

To the Editor:

I am writing in reference to the article "Guideline for Prevention of Catheter-Associated Urinary Tract Infections" [Infect Control 1981; 2(2):125-130.]

According to the article, it is recommended to refrain from daily meatal care with povidone-iodine solution and daily cleansing with soap and water. However, no substitution for catheter care was made. Could you please elaborate on this, since it sounds rather risky to just drop the above procedure for meatal care?

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*This letter was referred to Drs. Wong and Hooton, who wrote the following reply:*

Meatal care has been advocated for years as one measure to reduce the risk of urinary tract infection in catheterized patients. Studies have demonstrated that patients who are colonized at the meatal-catheter junction with certain microorganisms such as gram-negative bacteria and enterococci are more likely to develop bacteriuria than are patients who are not so colonized.<sup>1,2</sup>

It is believed that microorganisms migrate retrograde from the meatus along the periurethral mucous sheath into the bladder where they cause infection. Therefore, it has been theorized that removal of these microorganisms through meatal care would reduce the risk of infection. Early studies, in fact, did show some beneficial effects of

meatal care,<sup>3,4</sup> but these studies were conducted with patients who were maintained on an open drainage system or who were subjected to other kinds of interventions, such as antibiotic irrigation, which confounded the results.

In the only controlled prospective study of the efficacy of meatal care to date done with patients on closed drainage systems, Burke and his associates found that patients subjected to the two most commonly used regimens of meatal care (twice daily cleansing with povidone-iodine solution followed by application of povidone-iodine ointment, and daily cleansing with soap and water) had no lower incidence of catheter-associated bacteriuria than patients who received no special meatal care.<sup>5</sup> In a subgroup of female patients at high risk of infection, special meatal care regimens resulted in significantly higher rates of bacteriuria, suggesting that there may be some hazard associated with these regimens.

Given the statistical association between meatal colonization and bacteriuria,<sup>2</sup> the rationale for including meatal care procedures in the care of patients with indwelling urinary catheters is strong. The careful study by Burke and his associates, however, suggests that the two commonly practiced meatal care regimens are not effective and may even be harmful. Thus, we are faced with a dilemma when trying to make specific recommendations to hospitals regarding meatal care. Clearly, Burke's results

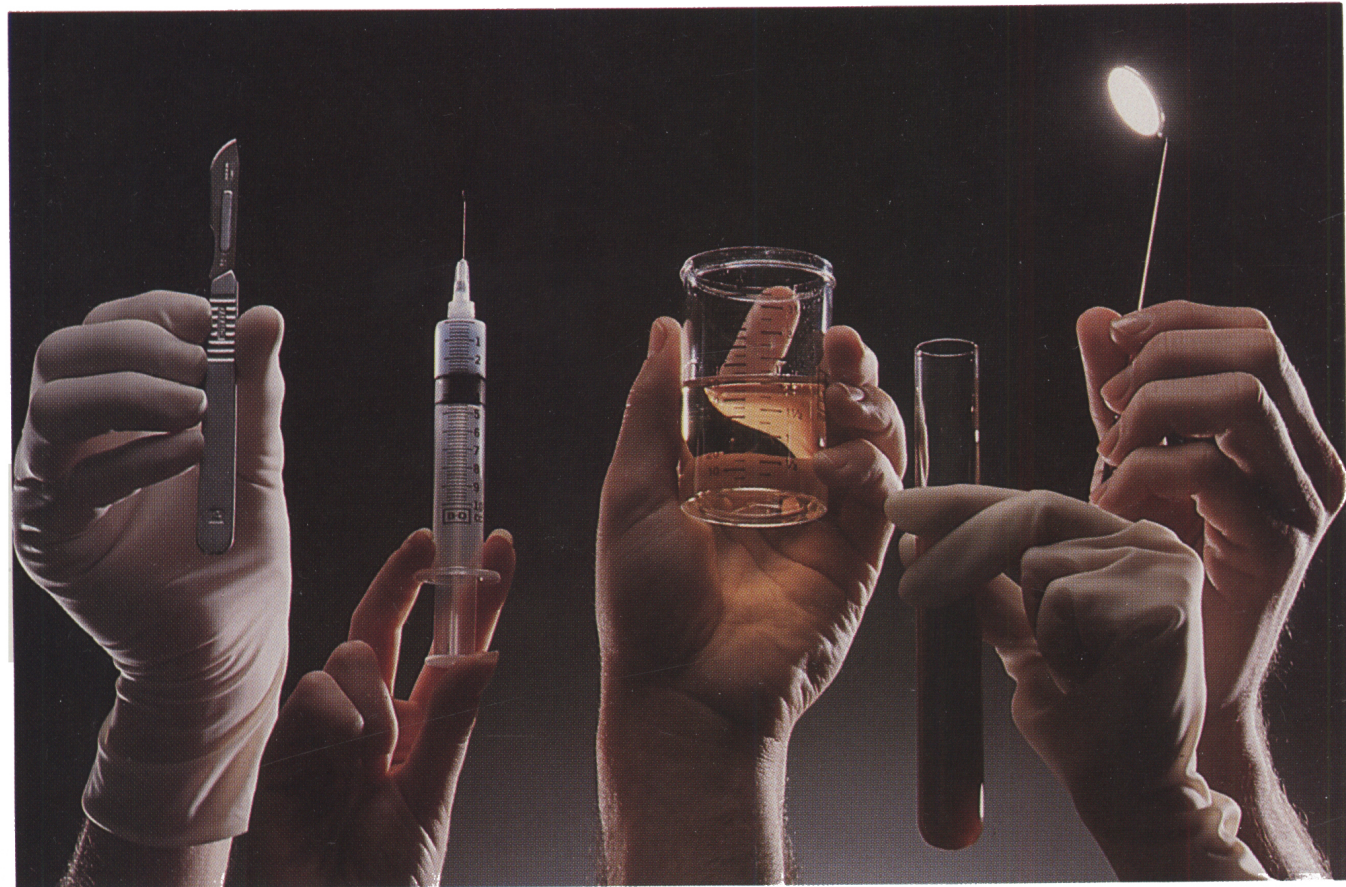
should be confirmed by other investigators, and further studies should be conducted to evaluate the value of alternative regimens of meatal care, such as more frequent application of povidone-iodine solution or ointment and the use of other antimicrobial formulations that have a more sustained antibacterial action. Until definitive data are available, hospitals may elect to continue regular meatal care, following regimens that have not specifically been shown to be ineffective in reducing the risk of infection, or to provide only the perineal cleansing that patients generally receive with the daily bath.

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1. Brehman B, Madsen PO. Route and prophylaxis of ascending bladder infection in male patients with indwelling catheters. *J Urol* 1972; 108:719-21.
2. Garibaldi RA, Burke JP, Britt MR, Miller WA, Smith CB. Meatal colonization and catheter-associated bacteriuria. *N Engl J Med* 1980; 303:316-8.
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4. Desautels RE, Linton KB, Miller H et al. Technical advances in the prevention of urinary tract infection. *J Urol* 1962; 87: 487-90.
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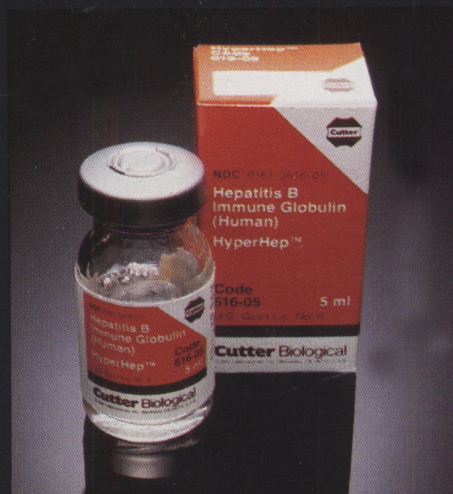
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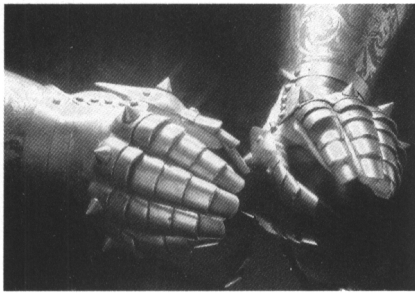
See following page for summary of prescribing information.



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# HYPERHEP™

## Hepatitis B Immune Globulin (Human)

### Summary of Prescribing Information

**DESCRIPTION** Hepatitis B Immune Globulin (Human)—HyperHep™—is a sterile solution of immunoglobulin (15–18% protein) which is prepared by cold alcohol fractionation from pooled venous plasma of individuals with high titers of antibody to the hepatitis B surface antigen (anti-HBs). The product is stabilized with 0.3 M glycine and contains 1:10,000 Thimerosal (a mercury derivative) as a preservative. The solution has a pH of 6.8 ± 0.4 adjusted with sodium carbonate. Each vial contains anti-HBs antibody equivalent to or exceeding the potency of anti-HBs in a U.S. reference hepatitis B immune globulin (Bureau of Biologics, FDA). The product is prepared from units of human plasma that have been tested and found non-reactive for hepatitis B surface antigen.

**INDICATIONS** Hepatitis B Immune Globulin (Human)—HyperHep™—is indicated for post-exposure prophylaxis following either parenteral exposure, e.g., by accidental "needle-stick," or direct mucous membrane contact (accidental splash), or oral ingestion (pipetting accident) involving HBsAg positive materials such as blood, plasma or serum. Use of hepatitis B immune globulin in other situations has been and continues to be evaluated, but there are not sufficient data at present on effectiveness, dosage and schedule for any other uses to be included as definite indications. There is currently some controversy over whether immune globulin containing a low or high anti-HBs titer is preferable in these other situations.

**CONTRAINDICATIONS** There are no specific contraindications for hepatitis B immune globulin. No adverse reactions have been seen in individuals with pre-existing hepatitis B surface antigen although data regarding this occurrence are limited.

**WARNING** Hepatitis B Immune Globulin (Human)—HyperHep™—should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immune globulin preparations.

**PRECAUTIONS GENERAL** Hepatitis B Immune Globulin (Human) should *not* be administered intravenously because of the potential for serious reactions. Injections 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.

**SPECIAL INSTRUCTIONS** Although systemic reactions to immune globulin preparations are rare, epinephrine should be available.

**CLINICALLY SIGNIFICANT PRODUCT INTERACTIONS** Live virus vaccines such as measles vaccine should not be given close to the time of hepatitis B immune globulin administration because antibodies in the globulin preparation may interfere with the immune response to the vaccination. No interactions with other products are known.

**PREGNANCY** No studies have been conducted in pregnant patients. Clinical experience with other immunoglobulin preparations administered during pregnancy suggests that there are no known adverse effects on the fetus from immune globulins per se, but there are no reported studies indicating whether or not such adverse effects occur.

**ADVERSE REACTIONS** Local pain and tenderness at the injection site, and urticaria and angioedema may occur; anaphylactic reactions, although rare, have been reported following the injection of human immune globulin preparations.

**OVERDOSE** Although no data are available, clinical experience with other immunoglobulin preparations suggests that the only manifestations would be pain and tenderness at the injection site.

**DOSE AND ADMINISTRATIONS** The recommended dose is 0.06 ml per kilogram of body weight; the usual adult dose is 3 to 5 ml. The appropriate dose should be administered as soon after exposure as possible (preferably within 7 days) and repeated 28–30 days after exposure. Hepatitis B Immune Globulin (Human) is administered intramuscularly, preferably in the gluteal or deltoid region.

**CAUTION** Federal (U.S.A.) law prohibits dispensing without prescription.

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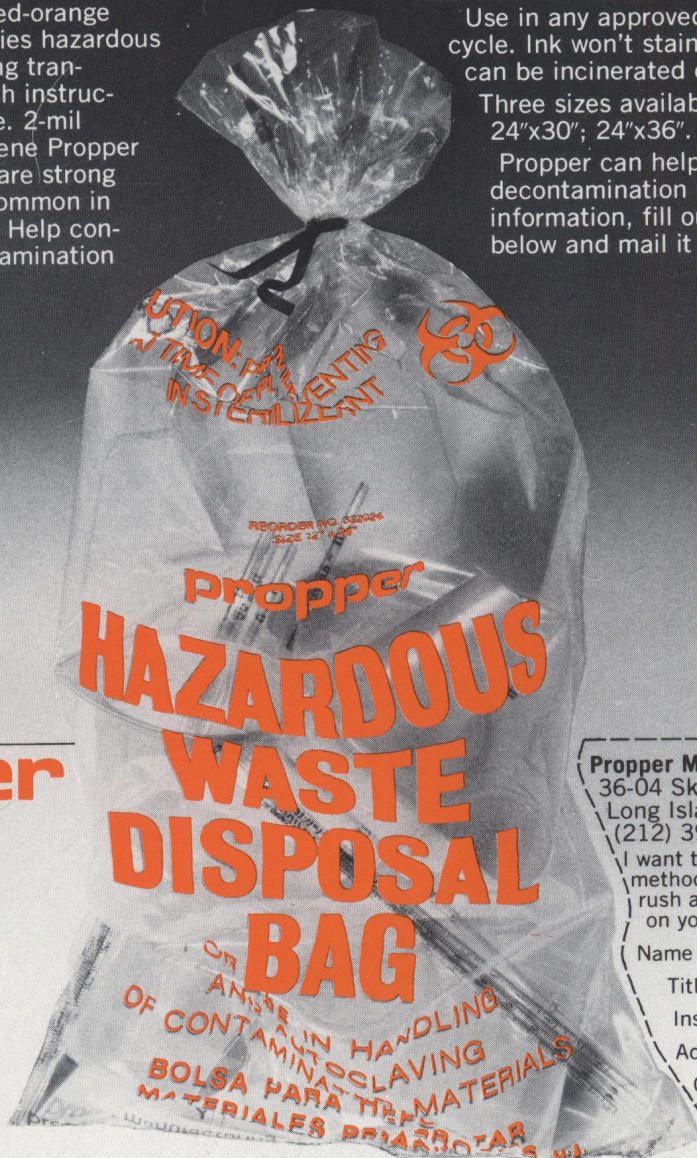
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