most important of these factors.[273] Resistance is not necessarily a "random event,"[1,2,4] and optimal antimicrobial use still should be an essential part of current practice.[4]

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Cross-Sectional Survey Sampling

To the Editor:

Cross-sectional survey sampling in hospital epidemiology usually treats samples of patients as representative of a "superpopulation" of all potential patients, with the objective of estimating underlying "baseline" values. However, in quality assurance tasks like monitoring quarterly blood product use,' it may be appropriate to consider the finite population at risk during a time interval specified and apply the finite population correction factor' to sample size and variance calculations. The question under study becomes whether care is within specifications during a given period rather than estimating underlying "baseline" rates.

The brief section on sampling in Credé and Hierholzerb (*Infect Control Hosp Epidemiol*, July 1989, 321-325) excellent summary of cross-sectional design suggests stratified random sampling and cluster sampling as alternatives to simple random sampling. Indeed, if differences between strata (i.e., between departments, wards, diagnostic groups, etc.) are the subject of interest, or an overall estimate is desired but strata means are likely to differ widely, or a sampling frame is available for groups but not individuals, then stratification, post-stratification, systematic or cluster sampling may be preferable to simple random sampling.

Individual strata sample size allocation may be equal, proportional or "Neyman" optimal; sampling rates in each of the strata need not be equal. Cluster selections may be random or by probability proportional to size.

Cochran's useful text[2] provides a different perspective on a distinction between stratified random and cluster sampling than one might infer from Credé and Hierholzer's reference to "higher density selection." In cluster sampling, the cluster group (department, ward, household, etc.) is selected and every individual in that group is included in the sample. Non-random inclusion of every individual within selected clusters, as when every patient on selected wards is included in "prevalence rounds," distinguishes cluster sampling from various forms of random sampling. A consequence is calculation of variance estimates by mean square error, *not* the binomial approximation we commonly rely upon with random sampling of proportional data.

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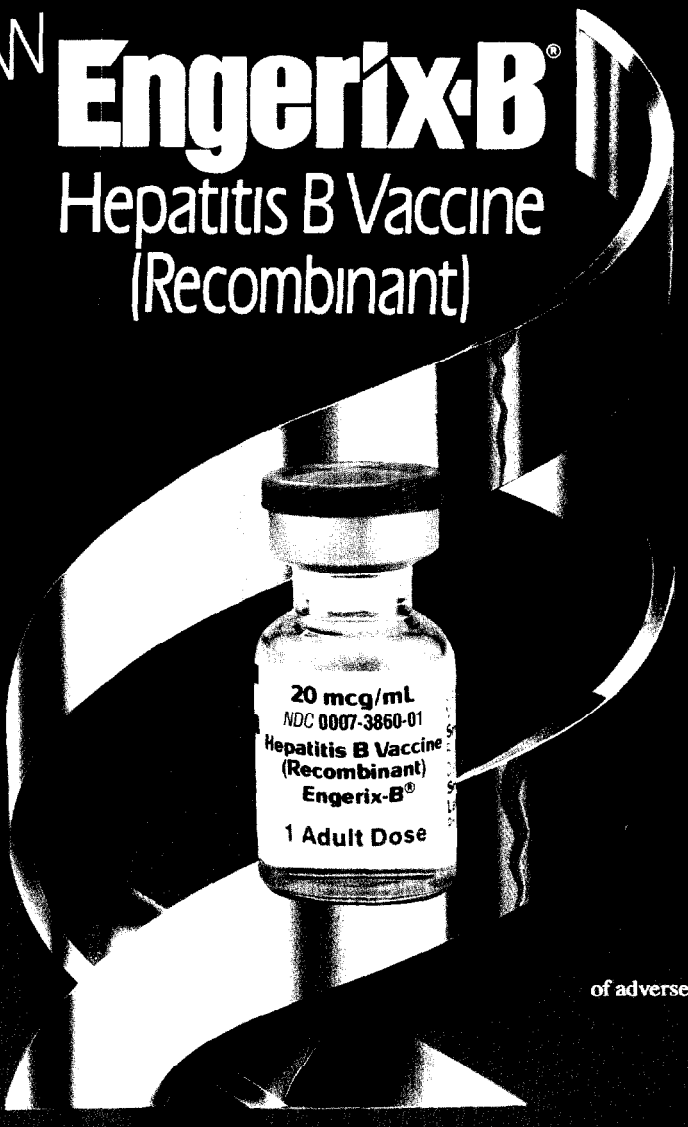

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CONTRAINDICATIONS: Hypersensitivity to yeast or any other component of the vaccine is a contraindication for use of the vaccine.

WARNINGS: Do not give 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 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 13,495 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 to 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 0007-3860-01 (package of 1)
NDC 0007-3860-11 (package of 10)
NDC 0007-3860-16 (package of 25)

10 mcg/0.5 mL in Single-Dose Vials in packages of 1 vial.

NDC 0007-3859-01 (package of 1)

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

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