

INFECTION CONTROL^{AND}

HOSPITAL EPIDEMIOLOGY

Volume 11, Number 5 • May 1990

EDITORIAL

- Antimicrobial Prophylaxis of Cesarean Section** 233
Ronald N. Jones, MD

ORIGINAL ARTICLES

- Interaction of Granulocytopenia and Construction Activity as Risk Factors for Nosocomial Invasive Filamentous Fungal Disease in Patients With Hematologic Disorders** 235
Stephen F. Weber, MD; James E. Peacock, Jr., MD; Kim-Anh Do, MS; Julia M. Cruz, MD; Bayard L. Powell, MD; Robert L. Capizzi, MD

- The Cumulative Probability of Occupationally-Acquired HIV Infection: The Risks of Repeated Exposures During A Surgical Career** 243
W. Paul McKinney, MD; Mark J. Young, MD

- Physicians' Perceptions About Increased Glove-Wearing in Response to Risk of HIV infection** 248
Lawrence S. Linn, PhD; Katherine L. Kahn, MD; Barbara Leake, PhD

- Brief Report: A Scheme to Review Infection Control Guidelines for the Purpose of Implementation in the Hospital** 255
W H. Seto, MD; T.Y. Ching, RN; Y.B. Chu, BSc; S.G. Ong, MD

DECISION ANALYSIS

- Using Decision Analysis to Assess the Quality of Quality Assurance** 260
Mary D. Nettleman, MD

SPECIAL COMMENTARY

- Criticism: A By-Product of Controlling Infection** 263
Ruth Davidhizar, RN, DNS, CS;
Connie Boonstra, RN, ADN

LETTERS TO THE EDITOR

- JCAHO Inspections for Tertiary Care Facilities** 226
Beth Raucher, MD; Franklin W. McKinley; David Crimmins; Barbara Dillon; Susan Marchione

- Prophylaxis of Cesarean Sections** 228
Elliot Frank, MD, FACP
(Reply) Steve H. Dougherty, MD; Vickie S. Williams, DO

- SHEA NEWSLETTER** 267

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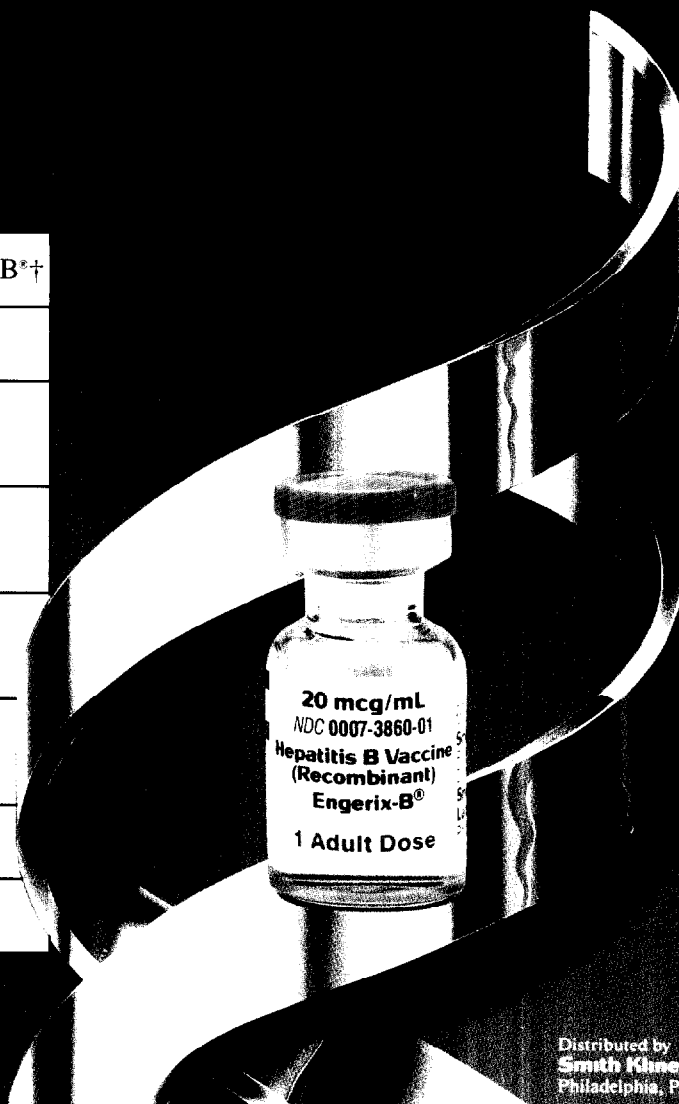
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PRECAUTIONS: General: As with any percutaneous vaccine, keep epinephrine available for use in case of anaphylaxis or anaphylactoid reaction.

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Nursing Mothers: It is not known whether Engerix B® is excreted in human milk. Because many drugs are excreted in human milk, use caution when giving Engerix B® to a nursing woman.

Pediatric Use: Engerix B® has been shown to be well tolerated and highly immunogenic in infants and children of all ages. Newborns also respond well, maternally transferred antibodies do not interfere with the active immune response to the vaccine.

ADVERSE REACTIONS: Engerix B® is generally well tolerated. During clinical studies involving over 10,000 individuals distributed over all age groups, no serious adverse reactions attributable to vaccine administration were reported. As with any vaccine, however, it is possible that expanded commercial use of the vaccine could reveal rare adverse reactions not observed in clinical studies.

Ten double-blind studies involving 2,252 subjects showed no significant difference in the frequency or severity of adverse experiences between Engerix B® and plasma-dewaxed vaccines. In 36 clinical studies, a total of 13,495 doses of Engerix B® were administered to 5,071 healthy adults and children who were initially seronegative for hepatitis B markers, and healthy neonates. All subjects were monitored for 4 days post administration. Frequency of adverse experiences tended to decrease with successive doses of Engerix B®. Using a symptom checklist,* the most frequently reported adverse reactions were injection site soreness (22%), and fatigue* (14%). Other reactions are listed below.

Incidence 1% to 10% of Injections: Induration; erythema; swelling; fever (>37.5°C); headache; dizziness.*

*Parent or guardian completed forms for children and neonates. Neonatal checklist did not include headache, fatigue or dizziness.

Incidence < 1% of Injections: Pain; pruritus; ecchymosis; sweating; malaise; chills; weakness; flushing; tingling; hypotension; influenza-like symptoms; upper respiratory tract illnesses; nausea; anorexia; abdominal pain; cramps; vomiting; constipation; diarrhea; lymphadenopathy; pain/stiffness in arm, shoulder or neck; arthralgia; myalgia; back pain; rash; urticaria; petechiae; erythema; somnolence; insomnia; irritability; agitation.

Additional adverse experiences have been reported with the commercial use of Engerix B® outside the United States. Those listed below are to serve as alerting information to physicians. Anaphylaxis; erythema multiforme; including Stevens-Johnson syndrome; angioedema; arthritis; tachycardia/palpitations; bronchospasm including asthma-like symptoms; abnormal liver function tests; migraine; syncope; paresis; neuropathy including hypoesthesia; paresthesia; Guillain-Barre syndrome and Bell's palsy; transverse myelitis; thrombocytopenia; eczema; purpura; herpes zoster; vertigo; conjunctivitis; keratitis; visual disturbances.

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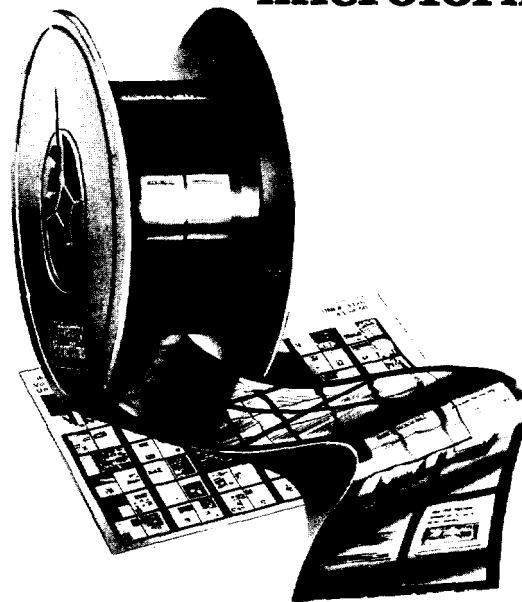
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1. Poovorawan Y, Sanpavat S, Pongpunlert W, et al: Protective efficacy of a recombinant DNA hepatitis B vaccine in neonates of HBe antigen-positive mothers. *JAMA* 1989; 261(22):3278-3281.
2. Based on Medi-Span® Hospital Formulary Pricing Guide, December 1989.
3. Data on file, SK&F.
4. Bush L, Moonsammv G, Boscia J: Evaluation of initiating a hepatitis B vaccination schedule with one vaccine and completing it with another. *Hepatology* 1989; 10:689.

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	The Cumulative Probability of Occupationally-Acquired HIV Infection: The Risks of Repeated Exposures During a Surgical Career W. Paul McKinney, MD; Mark J. Young, MD	243
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	Special Commentary Criticism: A By-Product of Controlling Infection Ruth Davidhizar, RN, DNS, CS; Connie Boonstra, RN, ADN	263
DEPARTMENTS	Information for Authors 222	Calendar of Events 266
	Letters to the Editor 226	SHEA Newsletter 267

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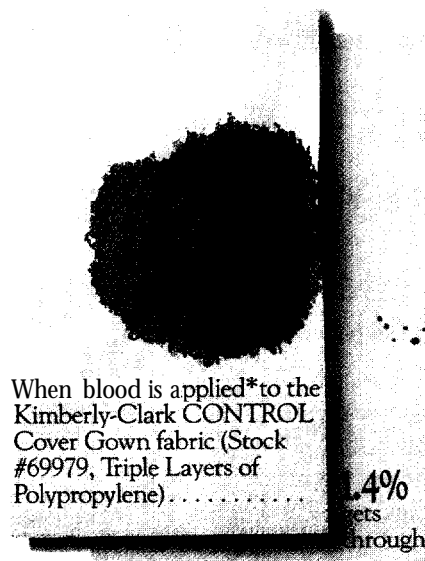
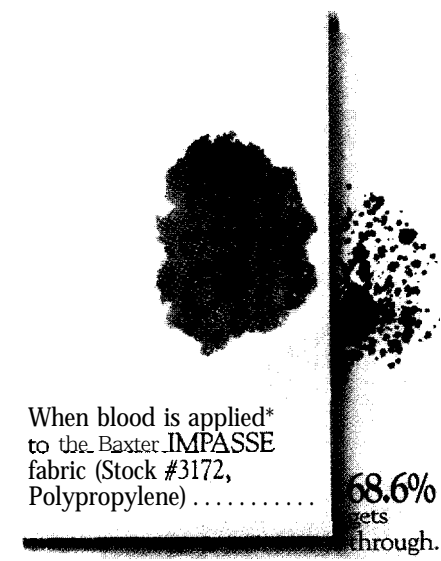
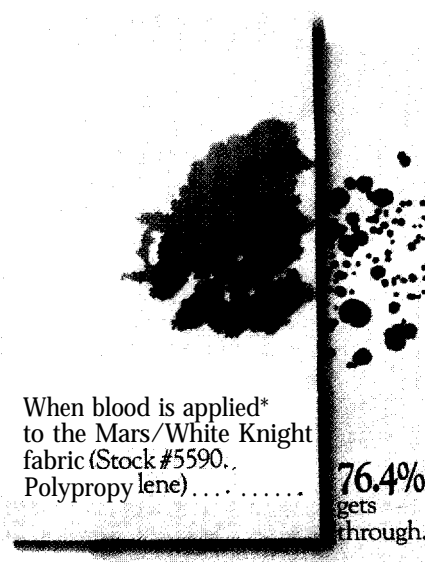
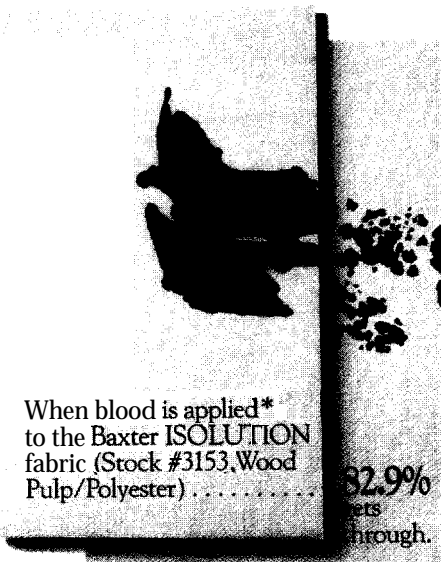
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1 Eisenach, K., T. Yamauchi, B. Johnson, and R. Clarke. 1989. Resistance of cover gowns to microbially contaminated human body fluids. Abstr. Annu. Meet. of Interscience Conf. on Antimicrob. Agents and Chemother., 604, p.202.

2 Klein, B.S., W.H. Perloff, and D.G. Maki. 1989. Reduction of nosocomial infection during pediatric intensive care by protective isolation. N. Engl. J. Med. 320: 1714-1721.

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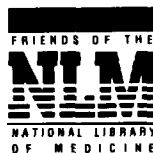
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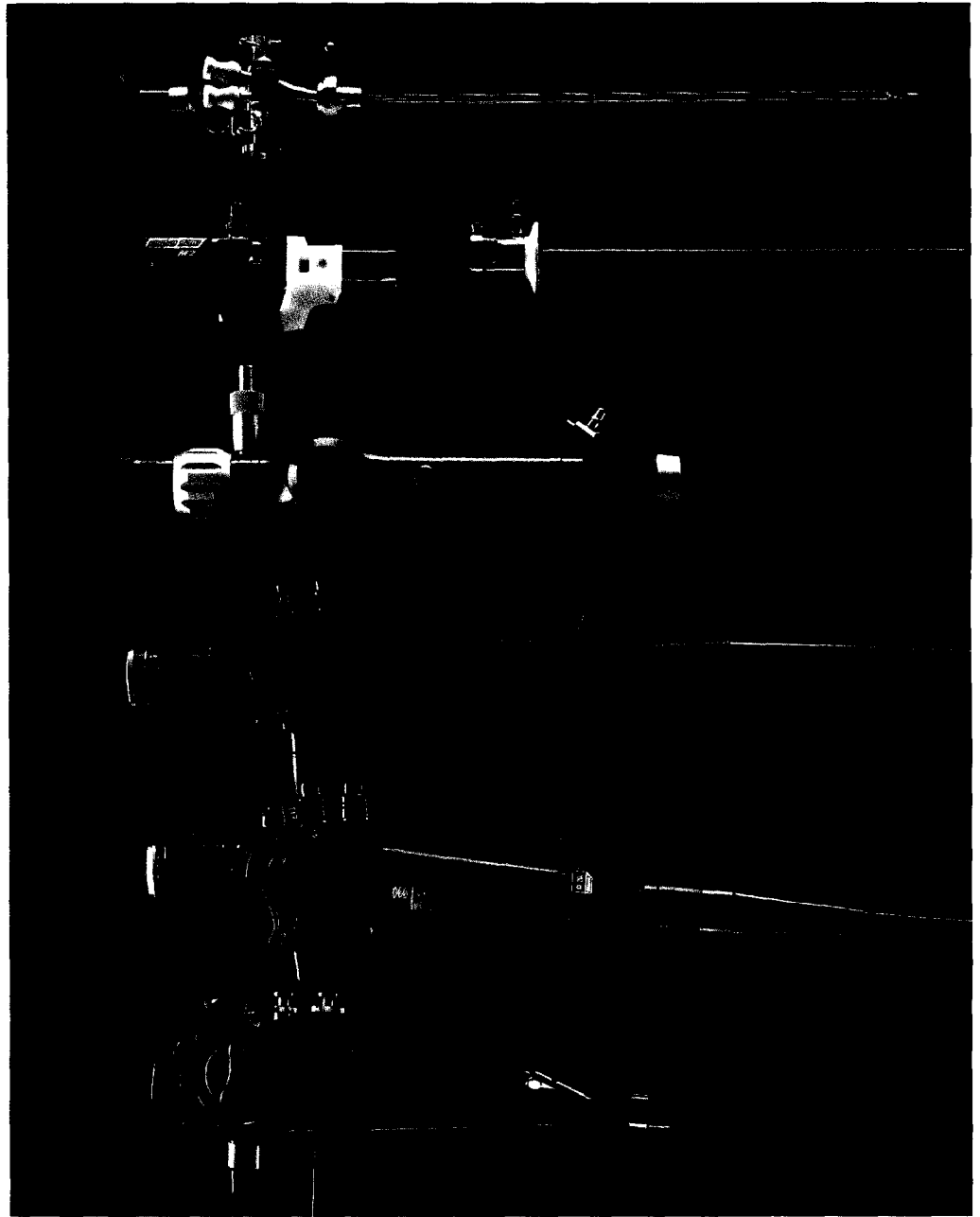
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