

INFECTION CONTROL^{AND}

HOSPITAL EPIDEMIOLOGY

Volume 11, Number 4 • April 1990

EDITORIALS

- Zeroing in on the Appropriate Management of Occupational Exposures to HIV-1** 175

David K. Henderson, MD

- The Choice of Microcomputer Software for Infection Control** 178

David R. Reagan, MD, PhD

ORIGINAL ARTICLES

- Detection of HIV Antibody and Antigen (p24) in Residual Blood on Needles and Glass** 180

Djamshid Shirazian, PhD;
Barry C. Herzlich, MD;
Foroozan Mokhtarian, PhD;
David Grob, MD

- A Comparison of Infection Control Software for Use by Hospital Epidemiologists in Meeting the New JCAHO Standards** 185

Sharon LaHaise, RN, PhD

- Increasing ICU Staff Handwashing: Effects of Education and Group Feedback** 191

Patricia M. Dubbert, PhD;
Jeffrey Dolce, PhD;
William Richter, MS; Mary Miller, MS;
Stanley W. Chapman, MD

- Brief Report: Reduction in the Frequency of Needle Recapping by Effective Education: A Need for Conceptual Alteration** 194

W.H. Seto, MD; T.Y. Ching, RN;
Y.B. Chu, BSc; F. Fielding, PhD

TOPICS IN CLINICAL EPIDEMIOLOGY

- Surveillance for Quality Assessment: III. The Critical Assessment of Quality Indicators** 197

William B. Crede, MD;
Walter J. Hierholzer, Jr., MD

TOPICS IN LONG-TERM CARE

- AIDS and Long-Term Care Facilities** 202

David W. Bentley, MD;
Lois Cheney, RN, MS, CIC

TOPICS IN CLINICAL MICROBIOLOGY

- Toxoplasma gondii** 207

Deborah J. Zygmunt, MD

- SHEA NEWSLETTER** 215

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‡Please see brief summary of prescribing information on adjacent page for a complete listing of adverse reactions, contraindications, warnings and precautions.

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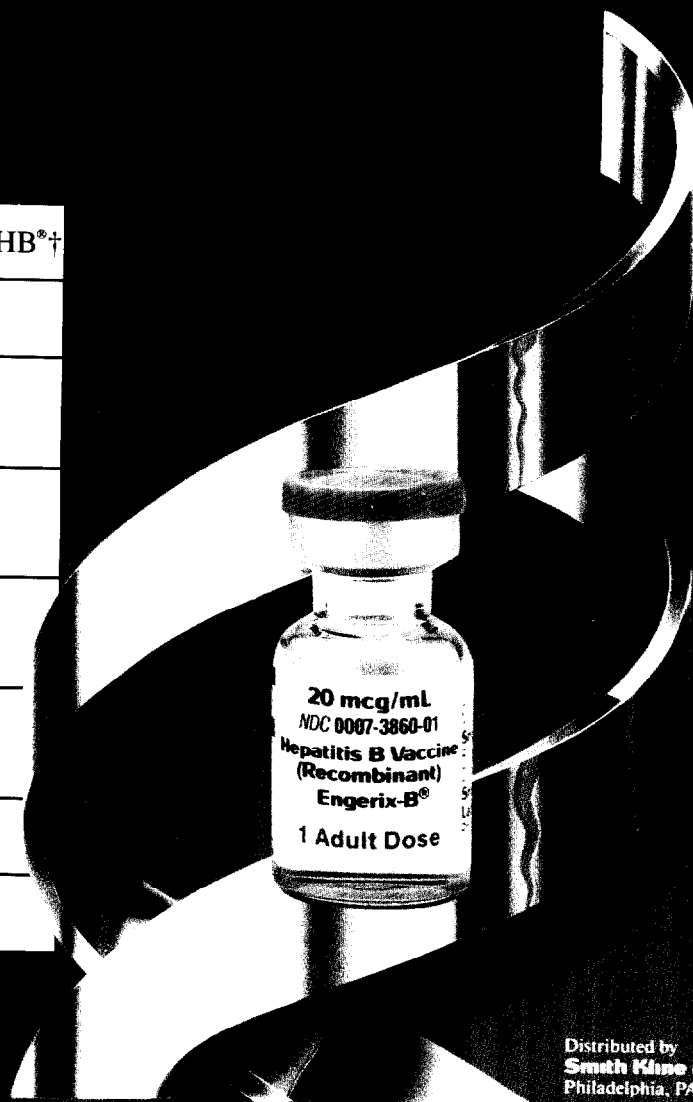
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	Yes	Yes
	Yes	No
	Yes	No
	Yes	No



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CONTRAINDICATIONS: Hypersensitivity to yeast or any other component of the vaccine is a contraindication for use of the vaccine.

WARNINGS: Do not give intradural injections to patients experiencing hypersensitivity after an Engerix-B injection (See CONTRAINDICATIONS).

Hepatitis B has a long incubation period. Hepatitis B vaccination may not prevent hepatitis B infection in individuals who had an unrecognized hepatitis B infection at the time of vaccine administration. Additionally, it may not prevent infection in individuals who do not achieve protective antibody titers.

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

As with any vaccine, delay administration, if possible, in persons with any febrile illness or active infection.

Pregnancy: Pregnancy Category C: Animal reproduction studies have not been conducted with Engerix-B®. It is also not known whether Engerix-B® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Give Engerix-B® to a pregnant woman only if clearly needed.

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-derived vaccines. In 36 clinical studies, a total of 13,488 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 ($>37.5^{\circ}\text{C}$); 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-Barré syndrome and Bell's palsy; transverse myelitis; thrombocytopenia; eczema; purpura; herpes zoster; vertigo; conjunctivitis; keratitis; visual disturbances.

Potential Adverse Experiences: In addition, certain other adverse experiences not observed with Engerix-B® have been reported with Hepavax-B®† and/or Recombivax HB®‡. Those listed below are to serve as alerting information to physicians: Optic neuritis.

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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, Moonsammy 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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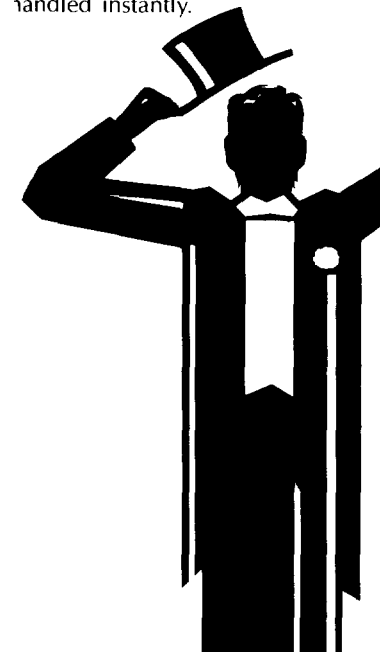
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EDITORIALS	Zeroing in on the Appropriate Management of Occupational Exposures to HIV-1	175
	David K. Henderson, MD	
ORIGINAL ARTICLES	The Choice of Microcomputer Software for Infection Control	178
	David R. Reagan, MD, PhD	
	Detection of HIV Antibody and Antigen (p24) in Residual Blood on Needles and Glass	180
	Djamshid Shirazian, PhD; Barry C. Herzlich, MD; Foroozan Mokhtarian, PhD; David Grob, MD	
	A Comparison of Infection Control Software for Use by Hospital Epidemiologists in Meeting the New JCAHO Standards	185
	Sharon LaHaise, RN, PhD	
SPECIAL SECTIONS	Increasing ICU Staff Handwashing: Effects of Education and Group Feedback	191
	Patricia M. Dubbert, PhD; Jeffrey Dolce, PhD; William Richter, MS; Mary Miller, MS; Stanley W. Chapman, MD	
	Brief Report: Reduction in the Frequency of Needle Recapping by Effective Education: A Need for Conceptual Alteration	194
	W.H. Seto, MD; T.Y. Ching, RN; Y.B. Chu, BSc; F. Fielding, PhD	
	Topics in Clinical Epidemiology Surveillance for Quality Assessment: III. The Critical Assessment of Quality Indicators	197
	William B. Crede, MD; Walter J. Hierholzer, Jr., MD	
DEPARTMENTS	Topics in Long-Term Care AIDS and Long-Term Care Facilities	202
	David W. Bentley, MD; Lois Cheney, RN, MS, CIC	
	Topics in Clinical Microbiology Toxoplasma gondii	207
	Deborah J. Zygmunt, MD	
	Calendar of Events	214
	SHEA Newsletter	215

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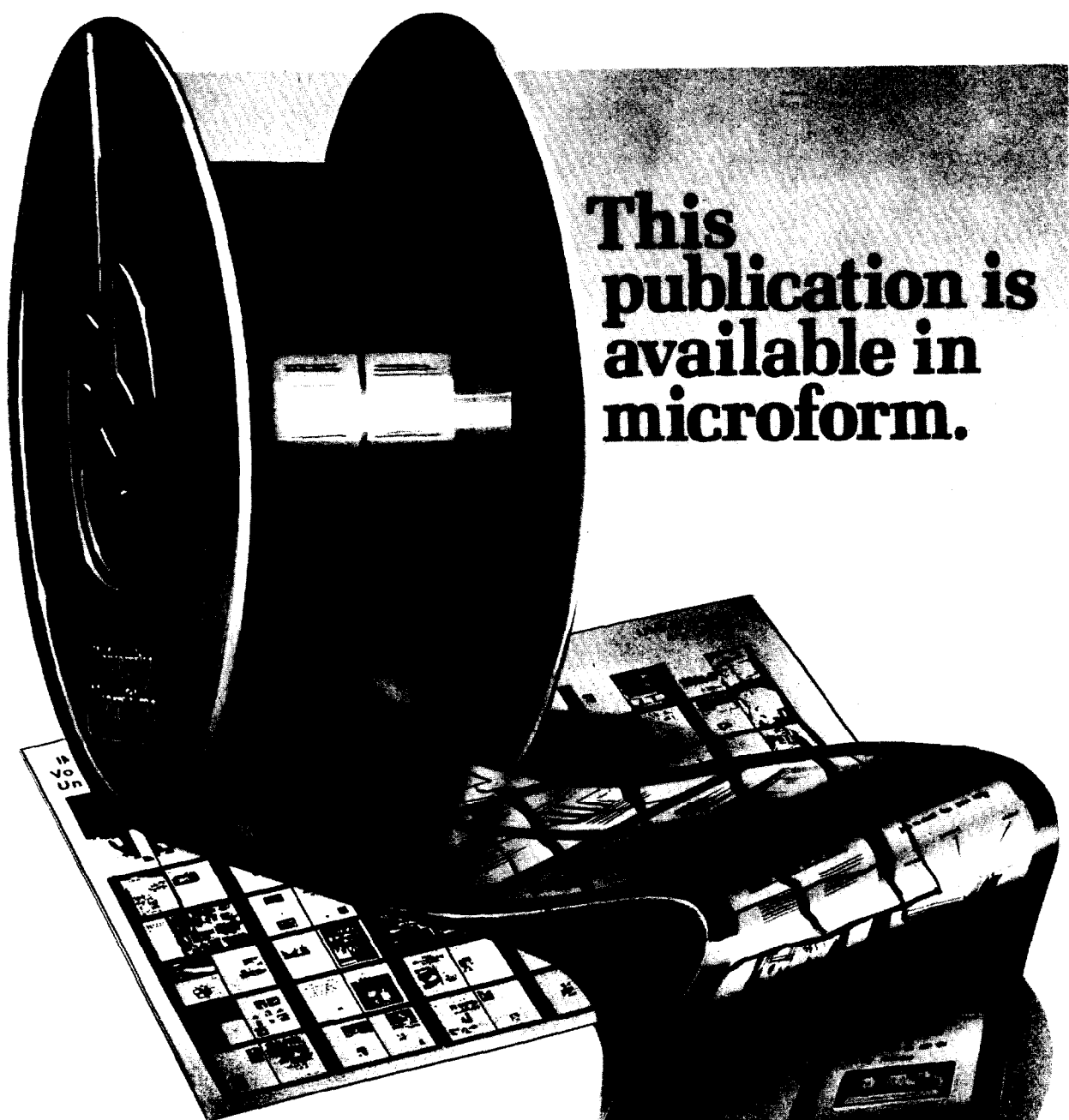




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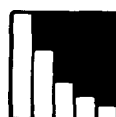
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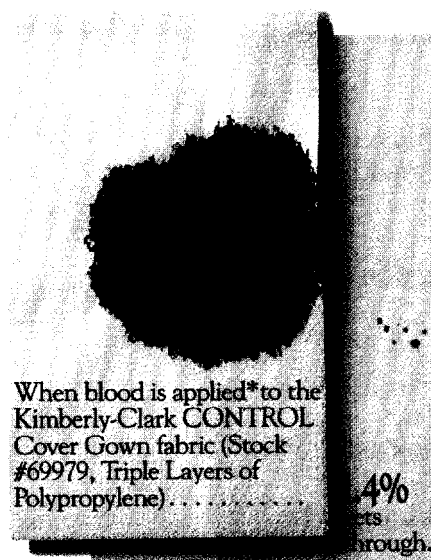
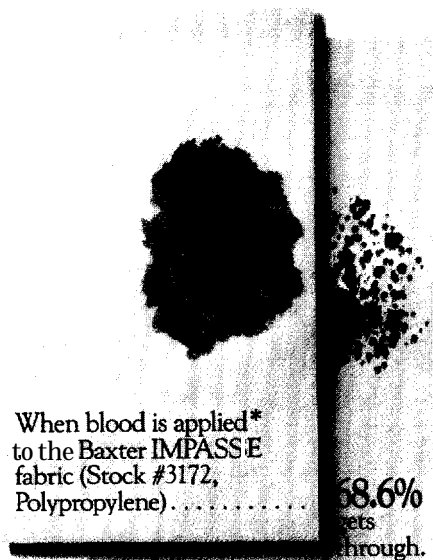
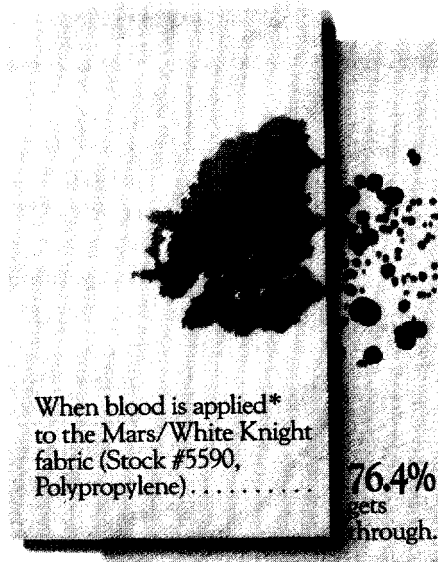
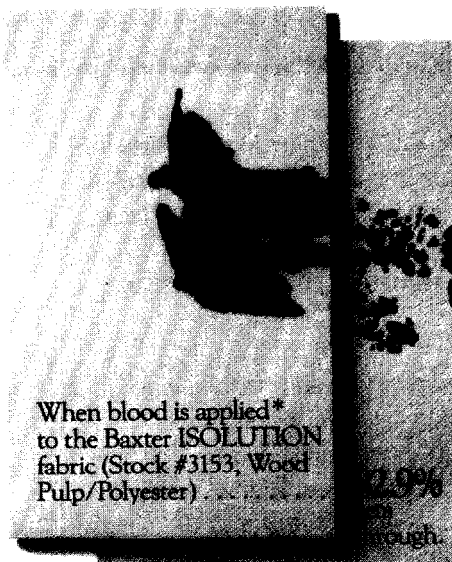
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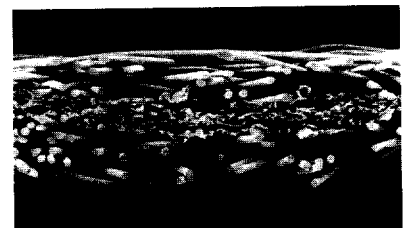
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2 Klein, B.S., W.H. Perloff, and D.G. Maki. 1989. Reduction of nosocomial infection during pediatric intensive care by protective isolation. N. Engl. J. Med. 320: 1714-1721.

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