(continued from page 334)

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## On Duplicate Publication of a Manuscript

**To the Editor:**

We write in response to the editorial in this issue of *Infection Control and Hospital Epidemiology* (ICHE) regarding the duplication of a manuscript.' Two essential matters will be dealt with. First, we will show that the two papers, though related, are not duplicates or redundant. Second, we will explain why our manner of cross-referencing between the two papers was appropriate.

The two papers in question are reports on a study regarding the application of influencing tactics, described by Kipnis, et al.[2] in the context of infection control.

In the first paper, published in ICHE, 45 infection control nurses (ICNs) were surveyed regarding the use of these tactics, and 65 ICNs were requested to predict the compliance of the ward nurses.[3] The usage responses of the ICNs were compared with the report by Kipnis, et al., who studied the use of tactics among managers.[2] Kipnis, et al. factor-analyzed their results, and this also was done for the usage responses of the 45 ICNs.

In the second paper, published in the *Journal of Hospital Infection* (JHI), the compliance responses of 881 ward nurses and the factor analysis of these responses were reported.[4] The pattern that emerged was found to be entirely different from that of Kipnis, et al[2] (except for one factor). We believe that this had special relevance for infection control and was worth reporting. Structures discovered through factor analysis are important ways for understanding human behavior,[5] though this may not be readily appreciated by those who are unfamiliar with behavioral research.

With such differences existing between the two papers, we certainly do not understand why they are considered by the editors of ICHE to be duplicates (implying that they are the same manuscript). Even "redundancy" is too strong a word because the structure and findings described in JHI are entirely new, and they have important applicational value. Nevertheless, in retrospect, we concede that more could have been done to highlight the inherent differences between the two papers.

The paper in ICHE was written first, and the revised version was accepted on January 16, 1989; unfortunately it was published more than one year later, in the March 1990 issue. The second paper, published in JHI, was written only after the first paper was completed. Therefore, when we were writing the first paper, the second paper was not referenced because it had yet to be written. However, when we were writing the second paper (accepted on August 25, 1989), we did quote the first paper. We also informed the editor of JHI about the first paper and its content. However, the JHI paper was published on February 1990, one month before the publication of the ICHE paper, giving the false impression that the JHI paper was written first.

When we submitted the second paper, we did not inform the editors of ICHE because we had referred to its paper in the references. In our experiences with other learned journals, this procedure has been acceptable. In fact, if this had not been done, scientific decorum would certainly have been broken. However, this was insufficient for the ICHE editors, and presumably, they would like to be informed of any subsequent reports related to studies that they have accepted for publication. We certainly respect their right to adopt such a stringent policy, but this was not evident in any of their editorial statements. It seems rather unjustified that we were accused of breaking such a stringent policy, when it had never been adequately communicated to contributors of ICHE.

Finally, we would like to refer to the editors' proposal to "draft a copyright statement modified from the policy of *The Annals of Internal Medicine*" for future contributions to the journal.[1] We do not understand why our papers were used to explain editorial policies when such a copyright statement is yet to be drafted. In all fairness, when a stringent policy is put into effect, adequate notice of that policy should be made before someone is faulted. Moreover, as explained earlier, we believe that our papers were neither duplicates nor redundant.

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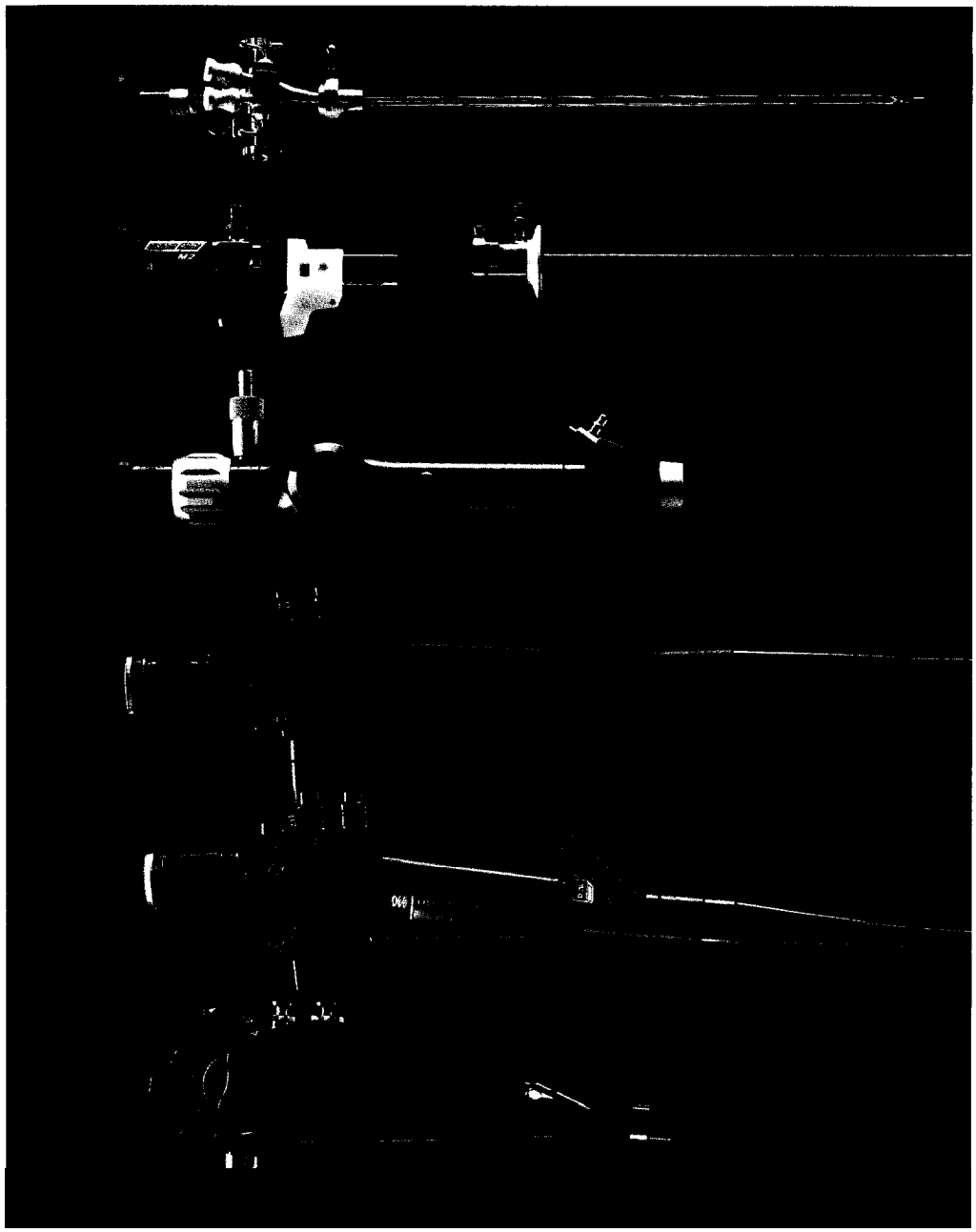
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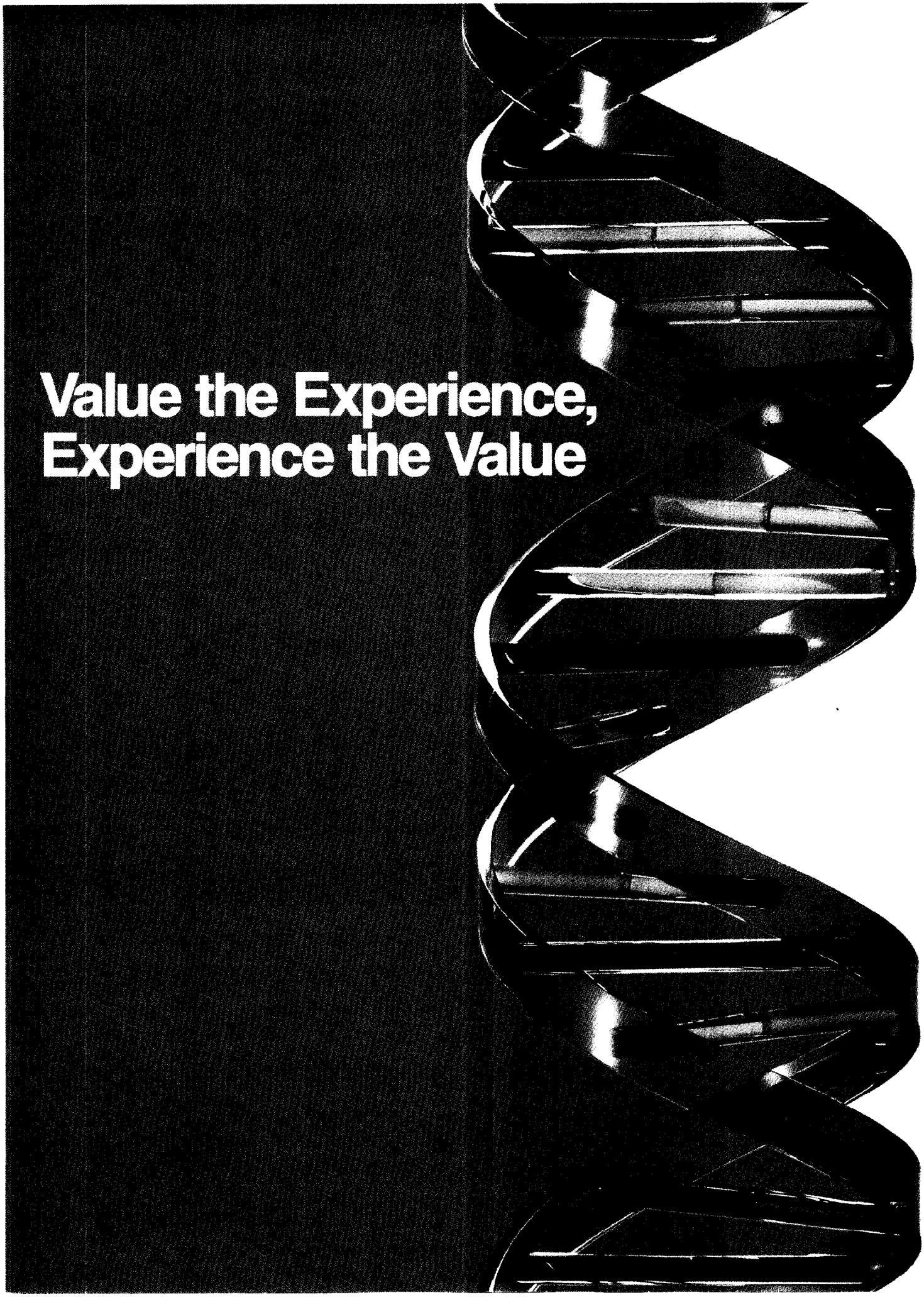



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# Value the Experience, Experience the Value

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

INDICATIONS AND USAGE

RECOMBIVAX HB is indicated for vaccination against Infection caused by all known subtypes of hepatitis B virus. RECOMBIVAX HB Dialysis Formulation is indicated for vaccination of adult predialysis and dialysis patients against infection caused by all known subtypes of hepatitis B virus.

Vaccination with RECOMBIVAX HB 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 the vaccine (see CONTRAINDICATIONS).

Because of the long incubation period for hepatitis B, it is possible for unrecognized infection to be present at the time the vaccine is given. The vaccine 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 the 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 the 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. Animal reproduction studies have not been conducted with the vaccine. It is also not known whether the vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. The vaccine should be given to a pregnant woman only if clearly needed.

Nursing Mothers

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

Pediatric Use

RECOMBIVAX HB has been shown to be usually 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 for recommended pediatric dosage and for recommended dosaoe for infants born to HBsAg-positive mothers

The safety and effectiveness of RECOMBIVAX HB Dialysis Formulation in children have not been established.

ADVERSE REACTIONS

RECOMBIVAX HB and RECOMBIVAX HB Dialysis Formulation are generally well tolerated. No serious adverse reactions attributable to the vaccine have been reported during the course of clinical trials. 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, 3,256 doses of RECOMBIVAX HB were administered to 1,252



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 (≥100°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; dysoeosia: 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.

The following additional adverse reactions have been reported with use of the marketed vaccine. In many instances, the relationship to the vaccine was unclear.

Hypersensitivity: Anaphylaxis and symptoms of immediate hypersensitivity reactions including rash, pruritus, urticaria. edema, angioedema. dyspnea, chest discomfort, bronchial spasm, palpitation, or symptoms consistent with a hypotensive episode have been reported within the first few hours after vaccination. An apparent hypersensitivity syndrome (serum-sickness-like) of delayed onset has been reported days to weeks after vaccination, including arthralgia/arthritis (usually transient), fever, and dermatologic reactions such as urticaria. ervthema multiforme, ecchymoses, and erythema nodosum (see WARNINGS and PRECAUTIONS).

Nervous System: Peripheral neuropathy including Bell's Palsy; muscle weakness; Guillain-Barre syndrome.

Special *Senses:* Optic neuritis.

Potential ADVERSE EFFECTS

In addition, a variety of adverse effects not observed in clinical trials with RECOMBIVAX HB or RECOMBIVAX HB Dialysis Formulation 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:

Nervous *System:* Neurological disorders such as myelitis including transverse myelitis: acute radiculoneuropathy; herpes zoster.

*Hematologic*: Thrombocytopenia.

*Special Senses:* Tinnitus; visual disturbances

RECOMBIVAX HB"
(Hepatitis B Vaccine [Recombinant], MSD)

DOSAGE AND ADMINISTRATION

Do *not* inject intravenous/v or *intradermally.*

RECOMBIVAX HB DIALYSIS FORMULATION (40 mcg/mL) IS INTENDED ONLY FOR ADULT PREDIALYSIS/DIALYSIS PATIENTS.

RECOMBIVAX HB (10 mcg/mL) IS NOT INTENDED FOR USE IN PREDIALYSIS/DIALYSIS PATIENTS.

RECOMBIVAX HB and RECOMBIVAX HB Dialysis Formulation *are* for intramuscular injection. The *deltoid* muscle is the preferred site for intramuscular injection in adults. Data suggest that injections given in the buttocks are frequently 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.

For persons at risk of hemorrhage following intramuscular injection, RECOMBIVAX HB may be administered subcutaneously. 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) who are at risk of hemorrhage following intramuscular injections.

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

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

| Age group | Initial | 1 month | 6 months |
|---|---|---|---|
| Birth* through 10 years of age | 0.25 mL (2.5 mcg) | 0.25 mL (2.5 mcg) | 0.25 mL (2.5 mcg) |
| 11-19 years of age | 0.5 mL (5 mcg) | 0.5 mL (5 mcg) | 0.5 mL (5 mcg) |
| ≥20 years | 1mL (10 mcg) | 1mL (10 mcg) | 1 mL (10 mcg) |

*Infants born of HBsAg-negative mothers.

The recommended RECOMBIVAX HB Dialysis Formulation vaccination regimen far predialysis/dialysis patients is as follows:

| Group | Formulation | Initial | 1 month | 6 months |
|---|---|---|---|---|
| Predialysis and Dialysis Patients | Dialysis 40 mcg/mL | 1 mL | 1 mL | 1 mL |

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

The recommended regimen for infants born of HBsAg-positive mothers is as follows:

| | Birth | Within 7 days | 1 month | 6 months |
|---|---|---|---|---|
| RECOMBIVAX HB | | 0.5 mL (5 mcg) | 0.5 mL (5 mcg) | 0.5 mL (5 mcg) |
| HEPATITIS B IMMUNE GLOBULIN | 0.5 mL | — | — | — |

Storage

Store vials at 2°–8°C (36°–46°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.

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