

Sue Crow, RN, MSN, Associate Editor of Infection Control, was asked to respond to Mr. Ferrara's comments.

Mr. Ferrara is correct. The proper wording for the homestudy course is "Principles of Epidemiology." It is not a homestudy course in hospital epidemiology. However, since there are no homestudy courses for Infection Control Nurses, I still recommend this course for nurses working in hospital epidemiology.

Sue Crow, RN, MSN
Associate Editor
Infection Control

EDITOR'S NOTE

The authors of "Infant Feeding Formula Contaminated by *Enterobacter Cloacae*" (*Infect Control* 1984; 5:115) wish to change the wording of recommendation #2 in the last paragraph of the letter. Recommendation #2 should read "bottles of feeding formula not be reused as microbial contamination can occur and may not be visibly evident."

We thank the authors for their clarification of this important point.

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DESCRIPTION: Rabies Immune Globulin (Human) IMOGAM® RABIES is a sterile solution of antirabies immunoglobulin (10-18% protein) for intramuscular administration. It is prepared by cold alcohol fractionation from pooled venous plasma of individuals immunized with Rabies Vaccine prepared from human diploid cells (HDCV). The product is stabilized with 0.3 M glycine and contains 1:10,000 sodium ethylmercurithiosalicylate (thimerosal) as a preservative. The globulin solution has a pH of 6.8 ± 0.4 adjusted with sodium hydroxide or hydrochloric acid. The product is standardized against the U.S. Standard Rabies Immune Globulin. The U.S. unit of potency is equivalent to the International Unit (I.U.) for rabies antibody. The product is prepared from units of human plasma that have been tested and found negative for hepatitis B surface antigen (HBsAg) by FDA-required tests.

CONTRAINDICATIONS: Rabies Immune Globulin (Human) should not be administered in repeated doses once vaccine treatment has been initiated. Repeating the dose may interfere with maximum active immunity expected from the vaccine.

WARNINGS: Rabies Immune Globulin (Human) should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immune globulin preparations or those individuals allergic to thimerosal.

Persons with specific IgA deficiency have increased potential for developing antibodies to

IgA and could have anaphylactic reactions to subsequent administration of blood products containing IgA.^{1,2}

PRECAUTIONS: *General*—Rabies Immune Globulin (Human) should not be administered intravenously because of the potential for serious reactions. Injection should be made intramuscularly and care should be taken to draw back on the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel. Although systemic reactions to immunoglobulin preparations are rare, epinephrine should be available for treatment of acute anaphylactoid systems. As with all preparations given intramuscularly, bleeding complications may be encountered in patients with bleeding disorders.

Drug Interactions—Live virus vaccines such as measles vaccines should not be given close to the time of Rabies Immune Globulin (Human) administration because antibodies in the globulin preparation may interfere with the immune response to the vaccination. Immunization with live vaccines should not be given within three months after Rabies Immune Globulin (Human) administration.

Pregnancy Category C—Animal reproduction studies have not been conducted with Rabies Immune Globulin (Human). It is also not known whether RIG(H) can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. RIG(H) should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS: Local or mild systemic adverse reactions to the globulin after intramuscular injections are uncommon^{3,4} and may be treated symptomatically. Local tenderness, soreness or stiffness of the muscles may occur at the injection site and may persist for several hours after injection. Urticaria and angioedema may occur. Anaphylactic reactions, although rare, have been reported following injection of human immune globulin preparations.

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4. Kjellman H. Adverse reactions to human immune serum globulin in Sweden (1969-1978) pp 143-150. Immunoglobulins: Characteristics and uses of intravenous preparations. Alving B.M. and Finlayson J.S., Editors. U.S. Dept. Health & Human Services, DHHS Publ. No. (FDA) 80-9005, Wash., D.C., 1980.

Issued January, 1984

RABIES VACCINE (HUMAN DIPLOID CELL) **IMOVAX® RABIES**

Wistar Rabies Virus Strain PM-1503-3M Grown in Human Diploid Cell Cultures

DESCRIPTION: The IMOVAX® RABIES Vaccine produced by Institut Merieux is a sterile, stable freeze-dried suspension of rabies virus prepared from strain PM-1503-3M obtained from the Wistar Institute, Philadelphia, Pennsylvania. The virus is harvested from infected human diploid cells, MRC-5 strain, concentrated by ultrafiltration and is inactivated by beta propiolactone. One dose of reconstituted vaccine contains less than 100 mg human albumin, less than 150 µg neomycin sulfate and 20 µg of phenol red indicator.

The vaccine contains no preservative or stabilizer. It should be used immediately after reconstitution.

The potency of Merieux IMOVAX® RABIES Vaccine is equal to or greater than 2.5 International Units of rabies antigen.

CONTRAINDICATIONS: For post-exposure treatment, there are no known specific contraindications to the use of Merieux IMOVAX® RABIES Vaccine. In cases of pre-exposure immunization, there are no known specific contraindications other than situations such as developing febrile illness, etc.

WARNINGS: Local or mild systemic adverse reactions to the vaccine are infrequent; they do not contraindicate continuing immunization and may be treated symptomatically. Neuroparalytic reactions such as encephalomyelitis, transverse myelitis and other central neuropathies have not been reported in recipients of vaccine produced in human diploid cell cultures. One case of Guillain-Barré syndrome temporally associated with rabies immunization has been reported.¹ It was followed by complete recovery. No cause-effect relationship was established. Should a neurological complication develop, vaccine treatment should be discontinued. Any serious reactions should

be immediately reported to the State Health Department or the Viral Disease Division, Bureau of Epidemiology, Centers for Disease Control, Atlanta, Georgia (telephone (404) 329-3696).

PRECAUTIONS: Epinephrine should be available for immediate use should an anaphylactoid reaction occur.

Drug Interactions—Corticosteroids and immunosuppressive agents may interfere with the development of active immunity and predispose the patient to developing rabies. They should not be administered during post-exposure therapy unless essential for the treatment of other serious conditions. If rabies post-exposure therapy is administered to persons receiving steroids or immunosuppressive therapy, it is especially important that serum be tested for rabies antibody to ensure that an adequate response has developed.

Usage in Pregnancy—Pregnancy is not a contraindication to rabies post-exposure therapy. Based on limited data, there have been no fetal abnormalities associated with rabies vaccination. If there is substantial risk of rabies exposure, pre-exposure treatment may also be indicated during pregnancy.

ADVERSE REACTIONS: Clinical experience with Merieux IMOVAX® RABIES Vaccine has resulted in a low incidence of adverse reactions when administered by the recommended route of injection. Local reactions consist of swelling, erythema, induration and slight ache. Their incidence has ranged from approximately 3% to 15%.^{2,3,4,5} Allergic reactions to Merieux rabies diploid cell vaccine are rare. In the few cases reported,¹ which ranged in severity from hives to anaphylactic shock, it was not necessary to discontinue the post-exposure prophylaxis regimen. Mild local or systemic reactions can be treated with anti-inflammatory, antipyretic agents, e.g., aspirin

and antihistamines. If an anaphylactic reaction should occur, epinephrine is indicated.

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Revised November, 1981

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