National Guideline for Rabies Prophylaxis and Intra-dermal Application of Cell Culture Rabies Vaccines

June, 2010

Disease Control Unit
Directorate General of Health Services
Mohakhali, Dhaka-1212,
Ministry of Health & Family Welfare
Bangladesh
MESSAGE

Rabies, a zoonotic viral disease and continues to be a public health problem in Bangladesh. It is estimated more than 2000 people die of Rabies and more than 100,000 persons take post-exposure treatment. But the exact magnitude of problem is much more.

Government of Bangladesh is determined to phase out the production and use of Nervous Tissue Vaccine (NTV) by December 2011 which is the sole human rabies vaccine available for post-exposure rabies vaccination in the public sector. Considering the WHO guidelines and recommendations of WHO technical expert group, National experts suggested and recommended the use of cost-effective vaccination schedules such as abbreviated multisite Zagreb protocol (4 dose, 3 visits) and updated Thai Red Cross (TRC) intradermal regimen to phase out NTV and to make available modern rabies vaccine in public sector.

To operationalise the introduction of cost-effective intradermal (ID) route there is an urgent need to develop national guidelines for ID application of human rabies vaccine, Director, Disease Control and Line Director CDC convened expert group meeting and framed these guidelines. I congratulate Director, Disease Control and board of editors for bringing out these guidelines.

I am very optimistic that these guidelines will be extremely useful for the country to make rational use of modern rabies vaccine and phase out NTV by 2011..

Prof. Dr. Shah Monir Hossain
Director General of Health Services
Rabies continues to be a major public health problem in Bangladesh killing an estimated 2000 people annually. This is a fatal disease but totally preventable by timely and appropriate post-exposure treatment. Based on vaccine utilization approximately 100,000 people receive post-exposure treatment yearly in the country. Production and use of Nervous Tissue Vaccine will be phased out very soon. Modern, safe and effective anti-rabies Cell Culture Vaccines (CCVs) will be used for post-exposure treatment in public sector. High cost and limited availability are limiting factors for its wider use. To overcome these problems, WHO recommended the use of intra-dermal (ID) application of CCVs which not only reduces the cost of post-exposure treatment but also allows wider coverage in available quantity of vaccines. Considering the WHO recommendation of experts, results of clinical trials and international experience, experts of Bangladesh recommends ID regimen phase wise. In first phase, only Dhaka Infectious Disease Hospital will serve as Anti-rabies centre for ID regimen. After its successful implementation, ID regimen will spread out to Division and then to District level hospitals. A need was felt to have a guideline for animal bite management including correct technique of intra-dermal inoculation of CCVs for its easier and wider implementation. An expert group meeting was held at IEDCR, Dhaka to formulate the guideline with participants including practitioners managing anti-rabies clinics, laboratory medicine practitioners, policy makers, public health experts from both public and private sector. The guideline from the consensus deliberations of the expert group, have been brought out in this publication.

It is sincerely hoped that the guideline will be of immense use for better management of animal bite cases and availability and affordability of modern rabies vaccine for all through introduction of cost-effective multisite ID schedule for post-exposure rabies prophylaxis.

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Introduction

Rabies, a dreadful zoonotic disease caused by rabies virus with horrifying symptoms. It is characterized by acute viral encephalitis which leads to fatality once the symptoms stated. The disease is invariably fatal and perhaps the most painful and horrible of all communicable diseases in which the sick person is tormented at the same time with thirst and fear of water (hydrophobia). This is almost 100% fatal but 100% preventable.

The disease is transmitted from animal to animal or from animal to human. Human infection by rabies virus usually occurs as a result of a transdermal bite or scratch from an infected wild or domestic animal especially dog in about 90 percent of cases.

Rabies is a neglected disease because it is the disease of the hardcore poor and no advocate for them. This is also a communicable disease but got very less importance than other communicable diseases where death is not inevitable.

This fearful disease still claims over 55,000 human lives annually. Most deaths occurred in Asia and Africa. Rabies, takes away live world wide in every 10 minutes and most victims are children. According to WHO, 1550 people die of rabies and about 100,000 people is getting post- exposure treatment (PET) each year. Recent survey by Disease control unit (2007) shows rabies death is more than 2000 per year in Bangladesh. Animal bites, if managed appropriately and timely the disease, is preventable to a large extent. In this regard the post-exposure treatment of animal bite cases is of prime importance.

An expert group meeting for strategic plan and finalizing the guidelines for prevention and control of rabies cases was held in IEDCR auditorium under Communicable Diseases Control, Directorate General of Health Services to bring out uniformity in post-exposure treatment practices. Following this, the national guidelines for management of animal bites formulated in 2010 to bring out uniformity in post-exposure treatment practices.

Until recently the Nervous Tissue Vaccine (NTV) was the mainstay for post-exposure prophylaxis. As per WHO recommendations, the production and use of this reactogenic vaccine should be gradually phased out from our country. Cell Culture Vaccines (CCV) are now being used for post-exposure prophylaxis in private and personal choice. Higher cost of intra-muscular application of CCV is a limiting factor for its wider use. To overcome this problem, WHO has recommended use of efficacious, safe and feasible intra-dermal (ID) route of inoculation of CCVs. India, Sri Lanka, Thailand and the Philippines have successfully adopted ID route of application of CCV against rabies as part of their policy. National authorities after expert consultation have approved the use of ID route for application of CCVs in Bangladesh in a phased manner. Hence, the guideline of prevention and control of rabies have been prepared with inclusion of correct technique of ID inoculation of CCVs.
Post-Exposure Treatment (PET)

2.1 Indication for PET

In rabies endemic country like Bangladesh, where animal rabies control programme is non-existent, every animal bite is potentially suspected as a rabid animal bite and hence management and care should be started immediately. Because of long incubation period, which is typical of most cases of human rabies, it is possible to institute post-exposure prophylaxis (PEP). It is desirable to initiate at the earliest to ensure that the individual will be immunized before the rabies virus reaches the central nervous system. However, people who present for treatment even months after a possible rabies exposure or animal bite should be evaluated and given PEP as if the event had occurred recently.

<table>
<thead>
<tr>
<th>ANIMALS TRANSMITTING RABIES</th>
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<tr>
<td><strong>Domestic</strong></td>
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<tr>
<td>Dogs &amp; Cats</td>
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*Note:*
- All exposures in wild are considered as category III exposures.
- Bite by fruit eating Bats or Rodents do not ordinarily necessitate rabies vaccination in Bangladesh. However, bites by Bats or rodents in unusual circumstances or in other countries may be considered for vaccination in consultation with an expert in the field of rabies.
- Vampire Bats in USA, Australia, south & central America are cause of non-classical Rabies.
To bring out uniformity globally, the classification of animal bite for post-exposure prophylaxis has been based on WHO recommendations (Table 1).

Table 1: Type of contact, exposure and recommended post-exposure prophylaxis

<table>
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<tr>
<th>Category</th>
<th>Type of contact</th>
<th>Recommended treatment</th>
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</table>
| I        | Touching or feeding of animals  
Licks on intact skin | None, if reliable case history is available |
| II       | Nibbling of uncovered skin  
Minor scratches or abrasions without bleeding. | Anti-Rabies vaccine  
Wound Management |
| III      | Single or multiple transdermal bites  
Or scratches, licks or broken skin  
Contamination of mucous membrane with saliva (i.e. licks). Exposure to bats ** | Administer rabies immunoglobulin and  
Administer Anti-Rabies vaccine immediately  
Wound Management |

*Stop treatment if dogs or cats remain healthy throughout an observation period of 10 days or if animal is euthanized and found to be negative for rabies by appropriate laboratory techniques.

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

**CATEGORY III EXPOSURES**

Vaccination status of the biting animal:
Unvaccinated animals: more likely to transmit rabies
Vaccinated animals: 1. A history of rabies vaccination in an animal is not always a guarantee that
the biting animal is not rabid
2. Can also transmit rabies if the vaccination of the biting animal was ineffective for any reason.
3. Animal vaccine failures may occur because of improper administration or poor quality of the vaccine, poor health status of the animal, and the fact that one vaccine does not always provide long-lasting protection against infection in dogs.

Provoked versus unprovoked bites:
Whether a dog bite was provoked rather than unprovoked should not be considered a guarantee that the animal is not rabid as it can be difficult to understand what an attacking dog considers provocation for an attack.

Observation of biting animal:
The treatment should be started immediately after the bite.
The treatment may be modified if animal involved (dog or cat) remains healthy throughout the observation period of 10 days by converting post-exposure prophylaxis to pre-exposure vaccination by skipping the vaccine dose on day 14 and administering it on day 28 while using Essen Schedule.
The observation period is valid for dogs and cats only. The natural history of rabies in mammals other than dogs or cats is not fully understood and therefore the 10-day observation period may not be applicable.

Bite by wild animals:
Bite by all wild animals should be treated as category III exposure.
Wild animal bites which are qualified for PEP in Bangladesh include bite by jackal, fox, wolf, mongoose, bear, leopard, wild cat and hyena

Bite by rodents:
Bites by domestic rats, mice, squirrel, hare and rabbits seldom require treatment.

Bat rabies:
Bat rabies has not been conclusively proved in Bangladesh and neighbouring countries and hence exposure to bats does not warrant treatment.

Special circumstances:
Pregnancy, lactation, infancy, old age and concurrent illness are not contraindications for rabies post-exposure prophylaxis in the event of an exposure.
Post-exposure prophylaxis against rabies takes preference over any other consideration since it is a life-saving procedure.
Moreover, rabies vaccine does not have any adverse effect on fetus, mother-to-be and the course of pregnancy. Hence complete post-exposure treatment should be given depending on the category of the exposure.
Post-exposure prophylaxis of immuno-compromised patients:

In patients and those in whom the presence of immunological memory is no longer assured as a result of other causes, proper and thorough wound management and antisepsis accompanied by local infiltration of rabies immunoglobulins (ERIG/HRIG) followed by anti-rabies vaccination (CCV) are of utmost importance.

Even immuno-compromised patients with category II exposures should receive rabies immunoglobulin in addition to a full post-exposure vaccination.

Preferably, if the facilities are available, anti-rabies antibody estimation should be done 10 days after the completion of course of vaccination.

Human-to-human transmission:

The risk of rabies transmission to other humans from a human rabies case is very minimal and there has never been a well documented case of human-to-human transmission, other than the few cases resulting from organ transplant.

However, people who have been exposed closely to the secretions of a patient with rabies may be offered PEP as a precautionary measure.

There is no presence of rabies virus in blood (no viraemia) and therefore blood or blood products may not be medium for rabies transmission.

Transmission through ingestion of food products of rabid animal:

There is no evidence of getting rabies infection through consumption of boiled or pasturized milk and cooked meat of suspected rabid animal. However the chance of transmission of rabies through unboiled or unpasturize milk and uncooked meat may be possible.

It is important to inform the public that milk or meat from rabid or suspected animals should not be consumed.

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**It is re-emphasized that post exposure prophylaxis should be started as early as possible after exposure. However, it should not be denied to person reporting late for treatment as explained previously.**

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2.2 Approaches to Post-Exposure Treatment (PET)

The Post-exposure treatment is a three pronged approach. All three carry equal importance and should be done simultaneously as per the category of the bite

- Management of animal bite wound
- Passive immunisation: Rabies Immunoglobulins (RIG)
- Active immunisation: Anti-Rabies Vaccines (ARV)
2.2.1 Management of animal bite wound

**Wound toilet:** Since the rabies virus enters the human body through a bite or scratch, it is imperative to remove as much saliva, and thereby the virus, from the wound as is possible by an efficient wound toilet that should not involve additional trauma. Since the rabies virus can persist and even multiply at the site of bite for a long time, wound toilet must be performed even if the patient reports late. (Table 2)

This can be done by prompt and gentle thorough washing with soap or detergent and flushing the wound with running water for 10-15 minutes. If soap and detergent are not immediately available wash with running water for at least 10 minutes. Avoid direct touching of wounds with bare hands. Later anti-septic will be used. Considering the importance of this step the anti-rabies clinics should have wound washing facilities.

The application of irritants (like chilies, oil, turmeric, lime, salt, etc) is unnecessary and damaging. In case irritants have been applied on the wound, enough gentle washing with soap or detergent to remove the extraneous material especially oil should be done followed by flushing with copious amount of water for 10-15 minutes immediately.

It should be noted that the immediate washing of the wound is a priority. However, the victim should not be deprived of the benefit of wound toilet as long as there is an unhealed wound which can be washed even if the patient reports late. The maximum benefit of the wound washing is obtained when fresh wound is cleaned immediately.

**Application of antiseptics:** After thorough washing and drying the wound, any one of the available chemical agents should be applied viz Povidone iodine (Betadine), Alcohol, Chloroxylenol (Dettol), Chlorhexidine Gluconate and Cetrimide solution (Savlon - in appropriate recommended dilution), etc.

**Table 2: Wound Management**

<table>
<thead>
<tr>
<th><strong>Do’s</strong></th>
<th><strong>Physical</strong></th>
<th><strong>Wash with running tap water or speedy running water</strong></th>
<th><strong>Mechanical removal of virus from the wound</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chemical</strong></td>
<td>Wash the wound with soap and water. Apply disinfectant</td>
<td></td>
<td>Inactivation of the virus</td>
</tr>
<tr>
<td><strong>Biological</strong></td>
<td>Infiltrate immunoglobulins (HRIG/ERIG) in the depth and around the wound in Category III exposures</td>
<td></td>
<td>Neutralization of the virus</td>
</tr>
<tr>
<td><strong>Don’ts</strong></td>
<td>• Touch the wound with bare hand</td>
<td></td>
<td><strong>Apply irritants like soil, chilies, oil, herbs, chalk, betel leaves etc.</strong></td>
</tr>
</tbody>
</table>
Local infiltration of rabies immunoglobulins:

In category III bites, rabies immunoglobulins should be infiltrated in the depth and around the wound to inactivate the locally present virus.

Suturing of wound should be avoided as far as possible. If surgically unavoidable, minimum loose sutures should be applied after adequate local treatment along with proper infiltration of rabies immunoglobulins.

Cauterisation of wound is no longer recommended as it leaves very bad scar, and does not confer any additional advantage over washing the wound with water and soap. Injection tetanus toxoid should be given to the un-immunised individual. To prevent sepsis in the wound, a suitable course of an antibiotic may be recommended.

2.2.2 Rabies Immunoglobulins (RIG)

The anti-rabies serum/rabies immunoglobulin provides passive immunity in the form of ready-made anti-rabies antibody to tide over the initial phase of the infection. Anti-rabies serum or RIG has the property of binding with the rabies virus, thereby resulting in the loss of infectivity of the virus.

Two types of RIGs are available and recommended to use:

Equine Rabies Immunoglobulins (ERIG): ERIG is of heterologous origin raised by hyper-immunisation of horses. However, currently manufactured ERIGs are highly purified and the occurrence of adverse events has been significantly reduced. Still these should be administered after skin sensitivity test. Half life of ERIG is 21 days.

Human Rabies Immunoglobulins (HRIG): HRIG are free from the side effects encountered in a serum of heterologous origin (i.e. of animal origin), and because of their longer half life, are given in half the dose of equine anti-rabies serum. The anti-rabies sera should always be brought to room temperature (20 – 25°C) before use. HRIG is a homologous biological preparation and does not require any prior sensitivity testing. HRIG preparation is available in concentration of 150 IU per ml.
Dose of rabies immunoglobulins:

Equine rabies immunoglobulins (ERIG): **40 IU per kg** body weight  upto a maximum of 3000 IU.

Human rabies immunoglobulins (HRIG): **20 IU per kg** body weight (maximum 1500 IU).

Administration of immunoglobulins:

As much of the calculated dose of RIG as is anatomically feasible should be infiltrated into and around the wounds (site of bite). Multiple needle injections into the wound should be avoided.

Remaining, if any, after all wounds have been infiltrated, 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 rabies immunoglobulin may not be sufficient to infiltrate all wounds. In these circumstances, it is advisable to dilute the immunoglobulins in sterile normal saline 2 to 3 fold to be able to permit infiltration of all wounds. The total recommended dose of immunoglobulin must not be exceeded as it may suppress the antibody production by the vaccine.

If immunoglobulin was not administered when vaccination was begun, it can be administered upto the 7th (seventh) day after the administration of the first dose of Anti-Rabies vaccine. Beyond the seventh day, Rabies Immunoglobulin (RIG) is not indicated since an antibody response to anti-rabies vaccine is presumed to have occurred.

Immunoglobulin should never be administered in the same syringe or at the same anatomical site as vaccine.
**Sensitivity test before administration of ERIG:** With antisera of equine origin, anaphylactic shock may occur and thus sensitivity testing is mandatory before giving ERIG. The protocol for skin sensitivity test is presented in Annexure I.

A negative skin test must never reassure the physician that no anaphylactic reaction will occur.

**Management if anaphylactic reaction occurs:**

1. Adrenaline: The dose is 0.5 ml of 0.1 percent solution (1 in 1000, 1mg/ml) for adults and 0.01 ml/kg body weight for children, injected intramuscularly(IM).
2. Inj Hydrocortisone: 100 mg stat and 6 hourly
3. Inj Chlormpheniramine :
4. Inj Ranitidine:

If patient is sensitive to ERIG, HRIG should be used. Patient who had prior exposure of antisera (e.g-Antitetanus serum, antidiptheric serum) should receive subcutaneous dose of Inj adrenaline (the requirement will be half dose of that required for treatment for anaphylaxis).

**Tolerance and side effects:**

1. There may be transient tenderness at the injection site.
2. Brief rise in body temperature.
3. Skin reactions are extremely rare.
4. RIG must never be given intravenously since this could produce symptoms of shock, especially in patients with antibody deficiency syndromes.
5. Serum sickness occurs in 1% to 6% of patients usually 7 to 10 days after injection of ERIG, but it has not been reported after treatment with HRIG. Serum sickness is characterized by joint pain, proteinuria etc. It can be managed by oral steroids, Non steroid antiinflammatory drugs (NSAID) and H2 blockers.

**Precautions to be taken while administering RIGs**

- All emergency drugs and facilities for managing any adverse reactions must be available.
- The RIG vial(s) taken out from refrigerator should be kept outside for a few minutes before administration to the patient (to warm it to room/body temperature).
- RIG should be administered before starting anti-rabies vaccination.
- RIG should not be administered in the same syringe as the vaccine or at the same site as vaccine.
- Pregnancy is not a contra-indicated for RIG and anti-rabies vaccination when indicated.
- The patient should not be on an empty stomach.
- While infiltrating RIG into bite wounds, care must be taken to avoid injecting into blood vessels and nerves. Anatomical feasibility must always be kept in mind while injecting RIG.
While injecting into finger tips, care must be taken to avoid compartment syndrome.

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.

Keep the patient under observation for at least one hour after ERIG administration and send home.

The treating physician should be prepared to manage anaphylaxis which could occur at any stage of administration of ERIG irrespective of the outcome of the skin sensitivity test.

Approach to a patient when rabies immunoglobulin is not available:

a. Proper wound toileting
b. Essen Schedule of Cell Culture Rabies Vaccines with double dose on day 0 at 2 different sites intramuscularly [0 day – (2 doses on left and right deltoid) 3, 7, 14 and 28 days].

It is emphasized that doubling the first dose of CCV is not a replacement to RIG.

2.2.3 Anti-Rabies Vaccines

Active immunization is achieved by administration of safe and potent CCVs. In Bangladesh, NTV is still used for post-exposure treatment in public sector. However, as this vaccine is reactogenic, the production will be stopped soon. Privately, CCVs are now used for active immunization. Very soon CCV will be available in public sector too.

Indications: All age groups of animal bite victims of Category II and III require the same number of injections and dose per injection. The Category III exposures, in addition require administration of rabies immunoglobulins as discussed earlier.

Storage and transportation: Though most Cell Culture Vaccines are marketed in freeze dried (lyophilised) form which is more tolerant of vagaries of temperature, yet it is recommended that these vaccines should be kept and transported at a temperature range of 2-8°C. Freezing does not damage the lyophilised vaccine but there are chances of breakage of ampoule containing the diluent. Liquid vaccines of nerve tissue or cell culture origin should never be frozen.

Reconstitution and storage: The lyophilised vaccine should be reconstituted with the diluent provided with the vaccine immediately prior to use. However, in case of unforeseen delay it should not be used after 6-8 hours of reconstitution.

Adverse effects with Cell Culture Vaccines: The Cell Culture Vaccines are widely accepted as the least reactogenic and safe rabies vaccines available today. However, few studies have now shown that adverse effects can be either general in nature or allergic in origin. The general
adverse reactions include sore arm, headache, malaise, nausea, fever and localized edema at the site of injection. Symptomatic treatment may be needed.

**Switch over from one brand/type of vaccine to the other:** Shifting from one brand/type of CCV to other brand/type should not be encouraged as literature supports that good immunity is best achieved with same brand/type. However under unavoidable circumstances, available brand/type may be used to complete PEP.

**Protective level of anti-rabies antibody:** Humoral antibodies play important role in protection against rabies and a titre of 0.5 IU/ml or more in serum as tested by Rapid Fluorescent Focus Inhibition Test (RFFIT) is considered as protective.

Currently available CCVs could be administered by IM regimen or approved CCVs could be administered by ID regimen.

### 2.2.3.1 Intra-muscular (IM) Regimen

The currently available vaccines and regimen in Bangladesh for IM administration are described below.

**Vaccines**

Cell Culture Vaccines

- Purified Vero Cell Rabies Vaccine (PVRV)
- Purified Chick Embryo Cell Vaccine (PCEC)

**Regimen:**

**Zagreb schedule:**
Four doses/Three visits (2-1-1) intramuscular regimen (DO, D7, D21)

In the abbreviated multisite schedule, the 2-1-1 regimen, one dose is given in the right arm and one dose in the left arm at day 0, and one dose applied in the deltoid muscle on days 7 and 21. The 2-1-1 schedule induces an early antibody response and may be particularly effective when post-exposure treatment does not include administration of rabies immunoglobulin.

**Essen schedule:**
Five doses/ Five visits (1-1-1-1-1) intramuscular regimen (DO, D3, D7, D14, D28)

Five doses/ Five Visits intramuscular regimen - The course for post-exposure prophylaxis should consist of intramuscular administration of five doses of CCV on days 0, 3, 7, 14 and 28 (D0, D3, D7, D14 and D28). The sixth injection (D90) should be considered as optional and should be given to those individuals who are immunologically deficient, are at the extremes of age and on steroid therapy. Day 0 (D0) indicates date of first injection not necessarily day of bite.
Because of the less doses to be used in 3 visits with similar efficacy, Government of Bangladesh has chosen the Zagreb schedule (2-1-1) for post-exposure rabies prophylaxis in Bangladesh. It has been adopted for PEP in Indonesia also.

Intramuscular (IM) schedules (WHO Recommendations):

Site of inoculation:

a. The deltoid region is ideal for the inoculation of these vaccines.
b. Gluteal region is not recommended because the fat presents in this region and poor absorption of antigen and hence impairs the generation of optimal immune response.
c. In case of infants and young children antero-lateral part of the thigh is the preferred site.

2.2.3.2 Intra-dermal (ID) Regimens

Concept of intra-dermal inoculation of anti-rabies vaccines (IDRV):

Intradermal regimens consist of administration of a fraction of intramuscular dose of certain Cell Culture rabies vaccine on multiple sites in the layers of dermis of skin.

The vaccines used are same; however route, dose and site of administration differ. The use of intra-dermal route leads to considerable savings in terms of total amount of vaccine needed for full pre- or post- exposure vaccination, thereby reducing the cost of active immunisation.

Single dose (0.5ml/1ml) of rabies vaccine/antigen when given by IM route gets deposited in the muscles. There after the antigen is absorbed by the blood vessels and is presented to antigen presenting cells which triggers immune response.

While using ID route, small amount (0.1ml) of rabies vaccines/antigen is deposited in the layers of the skin at multiple sites. The antigen is directly presented to the antigen presenting cells (without circulation/dilution in blood) at multiple sites triggering a stronger immune response.
Mechanism of action of ID RV:

Intra-dermal inoculation is deposition of approved 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 neutralising 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.

Principle of ID regimen (Diagrammatic representation)


General guidelines for use of IDRV (Intra-Dermal Rabies Vaccination)

- Vaccines to be applied by intra-dermal route of administration should be approved by WHO and National guidelines.
- The vaccine package leaflet should include a statement indicating that the potency as well as immunogenicity and safety allow safe use of vaccine by ID pre- and post-exposure.
- Post Marketing Surveillance (PMS) data should be maintained for minimum of two years by vaccine manufacturers on a pre-designed and approved protocol.
- Intra-dermal injections must be administered by staff trained in this technique.
- Vaccine vials must be stored at 2º to 8ºC after reconstitution.
• The total content of reconstituted vial should be used as soon as possible, but within 6 hours.

• All the reconstituted vaccines should be discarded after 6 hours of reconstitution and at the end of the day.

• Rabies vaccines formulated with an adjuvant should not be administered intra-dermally.

• Vaccine when given intra-dermally should raise a visible and palpable bleb in the skin.

• In the event that the dose is inadvertently given subcutaneously or intra-muscularly or in the event of spillage, a new dose should be given intra-dermally in near by site.

• Animal bite victims on chloroquine therapy (anti-malarial therapy) and other immunocompromised patients should be given ARV by intramuscular route.

• Only medical practitioners and health professionals who have completed short training course on application of ID schedule for rabies prophylaxis are permitted to use ID schedule.

Vaccines and regimen approved for ID use in the country

ID vaccination schedule is cost-effective, scientifically proved and WHO recommended vaccination schedule. It is widely practiced in Thailand, Sri Lanka and many states of India.

I/D schedule is not recommended for immunocompromised patients (patients on cytotoxic drugs, on long term steroids, positive for HIV/AIDS, on anti-malarial and biologics).

Considering the recommendations on intra-dermal application of rabies by WHO and results of safety, efficacy and feasibility trials conducted in India and other countries, Director General of Health Services, Bangladesh approved the use of reduced dosage intra-dermal vaccination (ARV-CCV) regimen for rabies post-exposure prophylaxis.

The following available CCV in Bangladesh have been approved by WHO currently for use by intra-dermal route.

Vaccines:

Purified Verocell Rabies Vaccine (PVRV)

Purified Chicken Embryo Cell Vaccine (PCECV)

Potency of approved vaccines: The vaccines should have stated potency of > 2.5 IU per IM dose, irrespective of reconstituted volume. The same vaccine is used for ID administration as
per stated schedule. 0.1 ml of vaccine, irrespective of reconstituted volume, is administered per ID site as per schedule below. **Note:** The WHO recommended dose for IDRV is 0.1 ml per site irrespective of 0.5 mL (PVRV) or 1.0 mL (PCECV) I/M vaccination dose. In this sense, 1.0 ml (PCECV) is cost-effective. Different doses were used at the beginning but thorough investigation of using 0.1 ml per site was approved irrespective of manufacturer. One thing we have to remember, IDRV is based on skill of the medical practitioner and there may be chance of slipping ID to S/C or I/M which must be taken into account. Since rabies does not give second chance, vaccination failure will have major setback and long term effect in mind of medical practitioners.

**Regimen**

**Updated Thai Red Cross Schedule (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 ID RV and may not be the day of rabies exposure/animal bite.

**WHO approved ID regimens for Post-Exposure Prophylaxis**

---

**Maintenance of vaccine vial in use**

- Use aseptic technique to with draw the dose
- Store in a refrigerator at 2ºC to 8ºC
- Reconstituted vaccines should be used as soon as possible or within 6 to 8 hours if kept at 2ºC to 8ºC. All unused reconstituted vaccine at the end of 6-8 hours must be discarded

**Materials required**

- A vial of rabies vaccine approved for ID RV 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 (1 ml syringe with hypodermic needle-Insulin syringe)
• Disinfectant swabs (e.g. 70% ethanol, isopropyl alcohol) for cleaning the top of the vial and the patients’ skin.

ID injection technique

Using aseptic technique, reconstitute the vial of freeze-dried vaccine with the diluent supplied by the manufacturer. With 1 ml syringe 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) 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 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. 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. Inject the remaining half the volume of vaccine (i.e. 0.1ml; either 10 or 4 units) on the opposite deltoid area.

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 then at an appropriate intradermal site.

Anti-rabies treatment centers which meet the following criteria may use ID administration: (Annexure- III)
• Have adequately trained staff to give ID inoculation of anti-rabies vaccine
• Can maintain cold chain for vaccine storage
• Ensure adequate supply of suitable syringes and needles for ID administration
• Are adequately well versed in management of open vial and safe storage practices.
• Open 24-hours a day and 7-days a week to attend the animal bite patients.

2.3 Post-Exposure Prophylaxis for previously vaccinated persons
Managing re-exposure following post-exposure treatment with TCV: (D0, D3)

If re-exposed, persons who have previously received full post-exposure prophylaxis (either by IM or ID route) with a potent cell-culture vaccine within last five years should now be given only two booster doses, intramuscularly (0.5ml/1ml)/intra-dermally (0.1 ml at 1 site) on days 0 and 3. Proper wound toilet should be done. RIG application is not necessary. In re-exposed case where person who have not received complete course of PEP by IM/ID route within 5 yrs or not sure about the number of doses, a complete PEP courses should be applied.
After five years animal bite case will be treated as a fresh case.

Managing exposure following pre-exposure prophylaxis with TCV: (D0,D3)

If after recommended pre-exposure prophylaxis within last five years, a vaccinated person is exposed to rabies, a proper wound toileting should be done and two IM/ID (0.1 ml at 1 site) doses of Cell Culture Vaccine be given on days 0 and 3. RIG application is not necessary.

Managing re-exposure following post-exposure treatment with NTV:

Persons who have previously received full post-exposure treatment with NTV should be treated as fresh case and may be given treatment as per merits of the case.

Pre-exposure Vaccination

Pre-exposure vaccination may be offered to high risk groups like laboratory staff handling the virus and infected material, clinicians and persons attending to human rabies cases, veterinarians, animal handlers and catchers, wildlife wardens, quarantine officers and travelers from rabies free areas to rabies endemic areas. Pre-exposure vaccination is administered as one full dose of vaccine intramuscularly or 0.1 ml intra-dermally on days 0, 7 and either day 21 or 28.

Laboratory staff and others at high continuing risk of exposure should have their neutralizing antibody titres checked every 6 months. If it is less than 0.5 IU/ml a booster dose of vaccine should be given. Such individuals on getting exposed to rabies virus after successful pre-exposure immunization require only two booster injections of vaccine given on days 0 and 3 without any anti-rabies serum/RIGs.

If possible, a pre-plan should be developed to use reconstituted vaccine for school children in local area but primo-vaccinates should be convinced to take two extra doses on D7 and D21 or 28. A reminder can be sent one day prior to vaccination schedule
Important points to be noted

- Administration of any type of ARV on the buttocks is not recommended
- For any person who has had direct or indirect contact with a rabies patient, PEP is not recommended except in special situations.
- Patients should be advised not to rub at the site of injection after administration of vaccine.
- Patients must be advised to complete full course of vaccine as per the advised schedule.
- All patients who receive rabies PEP should be given a document/card, clearly stating the date, month & year of vaccination and the type of vaccine used.

Documentation

A standard format should be used for recording and reporting of PEP and hydrophobia cases. The reporting format is presented in Annexure II. It will help to analyze rabies situation and provide technical guidance for formulating national policy for rabies control based on changing situation and arranging medical supplies. Rabies data entry into WHO RABNET is recommendable.
4. Decision Tree: Guide to Post-Exposure Prophylaxis (PEP)
Further Reading:


Annexure – I

Skin sensitivity test protocol while using ERIG

Before administering ERIG, it is always necessary to be ready to treat possible anaphylactic reactions with Inj. Adrenaline. The dose is 0.5 ml of 0.1 % solution (1 in 1000, 1mg/mL) for adults and 0.01 mL/kg body weight for children injected subcutaneously.

Inj. Hydrocortisone hemisuccinate (1–2 mg/kg), Inj. Pheneramine Maleate (0.8 mg/kg). Inj. Ranitidine (1 – 2 mg/kg), Inj. Deriphyllin ((0.5 mg/Kg), Inj. Dopamine intravenous fluids and oxygen cylinder should be kept ready & used if needed. ERIG should preferably be given in a hospital facility under close medical supervision.

Normally, one should follow the guidelines given in the package insert, which accompanies every vial of ERIG in the box. However, the general guidelines are as follows:

- Let the patient be in a sitting position.
- Record baseline pulse, blood pressure and respiratory rate of the patient
- Draw 0.1 ml (4 units) of sterile normal saline into an insulin syringe and inject it intradermally into flexor aspect of right forearm. This will raise a bleb/swelling of about 4-5 mm (control injection).
- Take 0.1 ml of ERIG in another insulin syringe and draw 0.9 ml of sterile normal saline into the same syringe and gently rotate and mix it in syringe.
- Inject 0.1ml of this 1:10 dilution of ERIG intradermally into the flexor aspect of left forearm raising a bleb/swelling of about 4-5 mm size (ERIG test dose)
- Keep a constant watch on the pulse, blood pressure and respiratory rate of the patient for the next 15 minutes & observe for any local or systemic reactions.

The skin sensitivity test is considered positive;

- If there is erythema and / or induration of > 10 mm in the left forearm (ERIG test dose) and the control right forearm showing no such local dermal reaction within 15 min
- Any increase or abrupt fall in blood pressure, syncope, hurried/difficult breathing, palpitation etc.

The skin sensitivity test is considered negative, when there is no reaction in both the forearms. A negative skin test must never reassure the physician that no anaphylactic reaction will occur subsequently.
Annexure-II
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 ☐

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: ________

<table>
<thead>
<tr>
<th>Day</th>
<th>Route of Administration (IM, ID)</th>
<th>Type of Vaccine</th>
<th>Due Date</th>
<th>Date of Admn.</th>
<th>Dose Site</th>
<th>Batch NO.</th>
<th>Exp. Dt</th>
<th>Adverse Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>28</td>
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<td></td>
</tr>
</tbody>
</table>

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 you muzzle dogs that bite and do not allow your dog to stray.
- Be a law abiding citizen by registering your dog.

Signature
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-III**

The following are the recommended guidelines for physical facilities and staff requirements for an anti-rabies clinic. (An ideal situation)

**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. Attendant - 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 Steroid
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
7 Computers, Multimedia, Printer, Scanner and other Accessories.
Prevention of Rabies

- H/O Dog Bite/Cat Bite
- H/O wild animal bite

Is there any evidence of Wound?

- Yes
- No

Category of Wound

- Category of wound III
- Category of wound II
- Category of wound I

Reliable History and Sign

- Yes
- No

Wound Toileting
Soap & Water; Antiseptics

PEP
a. RIG+ IM—Zagreb Schedule
b. RIG+ ID—Thai Redcross
(for cat III injury)

PEP
a. IM—Zagreb Schedule
b. ID—Thai Redcross
(for cat II injury)

Diagnosis And Management Chart

PEP
a. IM—Zagreb Schedule
b. ID—Thai Redcross
(for cat II injury)

PEP
RIG+ IM—Essen Schedule
(For cat II and III injury)

Is the patient pregnant?
H/o or current use of any Steroid or immunosuppressive drug intake
Any immunosuppressive disease condition( e.g-Leukaemia, lymphoma, malignancy, CKD etc)

Yes
# Treatment Chart

## Post Exposure Treatment (PET)

### WOUND MANAGEMENT

<table>
<thead>
<tr>
<th><strong>Do’s</strong></th>
<th>Physical</th>
<th>Wash with running tap water or speedy running water</th>
<th>Mechanical removal of virus from the wound</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical</td>
<td>Wash the wound with soap and water. Apply disinfectant</td>
<td>Inactivation of the virus</td>
<td></td>
</tr>
<tr>
<td>Biological</td>
<td>Infiltrate immunoglobulins (HRIG/ERIG) in the depth and around the wound in Category III exposures</td>
<td>Neutralisation of the virus</td>
<td></td>
</tr>
</tbody>
</table>

| **Don’ts** | |
|-----------| |
| • Touch the wound with bare hand | |
| • Apply irritants like soil, chilies, oil, herbs, chalk, betel leaves etc. | |

### IDRV

<table>
<thead>
<tr>
<th>D0, D3, D7, D28</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thai Red Cross Schedule: 2-2-0-2</td>
</tr>
<tr>
<td>Route: Intradermal</td>
</tr>
<tr>
<td>Every inj: 0.1 ml</td>
</tr>
<tr>
<td>Site: Deltoid</td>
</tr>
<tr>
<td>0.3.7.28: Inj at two deltoid</td>
</tr>
<tr>
<td>Total dose - 0.8 ml</td>
</tr>
<tr>
<td>Not to be used: Immunosuppressive conditions, antimalarials use</td>
</tr>
<tr>
<td>Steroid use etc</td>
</tr>
<tr>
<td>Store: 2-8 degree</td>
</tr>
<tr>
<td>Look: Visible and palpable bleb</td>
</tr>
<tr>
<td>Caution: Reconstituted vaccine to be used within 6 hours</td>
</tr>
<tr>
<td>Discard: after 6 hours of prepare</td>
</tr>
</tbody>
</table>

### IMRV

<table>
<thead>
<tr>
<th>Zagreb schedule: (DO, D7, D21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Four doses/Three visits (2-1-1)</td>
</tr>
<tr>
<td>Route: Intramuscular regimen</td>
</tr>
<tr>
<td>Site: Deltoid or Anterolateral thigh</td>
</tr>
<tr>
<td>Dose- 1 ml/inj</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Essen schedule: (DO, D3, D7, D14, D28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Five doses/ Five visits (1-1-1-1-1) intramuscular regimen</td>
</tr>
<tr>
<td>Route: Intramuscular regimen</td>
</tr>
<tr>
<td>Site: Deltoid or Anterolateral thigh</td>
</tr>
<tr>
<td>Dose- 1 ml/inj</td>
</tr>
</tbody>
</table>

### RIG (ERIG/HRIG)

<table>
<thead>
<tr>
<th>ERIG : 40 IU per kg body weight up to a maximum of 3000 IU.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRIG: 20 IU per kg body weight (maximum 1500 IU).</td>
</tr>
<tr>
<td>Route: Local and IM</td>
</tr>
<tr>
<td>Site: Infiltration around wound and Deltoid or anterolateral thigh</td>
</tr>
<tr>
<td>Duration: Within 7 days of 1st vaccine dose (D0)</td>
</tr>
<tr>
<td>Not to be used: After 7 days of 1st vaccine dose</td>
</tr>
<tr>
<td>Precaution: Skin test for ERIG</td>
</tr>
<tr>
<td>Danger: Anaphylaxis</td>
</tr>
<tr>
<td>Caution: At different site from that of vaccine</td>
</tr>
</tbody>
</table>
I. **Particulars of the patient:**

- **Name:**
- **Age (yr):**
- **Sex:** M/F
- **Address:** Village/area:
- **Upazilla:**
- **District:**
- **Occupation:** Dependent/ unemployed/ day labour/ official/ other
- **Socio-economic status:** Upper/ Middle/ Lower

II. **H/O Biting animal:**

- **Animal:** Dog/ Cat/ Monkey/ Mongoose/ Other, specify
- **Type of animal:** Pet/Stray/Wild
- **Vaccination status of animal:** Fully vaccinated/Partially vaccinated/ Unvaccinated/Not known
- **Classification of animal:** suspect rabid/healthy

III. **WOUND DESCRIPTION:**

- **Total No. of Wounds:**
- **Site of wound:** Head/Neck/Trunk/ Upperlimb/ Lower limb/ genitalia
- **Category of Exposure:** (WHO Classification): 1/II / III
- **Wound washed:** Water&Soap/only water/ Antiseptic/ other, specify

IV. **Vaccination status of the patient:**

- Fully vaccinated/partial vaccinated / unvaccinated / Not known

V. **Other personal data:**

- **History of taking immunosuppressant:** Yes/ No.

VI. **RIG Administration:**

- **Weight:** ..........kg;  **Type:** ...............
- **Dose required:** ..........IU
- **Test dose:** Yes/No;  **Reaction:** Yes/No;  **Full dose dilution:** Yes/No
- **If yes, amount of dilution........ml; Local infiltration: ...........ml and systemic;......ml.

### TCV Vaccination Card

<table>
<thead>
<tr>
<th>Day of vaccination</th>
<th>Route of administration</th>
<th>Due date of administration</th>
<th>Date of administration</th>
<th>Comment</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>IM</td>
<td>ID</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D0</td>
<td>২</td>
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<td>D3</td>
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<td>D7</td>
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<td>D14</td>
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<td>D21</td>
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<tr>
<td>D28</td>
<td>২</td>
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</tbody>
</table>

**Note:**