JULY 1985 VOLUME 6/NUMBER 7

INFECTION CONTROL

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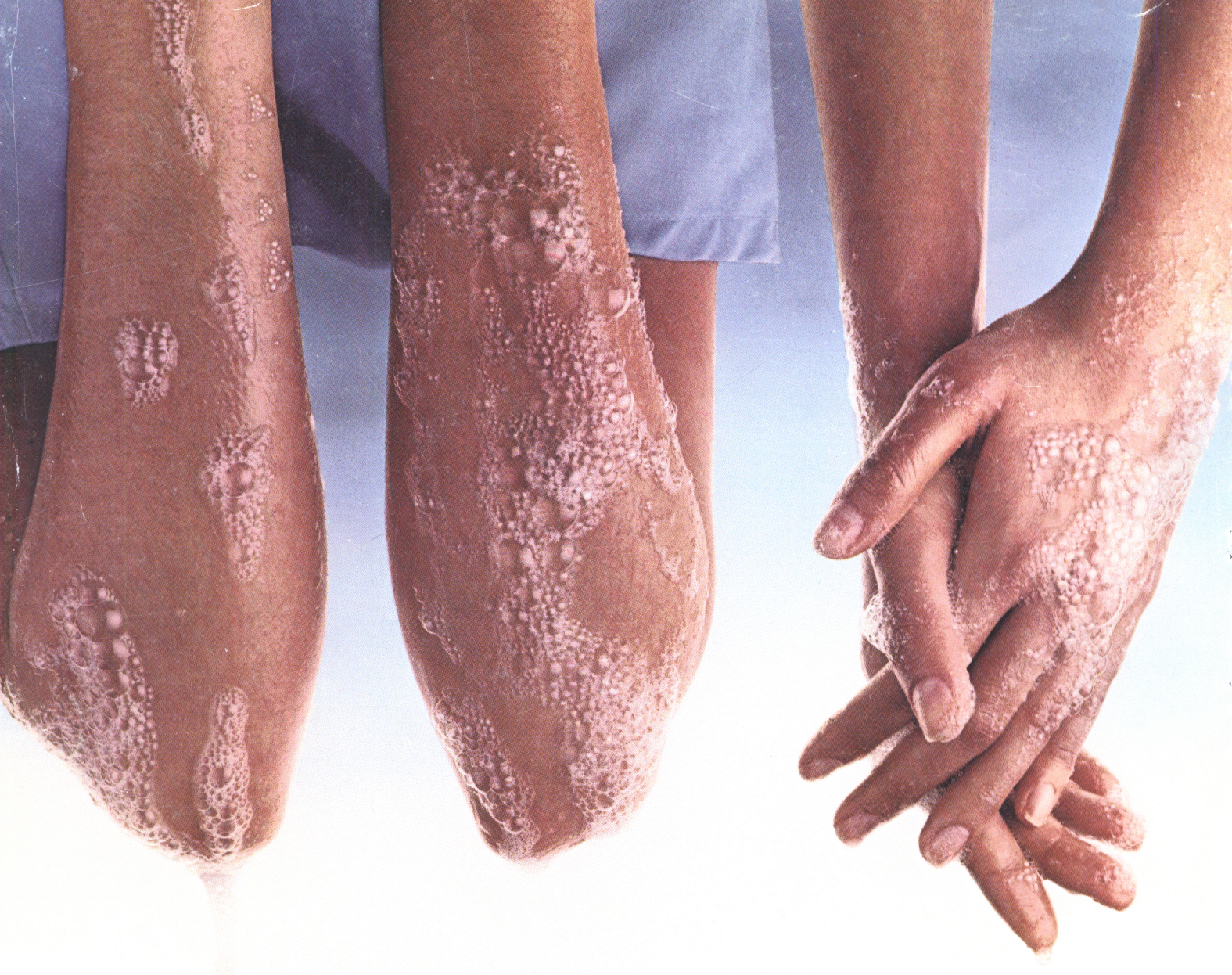
EDITORIAL

ORIGINAL ARTICLES



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INFECTION CONTROL®

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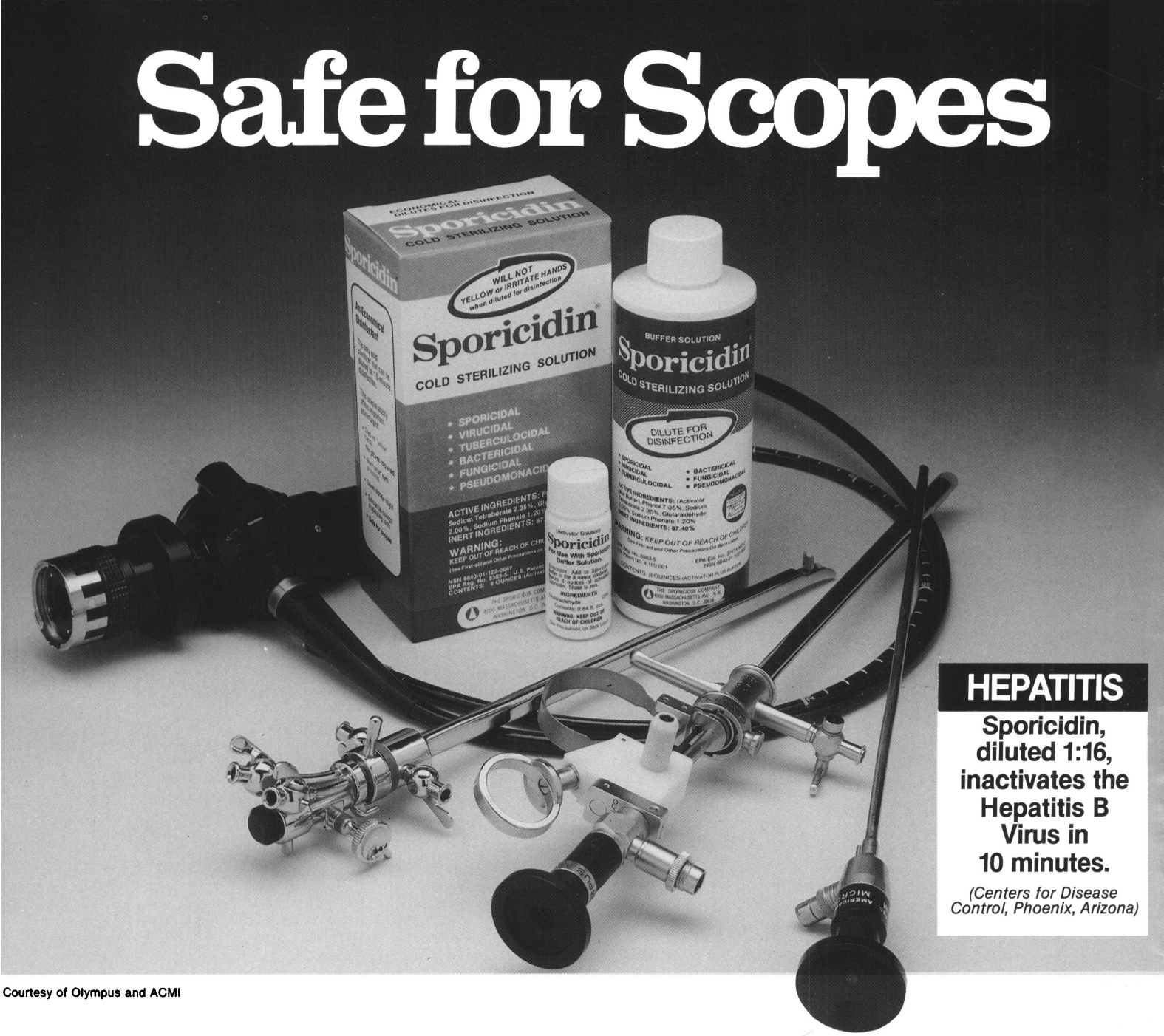

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Centers for Disease Control, Atlanta, GA (Guidelines. . . revised August 1982)

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Journal of Dental Research, Vol. 60, March 1981 (U.S. Army Institute of Dental Research, Wash., DC)

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Infection Control, 1(2): 90-93, 1980

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RABIES VACCINE (HUMAN DIPLOID CELL) U.S.P. IMOVAX® RABIES

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, PA.

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 albumin, less than 150 μg neomycin sulfate and 20 μg of phenol red indicator. The vaccine is for intramuscular use.

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: In both pre-exposure and post-exposure immunization, the full 1.0 ml dose should be given intramuscularly.

In the case of pre-exposure immunization, recently a significant increase has been noted in "immune complex-like" reactions in persons receiving booster doses of HDCV.[1] The illness characterized by onset 2-21 days post-booster, presents with a generalized urticaria and may also include arthralgia, arthritis, angioedema, nausea, vomiting, fever, and malaise. In no cases were the illnesses life-threatening. Preliminary data suggest this "immune complex-like" illness may occur in up to 6% of persons receiving booster doses and much less frequently in persons receiving primary immunization. Additional experience with this vaccine is needed to define more clearly the risk of these adverse reactions.[2,3]

Two cases of neurologic illness resembling Guillain-Barré syndrome[4,5] a transient neuroparalytic illness, that resolved without sequelae in 12 weeks and a focal subacute central nervous system disorder temporally associated with HDCV, have been reported.[6]

All serious systemic neuroparalytic or anaphylactic reactions to a rabies vaccine should be immediately reported to the state health department or the Division of Viral Diseases, Center for Infectious Diseases, CDC, 404-329-3095 during working hours, or 404-329-2888 at other times.[2]

PRECAUTIONS: *General*—When a person with a history of hypersensitivity must be given rabies vaccine, antihistamines may be given; epinephrine (1:1000) should be readily available to counteract anaphylactic reactions, and the person should be carefully observed after immunization.

While the concentration of antibiotics in each dose of vaccine is extremely small, persons with known hypersensitivity to any of these agents could manifest an allergic reaction. While the risk is small, it should be weighed in light of the potential risk of contracting rabies.

Drug Interactions—Corticosteroids, other immunosuppressive agents, and immunosuppressive illnesses can interfere with the development of active immunity and predispose the patient to developing rabies. Immunosuppressive agents should not be administered during post-exposure therapy, unless essential for the treatment of other conditions. When rabies post-exposure prophylaxis is administered to persons receiving steroids or other immunosuppressive therapy, it is especially important that serum be tested for rabies antibody to ensure that an adequate response has developed.[2]

Usage in Pregnancy—Pregnancy Category C. Animal reproduction studies have not been conducted with IMOVAX RABIES Vaccine. It is also not known whether the product can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Rabies vaccine should be given to a pregnant woman only if clearly needed.

Because of the potential consequences of inadequately treated rabies exposure and limited data that indicate that fetal abnormalities have not been associated with rabies vaccination, pregnancy is not considered a contraindication to post-exposure prophylaxis.[2,7] If there is substantial risk of exposure to rabies, pre-exposure prophylaxis may also be indicated during pregnancy.[2]

Pediatric Use—Both safety and efficacy in children have been established.

ADVERSE REACTIONS: Once initiated, rabies prophylaxis should not be interrupted or discontinued because of local or mild systemic adverse reactions to rabies vaccine. Usually such reactions can be successfully managed with anti-inflammatory and antipyretic agents (e.g. aspirin).

Reactions after vaccination with HDCV are less common than with previously available vaccines.[1,3,8] In a study using five doses of HDCV, local reactions, such as pain, erythema, and swelling or itching at the injection site were reported in about 25% of recipients of HDCV, and mild systemic reactions such as headache, nausea, abdominal pain, muscle aches and dizziness were reported in about 20% of recipients.[2]

Serious systemic anaphylactic or neuroparalytic reactions occurring during the administration of rabies vaccines pose a dilemma for the attending physician. A patient's risk of developing rabies must be carefully considered before deciding to discontinue vaccination. Moreover, the use of corticosteroids to treat life-threatening neuroparalytic reactions carries the risk of inhibiting the development of active immunity to rabies. It is especially important in these cases that the serum of the patient be tested for rabies antibodies. Advice and assistance on the management of serious adverse reactions in persons receiving rabies vaccines may be sought from the state health department or CDC.[2]

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RABIES IMMUNE GLOBULIN (HUMAN) U.S.P. IMOGAM® RABIES

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 symptoms. 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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