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INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY™

EDITORIAL

Universal Precautions: Still Missing the Point on Needlesticks 211
JANINE JAGGER, MPH, PHD; RICHARD D. PEARSON, MD

ORIGINAL ARTICLES

Effect of Educational Programs, Rigid Sharps Containers, and Universal Precautions on Reported Needlestick Injuries in Healthcare Workers 214
CALVIN C. LINNEMANN, JR., MD; CONSTANCE CANNON, RN; MARTHA DERONDE, RN; BRUCE LANPHEAR, MD

Needlestick Injury: Impact of a Recapping Device and an Associated Education Program 220
MICHAEL WHITBY, MD; PM STEAD, RN; JAKE M. NAJMAN, PHD

Duration of Response to Intramuscular Versus Low Dose Intradermal Hepatitis B Booster Immunization 226
W. PAUL MCKINNEY, MD; SUSAN K. RUSSLER, MD; MARY M. HOROWITZ, MD; RICHARD J. BATTIOLA, MD, MARTHA BI-FONG LEE, PHD

A Survey of Nosocomial Respiratory Viral Infections in a Children's Hospital: Occult Respiratory Infection in Patients Admitted During an Epidemic Season 231
PAUL N. GOLDWATER, FRACP, FRCPA; A. JAMES MARTIN, MRCP, FRACP; BROWNWYN RYAN RN; SYLVIA MORRIS, MASM; JILL THOMPSON, RN; T.W. KOK, MSC; CHRISTOPHER J. BURRELL, PHD, FRCPA

TOPICS IN CLINICAL EPIDEMIOLOGY

Surveillance for Quality Assessment: IV Surveillance Using a Hospital Information System 239
DAVID C. CLASSEN, MD; JOHN P. BURKE, MD; STANLEY L. PESTOTNIK, RPH; R. SCOTT EVANS, PHD; LANE E. STEVENS, BS

TOPICS IN LONG-TERM CARE

Antibiotic Resistance in Long-Term Care Facilities 245
JOSEPH F. JOHN, JR., MD; BRUCE S. RIBNER, MD

SPECIAL REVIEW

Disposal of Medical Waste: The New York Experience Under the Medical Tracking Act 251
BRUCE F. FARBER, MD

LETTERS TO THE EDITOR

Asepsis Plus/Minus Comfort 206
WILLIAM C. BECK, MD

Urinary Tract Colonization With Methicillin-Resistant *Staphylococcus aureus* (And Reply) 208
HARRY J. SILVER, MD; CAROL A. KAUFFMAN, MD, SUZANNE F. BRADLEY, MD; MARGARET S. TERPENNING, MD

PARADIGM Software 210
DAVID BIRNBAUM, MPH

SHEA NEWSLETTER 259

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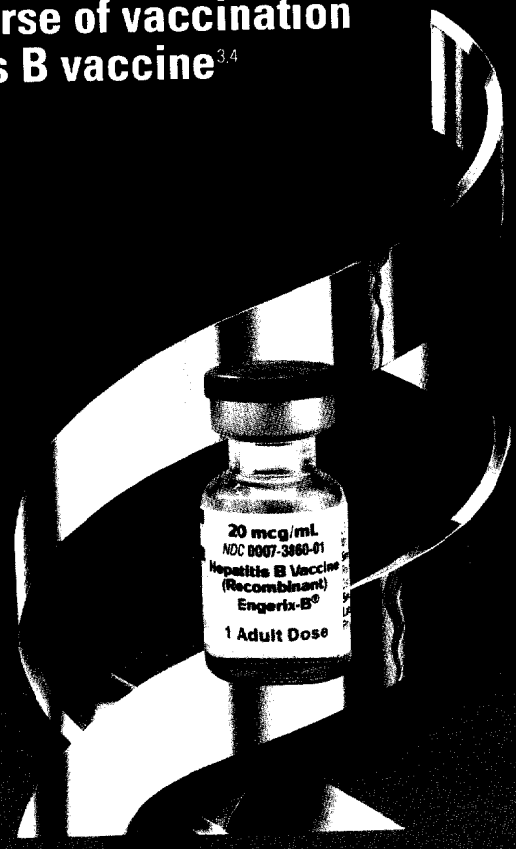
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‡Please see brief summary of prescribing information on adjacent page for a complete listing of adverse reactions, contraindications, warnings and precautions.

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Engerix-B®

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See complete prescribing information in SmithKline Beecham Pharmaceuticals literature or PDR. **The following is a brief summary.**

INDICATIONS AND USAGE: 'Engerix-B' is indicated for immunization against infection caused by all known subtypes of hepatitis B virus. Immunization is recommended in persons of all ages, especially those who are, or will be, at increased risk of exposure to hepatitis B virus.

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

WARNINGS: Do not give additional 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 percutaneous vaccine, keep epinephrine available for use in case of anaphylaxis M 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. Ge '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 plasmaderived 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-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 Heptavax-B®† and/or Recombivax HB®.‡ Those listed below are M serve as alerting information to physicians: Optic neuritis.

HOW SUPPLIED: 20 mcg/mL in Single-Dose Vials in packages of 1, 10 and 25 vials.

NDC 58160-860-01 (package of 1)
NDC 58160-860-11 (package of 10)
NDC 58160-860-16 (package of 25)

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NDC 58160-859-01 (package of 1)

†plasma-derived, Hepatitis B Vaccine, MSD
‡yeast-derived, Hepatitis B Vaccine. MSD.

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Dated issuance Sept. 1990

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References:
1. Poovorawan Y, Sanpavat S, Pongpunlert w. et al: Protective efficacy of a recombinant DNA hepatitis B vaccine in neonates of HBe ant'igen-positive mothers. *JAMA 1999;* 261(22):3278-3281. 2. Based on Medi-Span® Hospital Formulary Pricing Guide. December 1990. 3. Data on file. SmithKline Beecham Pharmaceuticals. 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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Vol. 12 No. 4 April 1991

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CONTENTS

EDITORIAL

Universal Precautions: Still Missing the Point on Needlesticks 211

JANINE JAGGER, MPH, PHD; RICHARD D. PEARSON, MD

ORIGINAL ARTICLES

Effect of Educational Programs, Rigid Sharps Containers, and Universal Precautions on Reported Needlestick Injuries in Healthcare Workers 214

CALVIN C. **LINNEMANN, JR., MD; CONSTANCE CANNON, RN; Martha DERONDE, RN; BRUCE LANPHEAR, MD**

Needlestick Injury: Impact of a Recapping Device and an Associated Education Program 220

MICHAEL WHITBY, MD; Pm STEAD, RN; JAKE M. NAJMAN, PhD

Duration of Response to Intramuscular Versus Low Dose Intradermal Hepatitis B Booster Immunization 226

W. PAUL MCKINNEY, MD; SUSAN K. RUSSLER, MD; MARY M. HOROWITZ, MD; RICHARD J. BATTIOLA, MD; MARTHA **BI-FONG Lee,** PHD

A Survey of Nosocomial Respiratory Viral Infections in a Children's Hospital: Occult Respiratory Infection in Patients Admitted During an Epidemic Season 231

PAUL N. GOldwater, FRACP, FRCPA; A. JAMES MARTIN, MRCP, FRACP; BROWNWYN RYAN, RN; SYLVIA **MORRIS, MASM; JILL THOMPSON, RN; T.W. KOK, MSc; CHRISTOPHER J. BURRELL, PHD, FRCPA**

TOPICS IN CLINICAL EPIDEMIOLOGY

Surveillance for Quality Assessment: IV Surveillance Using a Hospital Information System 239

DAVID C. CLASSEN, MD; JOHN P. BURKE, MD; STANLEY L. PESTOTNIK RPH; R. Scott EVANS, PHD; LANE E. STEVENS, BS

TOPICS IN LONG-TERM CARE

Antibiotic Resistance in Long-Term Care Facilities 245

JOSEPH F. JOHN, Jr., MD; BRUCE S. **RIBNER, MD**

SPECIAL REVIEW

Disposal of Medical Waste: The New York Experience Under the Medical Tracking Act 251

BRUCE F. FARBER, MD

DEPARTMENTS

Copyright and Republication Policy 202

Calendar of Events 204

Letters to the Editor 206

Correction 210

SHEA Newsletter 259

Information for Authors 262

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