products is to provide the immediate availability of neutralizing antibodies at the site of the exposure before it is physiologically possible for the patient to begin producing his or her own antibodies after vaccination. Therefore, passive immunization products should be administered to all patients presenting with exposure to rabies-infected material onto mucous membranes or into transdermal wounds.

A3.1 Classes of rabies biologicals and precautions for their use

There are three classes of rabies biological products for passive immunization available at present: human rabies immunoglobulin (HRIG); equine rabies immunoglobulin (ERIG), and highly purified F (ab')₂ products produced from ERIG. Most ERIG products currently being manufactured are highly purified and the occurrence of adverse events has been significantly reduced. Given that the clearance of F (ab')₂ fragments is more rapid than intact immunoglobulins, the Consultation recommended that in cases of multiple severe exposures, HRIG should be used for passive immunization. Most of the new ERIG preparations are potent, highly purified, safe and considerably less expensive than HRIG. However, they are of heterologous origin and carry a small risk of hypersensitivity reactions and therefore a skin test should be conducted prior to administration of ERIG and F (ab')₂ products according to the guidelines of the manufacturer. Serum sickness, using a highly purified ERIG product, appears among <1-2% of recipients and usually develops 1 week after administration. In the event of a positive skin test to ERIG or an F (ab')₂ product, HRIG should be administered. If HRIG is not available, ERIG or F (ab')₂ products should still be used but should be administered under the close supervision of competent staff located in adequate medical facilities.

A3.2 Dosage and administration

The dose for HRIG is 20 IU/kg body weight, and for ERIG and F (ab')₂ products is 40 IU/kg body weight. As much of the recommended dose of passive immunization products as is anatomically feasible should be infiltrated into and around the wounds. Multiple needle injections into the wound should be avoided. If a finger or toe needs to be infiltrated, care must be taken not to cause a compartment syndrome, which can occur when an excessive volume is infiltrated under pressure and blood circulation is impaired. In the event that a remainder of passive rabies immunization product is left after all wounds have been infiltrated, it should be administered by deep intramuscular injection at an injection site

distant from the vaccine injection site. Animal bite wounds inflicted can be severe and multiple, especially in small children. In such cases, the calculated dose of the passive rabies immunization product may not be sufficient to infiltrate all wounds. In these circumstances, it is advisable to dilute the passive immunization product in normal saline to a sufficient volume to be able to inject all wounds. A full course of vaccine should follow thorough wound cleansing and passive immunization.

A4.Vaccine administration for active immunization

Intramuscular regimens

Cell-culture or purified embryonated egg rabies vaccines having a potency of at least 2.5 IU per single intramuscular immunizing dose should be applied according to one of the following regimens.

-Five-dose intramuscular regimen (Essen regimen)

One dose of vaccine is administered intramuscularly on days 0, 3, 7, 14 and 28. Injections must be given in the upper arm (deltoid region) or, in small children, into the anterolateral thigh muscle. *Vaccine should never be administered into the gluteal region, where absorption is unpredictable.*

-Abbreviated multisite intramuscular regimen ("2-1-1" or Zagreb regimen)

One dose of vaccine is administered intramuscularly into the left and one into the right upper arm (deltoid region) on day 0 followed by one dose into the upper arm (deltoid region) on days 7 and 21. This schedule saves two clinic visits and one vaccine dose.

Intradermal regimens

A limited number of rabies vaccines have been recognized to date by WHO as safe and efficacious for post-exposure prophylaxis when administered by the intradermal route in two different regimens. Local manufacturers in rabies endemic countries are beginning to produce rabies vaccines. The intradermal use of these vaccines should be based on adherence to WHO requirements for that route and approval by national health authorities. 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.

-Updated Thai Red Cross intradermal regimen ("2-2-2-0-2" regimen)

Sufficient clinical evidence was presented to the Consultation indicating that a single dose of vaccine given on day 90 of the original Thai Red Cross regimen ("2-2-2-0-1-1" regimen) can be replaced if two doses of vaccine are given on day 28 ("2-2-2-0-2" regimen). The Thai Red Cross regimen considerably lowers the cost of vaccination as the total volume of vaccine required is much less than that needed for intramuscular regimens.

The schedule for the updated Thai Red Cross intradermal regimen is as follows: One dose of vaccine, in a volume of 0.1 ml is given intradermally at two different lymphatic drainage sites, usually the left and right upper arm, on days 0, 3, 7 and 28. Vaccine administered intradermally must raise a visible and palpable "bleb" in the skin. In the event that a dose of vaccine is inadvertently given

subcutaneously or intramuscularly, a new dose should be administered intradermally. Currently there are two vaccines that have been proven to be efficacious in the Thai Red Cross regimen: purified Vero cell rabies vaccine produced by Aventis Pasteur and purified chick embryo cell rabies vaccine produced by Chiron Vaccines.

-Eight-site intradermal regimen ("8-0-4-0-1-1" regimen)

One dose of 0.1 ml is administered intradermally at eight different sites (upper arms, lateral thighs, suprascapular region, and lower quadrant of abdomen) on day 0. On day 7, four 0.1 ml injections are administered intradermally into each upper arm (deltoid region) and each lateral thigh. Following these injections, one additional 0.1 ml dose is administered on days 28 and 90. This regimen lowers the cost of vaccine administered by intramuscular regimens and generally produces a higher antibody response than the other recommended schedules by day 14. It does not result in a significantly earlier antibody response and in order to ensure optimal treatment, a passive immune product must be administered to patients presenting with severe exposures. Only two commercial products are today considered safe and efficacious when administered according to this regimen. They include a human diploid cell vaccine produced by Aventis Pasteur and a purified chick embryo cell rabies vaccine produced by Chiron Vaccines. Intradermal injections must be administered by staff trained in this technique. Vaccine vials should be stored between 2 °C and 8 °C after reconstitution and the total content should be used as soon as possible, but at least within 8 hours. Rabies vaccines formulated with an adjuvant should not be administered intradermally.

A5. Post-exposure prophylaxis of previously vaccinated people

Individuals who are not immuno-compromised and who have been previously vaccinated with a potent and effective rabies vaccine that meets WHO criteria for vaccine production and have adequate documentation should receive a two booster series consisting of one intramuscular or intradermal dose on days 0 and 3. The administration of passive immunization is not required.

Local wound treatment should be completed as noted above. People, who have received pre-exposure or post-exposure vaccination using a vaccine of unproven potency, should receive a full post-exposure vaccination series including passive immunization.

A6. Post-exposure prophylaxis of HIV-infected people and HIV/AIDS patients

Several studies of patients with HIV/AIDS have reported that those with very low CD4 counts will mount a significantly lower or no detectable neutralizing antibody response to rabies. In such patients and those in whom the presence of immunological memory is no longer assured as a result of other causes, proper and thorough wound treatment as described above and antisepsis accompanied by local infiltration of a passive immunization product are of utmost importance. Immunocompromised patients with category II exposures should receive rabies immunoglobulin in addition to a full post-exposure vaccination series as listed

above. An infectious disease specialist with expert knowledge of rabies prevention should be consulted.

A7.Type of contact, exposure and recommended post-exposure prophylaxis

Table A1 should serve as a guide for post-exposure prophylaxis. In cases where exposure is questionable or a patient has a concurrent medical condition that may complicate post-exposure prophylaxis, an expert in the administration of rabies prophylaxis should be consulted.

Table A1

Type of contact, exposure and recommended post-exposure prophylaxis

Category	Type of contact with a suspect or confirmed rabid domestic or wild animal, or animal unavailable for testing^a	Type of exposure	Recommended post-exposure prophylaxis
I	Touching or feeding of animals Licks on intact skin	None	None, if reliable case history is available
II	Nibbling of uncovered skin Minor scratches or abrasions without bleeding	Minor	Administer vaccine immediately ^b Stop treatment if animal remains healthy throughout an observation period of 10 days ^c or if animal is proven to be negative for rabies by a reliable laboratory using appropriate diagnostic techniques
III	Single or multiple transdermal bites or scratches, licks on broken skin Skin Contamination of mucous membrane with saliva (i.e. licks) Exposures to bats ^d	Severe	Administer rabies immunoglobulin and vaccine immediately. Stop treatment if animal remains healthy throughout an observation period of 10 days or if animal is found to be negative for rabies by a reliable laboratory using appropriate diagnostic techniques

^a Exposure to rodents, rabbits and hares seldom, if ever, requires specific anti-rabies post-exposure prophylaxis.

^b If an apparently healthy dog or cat in or from a low-risk area is placed under observation, the situation may warrant delaying initiation of treatment.

^c This observation period applies only to dogs and cats. Except in the case of threatened or endangered species, other domestic and wild animals suspected as rabid should be humanely killed and their tissues examined for the presence of rabies antigen using appropriate laboratory techniques.

^d Post-exposure prophylaxis should be considered when contact between a human and a bat has occurred unless the exposed person can rule out a bite or scratch, or exposure to a mucous membrane.

Annexure - 2
GOI (DCGI) order

X-11026/23/05-D
Directorate General Of Health Services
(Drugs Section)

Nirman Bhawan, New Delhi
Dated, 28th February, 2006.

To

1. M/S Aventis Pasteur (Sanofi Pasteur) India Pvt. Limited
Chaitanya-1, Chaman Farm Village, Bundh Road
Gadaipur, New Delhi-110 030.
2. M/S Chiron Behring Vaccines Private Limited
Plot No. 3501/A, 3502 & 3503/A
Post Box No. 136, GIDC Estate, Ankleshwar-393 002.
Distt- Bharuch, Gujarat.

Sub: Use of Intradermal,(I.D) route for administration of Tissue Culture Anti Rabies Vaccine- regarding.

Sir ,

Based on the recommendation of the expert group as well as WHO, it has now been decided to allow I.D. route of administration for Tissue Culture based Anti Rabies Vaccine, in post –exposure treatment of patients in a phased manner.

In the first phase, the Schedules and vaccines endorsed by WHO (WHO TRS 931, year 2005) for i.d. route and the schedule recommended by ICMR Study may be permitted, which are as follows;

- **2-site schedule,**
- updated Thai Red Cross Regimens i.e 2-2-2-0-2,
- Thai Red Cross Regimen i.e 2-2-20-1-1 (WHO/EMC/Zoo/96.6 and ICMR study)
- **Vaccines recommended in the first phase for i.d route are;**
- (i) Purified vero cell Rabies Vaccines produced by Aventis Pasteur(Sanofi Pasteur) (ii) Purified Chick Embryo Cell Vaccine produced by Chiron Behring Vaccine Pvt. Ltd.

The unit dose of 0.1 ml of these vaccine having potency of at least 2.5 IU per single intramuscular immunizing dose should be applied as per recommended regimens.

Further the use of intradermal route may be approved initially for use in selected anti-rabies clinics which meet the following criteria:

- Attendance of minimum of 50 patients/day for Post – Exposure Treatment
- Have adequately trained staff to give i.d. inoculation;
- Can maintain cold chain for vaccine storage and ensure adequate supply of suitable syringes and needles for i.e. administration.
- Are adequately well versed in management of open vial and safe storage practices.

In view of above, you are allowed to market your licensed ARV through ID route, having the stated potency. And in the manner as recommended above. A copy of PMS Protocol and amended label along with its package insert for marketing of ARV through i.d. route may also be furnished to this Directorate.

While marketing you are advised to generate PMS data for two years. A copy of PMS protocol may also be furnished to this Directorate.

Yours faithfully,

(Ashwini Kumar)
Drugs Controller General (I)

Copy to;

1. PS to DGHS,
2. Director, NICD, Delhi. With reference to the recommendations of expert committee met on 15th Feb, 2006 at NICD, in the subject matter.

Nirmal Bhawan, New Delhi
Dated: 2/05/06

To

1. Pasteur Institute of India,
Coonoor TamilNadu
2. Human Biological Institute
Ooty, Chennai

Subject: Use of Intradermal (I.D) route for administration of Tissue Culture Anti Rabies Vaccine - regarding

Sir,

Based on the recommendation of the expert group as well as WHO, it has now been decided to allow I.D route of administration for Tissue Culture based Anti Rabies Vaccine, in post exposure treatment of patients.

The recommendation were based on bridging study for immunogenicity by ID route which had been designed to conform the immunogenicity by approved vaccine when given in much smaller doses by ID route as compare to IM injections.

The schedules and vaccines endorsed by WHO (WHO TRS 931, year 2005) for I.d route and the schedule recommended by ICMR study may be permitted, which are as follows;

- 7-Site Schedule,
updated Thai Red cross Regimens i.e 2-2-2-0-2.
- Vaccines recommended for I.d route are;
- (i) Purified vero cell Rabies Vaccines produced by Human Biological Institute Ooty Chennai (ii) Purified vero cell Rabies Vaccines produced by Pasteur Institute of India Coonoor Tamil Nadu

The unit dose of 0.1 ml of these vaccine having potency of at least 2.5 IU per single intramuscular immunizing dose should be applies as per recommended regimens.

Further the use of intradermal route may be approved initially for use in selected anti-rabies clinics which meet the following criteria

- Attendance of minimum of 50 patients/day for post -Exposure Treatment.
- Have adequately trained staff to give i.d inoculation;
- Can maintain cold chain for vaccine storage and ensure adequate supply of suitable syringes and needles for i.e administration.
- Are adequately well versed in management of open vial and safe storage practices.

In view of above, you are allowed to market your licensed ARV through ID route, having the stated potency, and in the manner as recommended above. While marketing, you are also require to generate. Safety and efficacy data of your licenced vaccine along with data on post-marketing surveillance A copy of PMS protocol and amended label along with its package insert for marketing of ARV through i.d route may also be furnished to this Directorate.

Yours Faithfully


(A.B. Ramteke)

Drugs Controller General(I)

Copy to :

1. PS to DGIIS
2. DDG(JS)
3. Directorate., NICD, Delhi . with reference to the recommendation of expert committee met on 3rd April, 2006 at NICO, in the subject matter.

[Note: A DCGI order dated 9th August 2006, has revised the eligibility criteria for intradermal administration of tissue culture rabies vaccines at anti-rabies clinics (ARC) in India from those with a minimum attendance of 50 patients per day to those with a minimum of 10 patients per day.]

Annexure- 3

IDRV CASE RECORD FORM

Sl. No. _____ OP No. _____ Date: _____

I. GENERAL PARTICULARS

Name: _____ Age & Sex: _____ Education: _____

Occupation: _____ Monthly Income: _____

Phone (0) : _____ (R) : _____ (M) : _____

Email: _____ Socio-Economic Status: Upper ☐ Middle ☐ Lower ☐ Poor ☐

II. DETAILS OF EXPOSURE

Type of Exposure: Lick / Scratch / Bite

Date of bite: _____ Time of bite: _____ Biting Animal: _____

Age: _____ Breed: _____ Type: Pet/Stray/Wild;

Bite: Provoked/Unprovoked; Bare Skin/Over Clothing;

Vaccination Status: Unvaccinated/Partially Vaccinated/Fully Vaccinated;

Circumstance of Bite: _____

Number of other persons bitten by same animal: _____

Fate of animal: Healthy/Sick/Died/Killed/Not Traceable/Unknown

Availability of biting animal (Dog/Cat) for 10 day observation: YES/NO

Classification: Proven rabid/suspect rabid/healthy

Postmortem/Lab report: Yes/No, if yes, Positive/Negative Method: _____

III. WOUND DESCRIPTION

Total No. of Wounds: _____

Brief Description of wound type: _____

Site: _____

Distribution of Wounds: Head/Neck: _____

Trunk: _____ UpperLimb: _____ Lower Limb: _____

Hands: _____ Genitals: _____

Category of Exposure: (WHO Classification): I/II / III

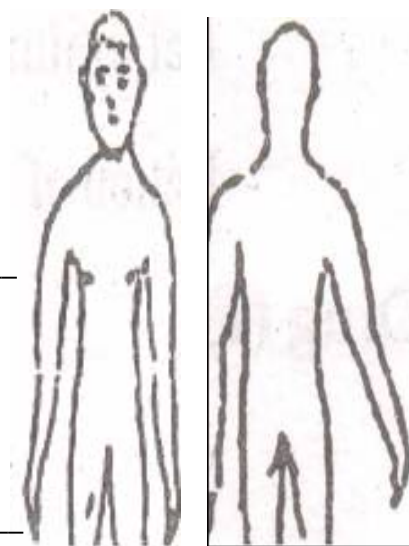
IV. WOUND TREATMENT

Wound washed: Water/Soap/Antiseptic (Specify)

Time interval between Bite and Wound Toilet: _____

Application of local irritants - Yes/No, If yes (Specify): _____

Wound dressed/sutured



V. HISTORY OF PREVIOUS ANTI-RABIES TREATMENT

Date(s): _____ Vaccine Type: _____ Doses : _____

Source : _____ Sera Type (details): _____

Any complications: _____

VI. OTHER PERSONAL DATA

History of taking immunosuppressant: _____

History of any concurrent illness/medication: _____

History of Allergy (Drug/Food): _____

History of Alcohol Intake: _____

History of Serum use in the Past: _____

VII. ADVICE

Wound Treatment: _____

Vaccine: _____

DAY	Route of Administration		Type of Vaccine	Due Date	Date of Admn.	Dose Site	Batch NO. Exp. Dt	Adverse Reaction	Treatment
	IM	ID							
D0									
D3									
D7									
D14									
D28									

VIII. RIG ADMINISTRATION

Weight _____ kg Type: _____ Dose req: _____ IU _____ mL.

Batch No: _____ Mfg. Date: _____ Exp. Date: _____

Test dose: Yes/No; Reaction: Yes/No; Full dose: Dilution Yes/No, If yes, _____ dilution; Local infiltration: _____ ml; Systemic: _____ ml

Duration of Observation & Outcome: _____

IX. DRUG (s) : _____

OTHERS: _____

Observation of Animal: _____

Follow-up: _____

HE material: _____ Post Card: Reply Received: Yes/No (date)

Note: Remind once again the patient of completing the course of vaccination.

Annexure - 4

IDRV patient card

Patient's copy

OPD No _____ Date of treatment: _____

Name: _____

Age: _____

Sex: _____

Address: _____

History of previous anti-rabies treatment

Date of last vaccination: _____

Full course of vaccination ☐

Partial treatment ☐

Patient's weight: _____ kg

1 Immunoglobulin - category III

HRIG 20 IU/Kg ☐ ERIG 40 IU /Kg ☐

2 ID treatment schedule and dosage

(category II without RIG; category III with RIG)

0.1mL per site X 2 sites (for all ID

approved vaccines)

Vaccine: Type & Brand: _____

Batch No: _____ Exp Date: _____

DAY	Route of Administration		Type of Vaccine	Due Date	Date of Admn.	Dose Site	Batch NO. Exp. Dt	Adverse Reaction
D0								
D3								
D7								
D14								
D28								

Treatment for adverse reaction: _____

Animal died / healthy after _____ days;

Brain of animal for rabies:

Positive/Negative

- Wash all wounds with running tap water and soap. Apply antiseptic
- Do not apply any irritants on the wound(s).
- Do not neglect dog bites and consult your doctor immediately.
- Follow the medical advice and complete the full treatment.
- During the 10 day observation period, look for the following signs of rabies in the biting dog / cat
 - ◆ Change in behavior - undue aggression/depression.
 - ◆ Running aimlessly and attacking others without any provocation.
 - ◆ Becomes too drowsy and withdraws itself to a corner.
 - ◆ Excessive Salivation /Change in voice.
 - ◆ Refusal to feed or eating unusual objects like stones, papers, wood, metal pieces etc.
 - ◆ Death of animal due to unknown cause.
- Vaccinate your dog against rabies at the age of 6 weeks, 6 months and thereafter once in every one to two years.
- Keep the vaccination card safely and produce the same to the doctor if the dog bites.
 - Do not provoke dogs. Avoid unknown dogs and enquire about the presence of dogs when visiting houses.
 - If your dog is known to bite, display a "beware of dogs" notice
 - Make sure your muzzle dogs that bite and do not allow your dog to stray.
- Be a law abiding citizen by registering your dog.

ANTI-RABIES VACCINATION CARD

Note: Please send this portion to Reporting officer / higher authorities.

OPD No:

Name of the ARC:

Date of Exposure:

Date of Treatment:

Name of the Patient:

Age: Sex:

Address:

Site of Bite / Exposure

Face/ Head Palm/ Foot

Upper Trunk Lower Trunk

Leg Hand Genitals

Type of wound

Superficial Multiple Deep

WHO Category of Exposure**Animal**

Dog Cat Monkey

Jackal

Others Specify

Pet Stray Wild

Vaccination status of animal

Fully vaccinated

Partially vaccinated

Unvaccinated Don't know

Signature of doctor and date
Address and stamp

History

Date of exposure

Type of animal

Cat/Dog- domestic

Cat/Dog-stray

Wild animal

Observation of animal

Possible

Not possible

Vaccination of animal

Two consecutive
Injections for the past 2-yrs Yes
- last one within 1 yr of bite

No

Not applicable

Behavior of animal

Normal

Suspicious

If all answers

Observe the Dog/cat

Treatment Regimen

RIG

ID Schedule 2 sites

Annexure -5

Observation of animals (dog / cat) for signs of rabies

During the ten day observation period any of the following signs must evoke suspicion of rabies:

- Change in behavior - undue aggression/depression.
- Running aimlessly and attacking others without any provocation.
- Becomes too drowsy and withdraws itself to a corner.
- Excessive Salivation.
- Change in voice.
- Refusal to feed or eating unusual objects like stones, papers, wood, metal pieces etc.
- Death of animal due to unknown cause.

Annexure-6

Guidelines to pet dog and cat owners

- Seek professional advice from a veterinarian on precautions to be taken before adopting a puppy and on how to care for it.
- Adopt puppies from a place where they have been well cared for.
- In case of adopting a stray dog, keep it in isolation for atleast a month to ensure it is not infected with rabies.
- Get your pet regularly and periodically examined by a qualified veterinarian.
- Vaccinate your dog against rabies at the age of 6 weeks, 6 months and thereafter once in every one to two years.
- Keep the vaccination card safely and produce the same to the medical doctor if the dog bites.
- Obtain a Municipal License, put a collar and keep your pet under leash in public places.
- Do not allow your pet to come in contact with community /street dogs / cats or other animals.
- If you have a dog at home, display a "*beware of dog*" warning notice.
- Take treatment even after pet dog bite including pups.
- Make sure you muzzle dogs that bite and do not allow your dog to stray.
- Do not provoke dogs. Avoid unknown dogs and enquire about the presence of dogs when visiting houses.
- Inform the Municipal authorities about sick / mad dogs.

Annexure - 7

REQUISITION FORM FOR SERA (RFFIT) TEST

Name of the ARC: _____

Complete postal address (including phones, fax, mobiles and E- Mails)

To,
The Director,

Sir,

Subject: RFFIT testing of sera samples

With reference to the above kindly test the accompanying sera samples (in cold chain) for rabies virus neutralizing anti-bodies (by RFFIT) and arrange to send the results to clinic.

Sl No	Name	Age	Sex	Label	Date & Day ⁺ of Sample	Vaccine & doses	Remarks	RFFIT result (IU/mL)
1								
2								
3								
4								
5.								

⁺ Routinely Day 0 (prevaccination) and D 14 samples are tested.

Thanking you,

Yours sincerely,

Name, Signature and seal of the Medical Officer

Date: _____

5. REFERENCES AND SUGGESTED FURTHER READING

- 1 WHO expert consultation on Rabies. Ninth report. Technical Report Series 931. Geneva: World Health Organization, 2006.
- 2 WHO Recommendations on Rabies Post-Exposure Treatment and the Correct Technique of Intradermal immunization against Rabies. Geneva: World Health Organization, 1997.
- 3 www.apcri.org; Official website of the Association for Prevention and Control of Rabies in India (APCRI).
- 4 www.who.int; Official website of the World Health Organization.
- 5 K.Park. Rabies. In K.Park eds. *Textbook of Preventive and Social Medicine*. 18th ed. M/S Banarasidas Bhanot, Jabalpur, India, 2005: 207-215.
- 6 www.kimscommunitymedicine.org; Official website of the Department of Community Medicine, KIMS, Bangalore.

6. Notes

Annexure - 4

IDRV patient card

Patient's copy

OPD No _____ Date of treatment: _____

Name: _____

Age: _____

Sex: _____

Address: _____

History of previous anti-rabies treatment

Date of last vaccination: _____

Full course of vaccination ☐

Partial treatment ☐

Patient's weight: _____ kg

1 Immunoglobulin - category III

HRIG 20 IU/Kg ☐ ERIG 40 IU /Kg ☐

2 ID treatment schedule and dosage

(category II without RIG; category III with RIG)

0.1mL per site X 2 sites (for all ID

approved vaccines)

Vaccine: Type & Brand: _____

Batch No: _____ Exp Date: _____

DAY	Route of Administration		Type of Vaccine	Due Date	Date of Admn.	Dose Site	Batch NO. Exp. Dt	Adverse Reaction
	IM	ID						
D0								
D3								
D7								
D14								
D28								

Animal died / healthy after _____ days;

Brain of animal for rabies:

Positive/Negative

- Wash all wounds with running tap water and soap. Apply antiseptic
- Do not apply any irritants on the wound(s).
- Do not neglect dog bites and consult your doctor immediately.
- Follow the medical advice and complete the full treatment.
- During the 10 day observation period, look for the following signs of rabies in the biting dog / cat
 - Change in behavior - undue aggression/depression.
 - Running aimlessly and attacking others without any provocation.
 - Becomes too drowsy and withdraws itself to a corner.
 - Excessive Salivation /Change in voice.
 - Refusal to feed or eating unusual objects like stones, papers, wood, metal pieces etc.
 - Death of animal due to unknown cause.
- Vaccinate your dog against rabies at the age of 6 weeks, 6 months and thereafter once in every one to two years.
- Keep the vaccination card safely and produce the same to the doctor if the dog bites.
 - Do not provoke dogs. Avoid unknown dogs and inquire about the presence of dogs when visiting houses.
 - If your dog is known to bite, display a "beware of dogs" notice
 - Make sure your muzzle dogs that bite and do not allow your dog to stray.
- Be a law abiding citizen by registering your dog.

ANTI-RABIES VACCINATION CARD

Note: Please send this portion to
Reporting officer / higher authorities.

OPD No:

Name of the ARC:

Date of Exposure:

Date of Treatment:

Name of the Patient:

Age: Sex:

Address:

Site of Bite / Exposure

Face/ Head Palm/ Foot

Upper Trunk Lower Trunk

Leg Hand Genitals

Type of wound

Superficial Multiple Deep

WHO Category of Exposure

Animal

Dog Cat Monkey

Jackal

Others Specify

Pet Stray Wild

Vaccination status of animal

Fully vaccinated

Partially vaccinated

Unvaccinated

Don't know

Signature of doctor and date
Address and stamp

History

Date of exposure

Type of animal

Cat/Dog- domestic

Cat/Dog-stray

Wild animal

Observation of animal

Possible

Not possible

Vaccination of animal

Two consecutive
Injections for the past 2-yrs Yes
- last one within 1 yr of bite

No

Not applicable

Behavior of animal

Normal

Suspicious

If all answers
Observe the Dog/cat

Treatment Regimen

RIG

ID Schedule 2 sites