INFECTION CONTROL

HOSPITAL EPIDEMIOLOGY

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EDITORIAL POLICE STATEMENT		AIDS	
Duplicate Publication of a Manuscript Richard P. Wenzel, MD, MSc; Dennis G. Maki, MD; Sue Crow, MSN, RN, CIC; William Schaffner, MD; John E. McGowan, Jr., MD	341	Risky Business: Using Necessarily Imprecise Casualty Counts to Estimate Occupational Risks for HIV-I Infection Susan E. Beekmann, BS; Barbara J. Fahey, BSN; Julie L. Gerberding, MD; David K. Henderson, MD	371
ORIGINAL ARTICLES			
Control of Epidemic Methicillin-Resistant	343	EMPORIATRICS	
Staphylococcus aureus Katherine A. Murray-Leisure, MD; Sandra Geib, RN; Diane Graceley; Arline B. Rubin-Slutsky, RN;		Emporiatrics: Protecting Travelers From Malaria Mary D. Nettleman, MD	380
Narendra Saxena, MD; H. Arnold Muller, MD; Bruce H. Hamory, MD		STATISTICS FOR HOSPITAL EPIDEMIOLOGY	
Adverse Exposures and Universal Precautions Practices Among a Group of Highly Exposed Health Professionals Mary E. Willy, MPH, BSN; Gita L. Dhillon, MS, CNM;	351	Practical Considerations in Designing Data Collection Forms Patricia A. Wasek, BA	384
Nancy L. Loewen, MS, CNM; Robert A. Wesley, PhD; David K. Henderson, MD		LETTERS TO THE EDITOR	
		Pseudoepidemic of Rhodotorula rubra in Patients Undergoing Fiberoptic Bronchoscopy	334
SPECIAL COMMENTARIES	057	Marian Kennedy, RN	
The Influenza Vaccination Demonstration Project: An Expanded Policy Goal David S. Fedson, MD	357	(Reply) William A. Rutala, PhD; Karen K. Hoffmann, RN, MS; David J. Weber, MD	
		On Duplicate Publication of a Manuscript	336
Infection Control for Home Health Bryan Simmons, MD; Martha Trusler, RN;	362	W.H. Seto, MD; S.G. Ong, MD; T.Y. Ching, RN	
Jane Roccaforte, MD; Philip Smith, MD;		SHEA NEWSLETTER	391

Rebecca Scott, RN

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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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Can be used to complete a course of vaccination initiated with another hepatitis B vaccine^{3,4}

	Engerix-B°	Recombivax H	[B®
	20	10	
	Yes	Yes	
The second secon	Yes	No	
	Yes	Yes	
	Yes	No	
,	Yes	No	
	Yes	No	

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See complete prescribing information in SK&F literature or PDR. The following is a brief summary.

INDICATIONS AND U.S.A.G.E.: 'Engerix.B' is indicated for immunization against infection caused by all known subtypes of hepatilis B virus Immunization is recommended in persons of all ages, especially those who are or will be, at increased risk of exposure to hepatilis El virus

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

WARNINGS: Do not give additional injections to patients experiencing hypersensitivity alter 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 a "unrecognized hepatitis B infection at the time of vaccine administration Additionally, it may not pre rent infection in individuals who do not achieve protective antibody titers

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

As with any vaccme, delay administration, if possible, in persons with any tebrile illness or active infection.

Prognancy: Pregnancy Category C Animal reproduction studies have not been conducted with Engerix B ts also not known whether Engerix B can cause letal harm when administered to a pregnant woman or can affect reproduction capacity Give Engenx B to a pregnant woman only if clearly needed

Nursing Mothers: It is not known whether 'Engerix-B' is excreted in human ause 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 senous adverse reactions attributable to vaccine administration were reported As with any vaccine, however, it is possible that expanded Commercial use of the vaccine could weal rare adverse reactions not observed in chiefed chudic. 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-dewed 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 markerst and healthy enonates. 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 fallique* (14%) Other reactions are listed below. reactions are listed below

Incidence 1% to 10% of injections: Induration; erythema; swelling, fever

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

incidence < 1% of Injections: Pam: pruritus; ecchymosis; sweating malaise; chills; weakness, flushmg, tingling: hypotension; influenza-like symp toms; upper respiratory tract illnesses; nausea. anorexia, abdominal pani/cramps; vomiting; constipation. diarrhea; lymphadenopathy; pain/stitlness in arm, shoulder or neck arthralgia; myalpia; back pain; rash, urticaria; petechiae; erythema; somnolence. insomnia; irritability; agitation

Additional adverse expenence. Insomma, initiating; agriation
Additional adverse expenences have been reported with the commercial use
of 'Engers 8' outside the United States Those listed below are to serve as
alerting information to physicians. Anaphylaxis; erythema multiforme includmg Stevens-Johnson syndrome; angioedema, arthritis; tachycardia/palpitations; bronchospasm including asthma-like symptoms, abnormal liver function tests, migraine; syncope; paresus; neuropathy including hypoesthesia,
gaesthesia, Gulliain-Barfe syndrome and Bell's palsy, transverse myelitis;
thrombocytopenia; eczema; purpura; herpes zoster; vertigo; conjunctivitis;
keralitis, visual disturbances

Polential 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 to serve as alerting information to

HOW SUPPLIED: 20 mcg/mL in Single Dose Vials in packages of 1.10 and

NDC 0007-3860-01(package of 1) NDC 0007-3860-11(package of 10) NDC 0007-3860-16 (package of 25)

10 mcgl0.5 mLin Single-Dose Vials in packages of 1 vial

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Date of issuance Aug 1939

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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 antigen-positive mothers. JAMA 1989; 261(22):3278-3281. HBe antigen-positive molners. JAMA 1989; 201(22):32/8-3281.

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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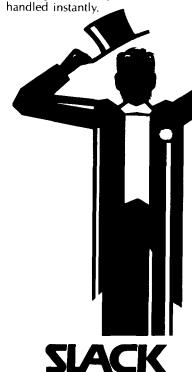
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SPECIAL SECTIONS	Special Commentaries The Influenza Vaccination Demonstration Project: An Expanded Policy Goal David S. Fedson, MD			357	
	Infection Control for Ho Bryan Simmons, MD; M Jane Roccaforte, MD; Pl	artha Trusle		362	
	AIDS Risky Business: Using Moderation to Estimate Occupation Susan E. Beekmann, BS Julie L. Gerberding, MD	al Risks for 5; Barbara J.	Fahey, BSN;	371	
	Emporiatrics Emporiatrics: Protecting Travelers From Malaria Mary D. Nettleman, MD				
	Statistics for Hospital Epidemiology Practical Considerations in Designing Data Collection Forms Patricia A. Wasek, BA				
DEPARTMENTS	Letters to the Editor	334	SHEA Newsletter	391	
	Calendar of Events	390	Classified Marketplace	Cover 3	

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