

continued from page 90

room to avoid exposing other patients to real or perceived danger of contagion. To avoid alarming patients with other medical problems and yet conserve hospital beds, our hospital has adopted a policy of rooming patients with AIDS together if the patients do not have a respiratory tract infection with tuberculosis, open wounds, or diarrhea, and if they are able to maintain their personal hygiene. This policy is in accordance with published guidelines for isolation precautions in hospitals.^{1,2} One of our patients was inadvertently placed in a room with another patient in violation of these guidelines with a result that dramatically emphasizes the potential danger of violating these guidelines.

This 28-year-old man with AIDS was electively admitted for treatment of cytomegalovirus retinitis. He had been successfully treated for *Pneumocystis carinii* pneumonia five months earlier. Except for the development of the retinitis and recurrent oral candidiasis, his health was good. He had been gaining weight since recovering from the pneumonia and he denied having fevers or diarrhea. The fifth day of hospitalization he developed explosive diarrhea, headache, and high fever. Specimens of blood and stool both yielded *Salmonella* group B. He responded to ampicillin, and has been maintained on amoxicillin to prevent relapse. An investigation revealed that he had shared a hospital room and bathroom for 24 hours with another AIDS patient who had diarrhea subsequently diagnosed as caused by *Salmonella* group B, with an identical antibiogram to the isolate from our patient. No other potential sources of infection for our patient were identified, and we believe the infection was transmitted from one patient to the other.

The diarrhea in the one patient was not recognized by the staff at the time these patients were placed in the same semiprivate room. No direct contact between them occurred, and their room assignments were promptly changed when the diarrhea was noted. Unfortunately, transmission of infection had already occurred. This experience emphasizes the danger of nosocomial infection to immunosuppressed patients and the importance

of strictly adhering to published guidelines. Since bed assignments are often made by personnel other than the attending physician, the persons responsible for bed assignments should be informed of the relevant diagnosis of patients, not only at the time of admission but also whenever new diagnoses are established. The practice of cohorting patients with AIDS should be exercised with caution.

REFERENCES

1. Centers for Disease Control: *Guidelines for Isolation Precautions in Hospitals*. Atlanta: US Public Health Service, 1983.
2. Centers for Disease Control: Acquired immune deficiency syndrome (AIDS): Precautions for clinical and laboratory staff. *MMWR* 1982; 3:527-580.

Ramon Ramirez, MD

Fellow in Training, Infectious Diseases

Joan Otten, BSN, RN

Assistant Administrator,
Quality Assurance, Infection Control

Gordon M. Dickinson, MD

Associate Professor of Medicine
Division of Infectious Diseases
University of Miami School of Medicine
Miami, Florida

Proper Handling of Dirty Linen

To the Editor:

A recurring question of proper handling of dirty linen in Skilled Nursing Facilities has promoted this inquiry. Some surveyors insist on wearing gowns and gloves whenever they handle dirty linen. What guidelines are recommended by the Editorial Board of *Infection Control*?

Harry J. Silver, MD
Los Angeles, CA

Ms. Sue Crow responds to Dr. Silver's letter:

Dear Dr. Silver:

The Editorial Board of *Infection Control* does not provide infection control guidelines, but I offer my own response to your question.

Gowns and gloves are not necessary for routine handling of dirty linen. It

is much more efficient and less costly to assure that the dirty linen does not come into direct contact with personnel's attire and for personnel to wash their hands thoroughly after handling the linen. Gloves may be necessary if the linen is saturated with body fluids and/or if the employees have cuts or scratches on their hands.

As you know, various organizations follow various regulations. If wearing gowns and gloves is indeed a policy, you may want to challenge the policy. It is up to us to suggest change not only in the health care institutions, but also in the community.

Sue Crow, MSN, RN, CIC
Nurse Epidemiologist

Letters to the Editor should be addressed to INFECTION CONTROL Editorial Offices, C41 General Hospital, University of Iowa Hospitals and Clinics, Iowa City, IA 52242. All letters must be typed, double spaced, and may not exceed four pages nor include more than one figure or table. The editors reserve the right to edit for purposes of clarity or brevity.

New Managing Editor in Editor's Office

Marikay Klein has accepted the position of Managing Editor in the INFECTION CONTROL editorial offices in Iowa City, Iowa. For five years Marikay was involved with the design and production of college textbooks at Wm. C. Brown Publishers in Dubuque, Iowa. She received a degree in Journalism and Graphic Design from The University of Iowa and has studied at the Centre for Journalism at the City University of London. In addition, Marikay has worked as a freelance graphic designer, illustrator, and copy editor. She can be reached at 319-356-0463.

Merck Sharp & Dohme Research Laboratories... Unlocking the potential of DNA



For a Brief Summary of Prescribing Information for RECOMBIVAX-HB® (Hepatitis B Vaccine [Recombinant], MSD), please see fourth page of this advertisement.
<https://doi.org/10.1017/S0195941700067230> Published online by Cambridge University Press

Introducing New

Recombivax-HB[®]

(Hepatitis B Vaccine [Recombinant] | MSD)

The first genetically designed vaccine for humans

Another choice

To help prevent hepatitis B in those at increased risk

- Derived from yeast by means of advanced biotechnology (not derived from plasma)
- Produces a protective antibody comparable to that of HEPTAVAX-B[®] (Hepatitis B Vaccine, MSD)
- Provides an alternative to vaccination with HEPTAVAX-B

HEPTAVAX-B and RECOMBIVAX-HB are contraindicated in the presence of hypersensitivity to any component of the vaccine.

Patients who develop symptoms suggestive of hypersensitivity after an injection should not receive further injections of HEPTAVAX-B or RECOMBIVAX-HB.





Another chance

To help protect yourself...your family... and your career

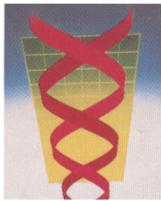
- *Against contracting and transmitting hepatitis B, a potentially serious disease*
- *Against developing an irreversible chronic-carrier state*

To help protect your institution

- *Against the costs of accidental exposure*
- *Against the devastation of a hepatitis B outbreak*

Because of the long incubation period for hepatitis B, it is possible for unrecognized infection to be present at the time HEPTAVAX-B® (Hepatitis B Vaccine, MSD) or RECOMBIVAX-HB® (Hepatitis B Vaccine [Recombinant], MSD) is given. HEPTAVAX-B or RECOMBIVAX-HB may not prevent hepatitis B in such patients.

For a Brief Summary of Prescribing Information for RECOMBIVAX-HB, please see following page. For a Brief Summary of Prescribing Information for HEPTAVAX-B, please see last page of this advertisement.



Recombivax-HB®

(Hepatitis B Vaccine [Recombinant] | MSD)

INDICATIONS AND USAGE

RECOMBIVAX-HB is indicated for immunization against infection caused by all known subtypes of hepatitis B virus.

RECOMBIVAX-HB will not prevent hepatitis caused by other agents, such as hepatitis A virus, non-A, non-B hepatitis viruses, or other viruses known to infect the liver.

Vaccination is recommended in persons of all ages who are or will be at increased risk of infection with hepatitis B virus. In areas with high prevalence of infection, most of the population are at risk of acquiring hepatitis B infection at a young age. Therefore, vaccination should be targeted to prevent such transmission. In areas of low prevalence, vaccination should be limited to those who are in groups identified as being at increased risk of infection.

CONTRAINDICATIONS

Hypersensitivity to yeast or any component of the vaccine.

WARNINGS

Patients who develop symptoms suggestive of hypersensitivity after an injection should not receive further injections of RECOMBIVAX-HB (see CONTRAINDICATIONS).

Because of the long incubation period for hepatitis B, it is possible for unrecognized infection to be present at the time RECOMBIVAX-HB is given. RECOMBIVAX-HB may not prevent hepatitis B in such patients.

PRECAUTIONS

General

As with any percutaneous vaccine, epinephrine should be available for immediate use should an anaphylactoid reaction occur.

Any serious active infection is reason for delaying use of RECOMBIVAX-HB except when, in the opinion of the physician, withholding the vaccine entails a greater risk.

Caution and appropriate care should be exercised in administering RECOMBIVAX-HB to individuals with severely compromised cardiopulmonary status or to others in whom a febrile or systemic reaction could pose a significant risk.

Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with RECOMBIVAX-HB. It is also not known whether RECOMBIVAX-HB can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. RECOMBIVAX-HB should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether RECOMBIVAX-HB is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when RECOMBIVAX-HB is administered to a nursing woman.

Pediatric Use

RECOMBIVAX-HB has been shown to be usually well tolerated and highly immuno-

RECOMBIVAX-HB®

(Hepatitis B Vaccine [Recombinant], MSD)

genic 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. See DOSAGE AND ADMINISTRATION for recommended pediatric dosage and for recommended dosage for infants born to HBsAg positive mothers.

ADVERSE REACTIONS

RECOMBIVAX-HB is generally well tolerated. No serious adverse reactions attributable to the vaccine have been reported during the course of clinical trials. No serious hypersensitivity reactions have been reported. No adverse experiences were reported during clinical trials which could be related to changes in the titers of antibodies to yeast. As with any vaccine, there is the possibility that broad use of the vaccine could reveal adverse reactions not observed in clinical trials.

In a group of studies, 3258 doses of vaccine were administered to 1252 healthy adults who were monitored for 5 days after each dose. Injection site and systemic complaints were reported following 17% and 15% of the injections, respectively.

The following adverse reactions were reported:

Incidence Equal to or Greater than 1% of Injections

LOCAL REACTION (INJECTION SITE)

Injection site reactions consisting principally of soreness and including pain, tenderness, pruritus, erythema, ecchymosis, swelling, warmth, and nodule formation.

BODY AS A WHOLE

The most frequent systemic complaints include fatigue/weakness; headache; fever ($\geq 100^{\circ}\text{F}$); malaise.

DIGESTIVE SYSTEM

Nausea; diarrhea.

RESPIRATORY SYSTEM

Pharyngitis; upper respiratory infection.

Incidence Less than 1% of Injections

BODY AS A WHOLE

Sweating; achiness; sensation of warmth; lightheadedness; chills; flushing.

DIGESTIVE SYSTEM

Vomiting; abdominal pains/cramps; dyspepsia; diminished appetite.

RESPIRATORY SYSTEM

Rhinitis; influenza; cough.

NERVOUS SYSTEM

Vertigo/dizziness; paresthesia.

INTEGUMENTARY SYSTEM

Pruritus; rash (non-specified); angioedema; urticaria.

MUSCULOSKELETAL SYSTEM

Arthralgia including monoarticular; myalgia; back pain; neck pain; shoulder pain; neck stiffness.

HEMIC/LYMPHATIC SYSTEM

Lymphadenopathy.

PSYCHIATRIC/BEHAVIORAL

Insomnia/disturbed sleep.

SPECIAL SENSES

Earache.

UROGENITAL SYSTEM

Dysuria.

CARDIOVASCULAR SYSTEM

Hypotension.

Potential ADVERSE EFFECTS

In addition, a variety of adverse effects, not observed in clinical trials with RECOMBIVAX-HB, have been reported with HEPTAVAX-B® (Hepatitis B Vaccine, MSD) (plasma-derived hepatitis B vaccine). Those listed below are to serve as alerting information to physicians:

Hypersensitivity: An apparent hypersensitivity syndrome of delayed onset has been

RECOMBIVAX-HB®

(Hepatitis B Vaccine [Recombinant], MSD)

reported days to weeks after vaccination. This has included the following findings: arthritis (usually transient), fever, and dermatologic reactions such as urticaria, erythema multiforme, or ecchymoses. **Nervous System:** Neurological disorders such as optic neuritis, myelitis including transverse myelitis; acute radiculoneuropathy including Guillain-Barré syndrome; peripheral neuropathy including Bell's palsy and herpes zoster.

Hematologic: Thrombocytopenia.

Special Senses: Tinnitus; visual disturbances.

DOSAGE AND ADMINISTRATION

Do not inject intravenously or intradermally.

RECOMBIVAX-HB is for intramuscular injection. The deltoid muscle is the preferred site for intramuscular injection in adults. Data suggest that injections given in the buttocks frequently are given into fatty tissue instead of into muscle. Such injections have resulted in a lower seroconversion rate than was expected. The anterolateral thigh is the recommended site for intramuscular injection in infants and young children.

RECOMBIVAX-HB may be administered subcutaneously to persons at risk of hemorrhage following intramuscular injections. However, when other aluminum-adsorbed vaccines have been administered subcutaneously, an increased incidence of local reactions including subcutaneous nodules has been observed. Therefore, subcutaneous administration should be used only in persons (e.g., hemophiliacs) at risk of hemorrhage following intramuscular injections.

The immunization regimen consists of 3 doses of vaccine. The volume of vaccine to be given on each occasion is as follows:

Group	Pediatric	Initial	1 month	6 months
Younger Children (Birth to 10 years of age)	Pediatric 5mcg/0.5 mL	0.5 mL	0.5 mL	0.5 mL
Adults and Older Children	Adult 10 mcg/1.0 mL	1.0 mL	1.0 mL	1.0 mL

Since there have been no clinical studies in which a vaccine series was initiated with HEPTAVAX-B® (Hepatitis B Vaccine, MSD) and completed with RECOMBIVAX-HB, or vice versa, it is recommended that the 3-dose series be completed with the same vaccine that was used for the initial dose.

Whenever revaccination or administration of a booster dose is appropriate, RECOMBIVAX-HB may be used.

For dosage for infants born of HBsAg positive mothers and for dosage for known or presumed exposure to HBsAg, see the Prescribing Information.

The vaccine should be used as supplied; no dilution or reconstitution is necessary. The full recommended dose of the vaccine should be used.

Storage

Store vials at 2–8°C (35.6–46.4°F). Storage above or below the recommended temperature may reduce potency.

Do not freeze since freezing destroys potency.

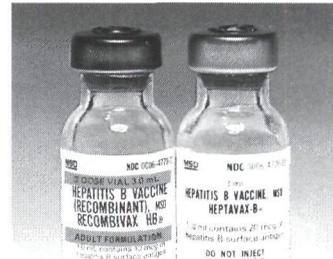
For more detailed information, consult your MSD Representative or see Prescribing Information. Merck Sharp & Dohme, Division of Merck & Co., Inc., West Point, PA 19486. (200)

MSD
MERCK
SHARP
DOHME

Make a choice... Don't take a chance

New
Recombivax-HB[®]
(Hepatitis B Vaccine [Recombinant] | MSD)

Also available
Heptavax-B[®]
(Hepatitis B Vaccine | MSD)



■ Produced by genetic design ■ Produced by traditional design

BOTH

are highly effective against hepatitis B and help prevent its many potential complications and sequelae.

BOTH

provide highly effective protection for the health-care professional, thereby protecting against possible transmission to family members.

BOTH

help protect against becoming a chronic carrier and the potential devastating effect on a health-care career.

BOTH

help protect hospitals against the costly occurrence of a hepatitis B outbreak.

For a Brief Summary of Prescribing Information for HEPTAVAX-B, please see following page.

MSD
MERCK
SHARP &
DOHME

Heptavax-B®

(Hepatitis B Vaccine | MSD)

HEPTAVAX-B®
(Hepatitis B Vaccine, MSD)

HEPTAVAX-B®
(Hepatitis B Vaccine, MSD)

INDICATIONS AND USAGE

HEPTAVAX-B is indicated for immunization against infection caused by all known subtypes of hepatitis B virus.

HEPTAVAX-B will not prevent hepatitis caused by other agents, such as hepatitis A virus, non-A, non-B hepatitis viruses, or other viruses known to infect the liver.

Vaccination is recommended in persons of all ages, especially those who are or will be at increased risk of infection with hepatitis B virus.

CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine.

WARNINGS

Persons with immunodeficiency or those receiving immunosuppressive therapy require larger vaccine doses and respond less well than do healthy individuals.

Because of the long incubation period for hepatitis B, it is possible for unrecognized infection to be present at the time HEPTAVAX-B is given. HEPTAVAX-B may not prevent hepatitis B in such patients. Patients who develop symptoms suggestive of hypersensitivity after an injection should not receive further injections of HEPTAVAX-B.

PRECAUTIONS

General

As with any parenteral vaccine, epinephrine should be available for immediate use should an anaphylactoid reaction occur. Any serious active infection is reason for delaying use of this vaccine except when, in the opinion of the physician, withholding the vaccine entails a greater risk. Caution and appropriate care should be exercised in administering this vaccine to individuals with severely compromised cardiopulmonary status or to others in whom a febrile or systemic reaction could pose a significant risk.

Pregnancy

Pregnancy Category C. It is not known whether the vaccine can cause fetal harm when administered to pregnant women or can affect reproductive capacity. The vaccine should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Studies in 12 lactating women have failed to reveal evidence of this vaccine being secreted in breast milk.

Pediatric Use

This vaccine 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. See DOSAGE AND ADMINISTRATION section in Prescribing Information for recommended pediatric dosage and for recommended dosage for infants born to HBsAg positive mothers.

ADVERSE REACTIONS

HEPTAVAX-B is generally well tolerated. No serious adverse reactions attributable to vaccination were reported during the course of clinical trials involving administration of HEPTAVAX-B to over 19,000 individ-

uals. As with any vaccine, there is the possibility that broad use of the vaccine could reveal rare adverse reactions not observed in clinical trials. In three double-blind placebo-controlled studies among 3,350 persons, the overall rates of adverse reactions reported by vaccine recipients (24.3%, 21.5%, and 22.8%) did not differ significantly from those of placebo recipients (21.4%, 18.7%, and 21.9%). Approximately half of all reported reactions were injection-site soreness, which occurred somewhat more frequently among vaccine recipients.

In another group of studies, 3,516 doses of vaccine were administered to 1,255 healthy adults. Vaccinees were monitored for 5 days after each dose, and the following adverse reactions were reported:

	% of doses
BODY AS A WHOLE	
Injection site reactions, consisting principally of soreness, and including erythema, swelling, warmth and induration	12.3
Fatigue/asthenia	1.9
Malaise	0.8
Fever ($\geq 100^\circ\text{F}$)	1.8
Chills	0.4
Sensation of warmth	0.4
Irritability	0.1
Diaphoresis	0.1
DIGESTIVE SYSTEM	
Gastrointestinal illness including anorexia, nausea, vomiting, abdominal pain and diarrhea	2.0
Abdominal cramps	0.3
HEMATOLOGIC AND LYMPHATIC SYSTEM	
Adenitis	0.1
MUSCULOSKELETAL SYSTEM	
Myalgia	1.2
Arthralgia	0.7
NERVOUS SYSTEM	
Headache	3.1
Dizziness	0.5
Disturbed sleep	0.2
Paresthesia	0.2
RESPIRATORY SYSTEM	
Upper respiratory illness	2.5
INTEGUMENTARY SYSTEM	
Rash (non-specific)	0.3

In a double-blind, placebo-controlled, clinical trial of 1,330 health-care workers, the frequency of elevations in SGPT (ALT) in vaccine recipients was not significantly different from that in placebo recipients. In marketed use of the vaccine, non-specific abnormalities in SGPT (ALT) and other liver function tests have been reported, but no causal relationship has been established.

The following additional adverse reactions have been reported with use of the marketed vaccine.

Hypersensitivity Reactions
Symptoms of immediate hypersensitivity including urticaria, angioedema, and pruritus have been reported rarely within the first few hours after vaccination. An apparent hypersensitivity syndrome of delayed onset has been reported rarely, days to weeks after vaccination. This has included the following findings: arthritis (usually transient), fever, and dermatologic reactions such as urticaria, erythema multiforme, or ecchymoses.

Nervous System
Neurological disorders such as: optic neuritis; myelitis, including transverse myelitis; acute radiculoneuropathy, including Guillain-Barré syndrome; peripheral neuropathy, including Bell's palsy and herpes zoster.

Hematologic
Thrombocytopenia.

Special Senses

Tinnitus, visual disturbances.

Integumentary System

Flushing.

DOSAGE AND ADMINISTRATION

Do not inject intravenously or intradermally.

HEPTAVAX-B is for intramuscular injection. The deltoid muscle is the preferred site for intramuscular injection in adults. Data suggest that injections given in the buttocks frequently are given into fatty tissue instead of into muscle. Such injections may result in a lower seroconversion rate than is expected. The anterolateral thigh is the recommended site for intramuscular injection in infants and children.

HEPTAVAX-B may be administered subcutaneously to persons at risk of hemorrhage following intramuscular injections. The immune responses and clinical reactions following intramuscular and subcutaneous administration of HEPTAVAX-B have been shown to be comparable. However, when other aluminum-adsorbed vaccines have been administered subcutaneously, an increased incidence of local reactions including subcutaneous nodules has been observed. Therefore, subcutaneous administration should be used only in persons (e.g., hemophiliacs) at risk of hemorrhage following intramuscular injections.

Shake well before withdrawal and use. Thorough agitation at the time of administration is necessary to maintain suspension of the vaccine.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

The immunization regimen consists of 3 doses of vaccine. The volume of vaccine to be given on each occasion is as follows:

Group	Formulation	Initial	1 month	6 months
Younger Children (Birth to 10 years of age)	Pediatric 10 mcg/0.5 mL	0.5 mL	0.5 mL	0.5 mL
Adults and Older Children	Adult 20 mcg/1.0 mL	1.0 mL	1.0 mL	1.0 mL
Dialysis Patients and Immuno-compromised Patients	Adult 20 mcg/1.0 mL	2.0 mL*	2.0 mL*	2.0 mL*

*Two 1.0 mL doses given at different sites.

For dosage for infants born of HBsAg positive mothers and for dosage for known or presumed exposure to HBsAg, see the Prescribing Information.

The vaccine should be used as supplied; no dilution or reconstitution is necessary. The full recommended dose of the vaccine should be used.

Storage

Store vials at 2–8°C (35.6–46.4°F). Storage above or below the recommended temperature may reduce potency.

Do not freeze since freezing destroys potency.

For more detailed information, consult your MSD Representative or see Prescribing Information. Merck Sharp & Dohme, Division of Merck & Co., Inc., West Point, PA 19486. [207]

MSD
MERCK
SHARP &
DOHME