booster dose, a check of antibody status, or administration of HBIG following documented parenteral exposure to HBV contaminated blood?

Some considerations are the extremely high cost of vaccination (~ $100 per person), the need for more data on side effects collected from larger groups of vaccinees, and the suggestion that cost benefit analyses produce cost savings to society from HBV vaccination only when the annual incidence of HBV is 2% or more. With these in mind, it seems logical to restrict initial vaccination efforts within acute care hospitals to personnel employed in hemodialysis units, clinical chemistry, serology labs, and blood banks. In these areas, incidence rates of 3% per year have been shown. Hard incidence data have not been published for other groups, but vaccination of operating room personnel, practicing surgeons, anesthesiologists, and pathologists, emergency room staff and possibly phlebotomists, seems defensible. I do not think that current data support the use of HBV vaccine in non-surgical physicians, in general ward medicine, surgery, pediatric nurses, or among housekeeping, x-ray, laundry, inhalation therapy or other ancillary health personnel, who are based in acute care hospitals. The above suggestions are made in reference to data from Pattison[11] and others suggesting that frequent exposure to blood is the major risk factor for HBV infection in hospital personnel.

The HBV vaccine will not appreciably diminish the risk of exposure to HBV among hospital personnel for many years, if ever, since fully 50% of reported cases of HBV infection in a community are sporadic and some high-risk groups may prove difficult to vaccinate. It may offer protection against clinical disease and the severe sequelae of infection of small groups of hospital workers who are at a higher than usual risk of exposure to, and acquisition of, HBV infection in the hospital setting. Vaccination will not relieve hospitals of the need to isolate patients with hepatitis, to identify chronic carriers, or to handle blood products carefully because immunity can be overwhelmed by massive inocula, and because non A non B hepatitis is still a concern.

With the licensure and availability of this new vaccine, the need for careful epidemiologic investigation and well-organized hospital employee health services is increasing. Well-controlled studies to define the level of increased risk of HBV infection in hospital personnel are critically needed. Careful followup of large groups of vaccinated individuals for untoward effects over the short and long term are also necessary. Only after such data are collected can better, and more defensible, recommendations for the use of HBV vaccine in hospital personnel be made.

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Hepatitis B Vaccine: Its Risks and Benefits

The advent of a vaccine to prevent hepatitis B is the culmination of a 25-year explosion of knowledge concerning the disease. From the discovery of the Australia antigen to the development of a vaccine from an as yet uncultivable virus, this is the story of a triumph of medical research that equals other major breakthroughs in medicine this century.

One group to benefit will be medical workers, especially those who are exposed to blood and blood products. The vaccine comes at a time when we recognize that the problem of unidentified hepatitis carriers has increased sharply with the arrival in the U.S. over the past few years of immigrants from areas of the world where the disease is endemic. In addition, new medical technologies which rely increasingly on intravascular monitoring, expose more health care workers to more patients' blood than ever before.

Hepatitis B is viewed by the average physician or nurse with the same fear that once was reserved for streptococcal infection in the pre-penicillin era. Everyone knows or has heard of someone who has died from the disease. So it is to an unusually receptive audience that the vaccine is offered. Past experiences with immunization programs for medical personnel have shown that they are apathetic if not overtly hostile toward plans to vaccinate them against rubella or influenza.[1,2] Because of their fear of hepatitis, they are unlikely to react similarly in this case. Some of the concern about immunization has been founded in fact, but much has been misunderstanding of the risks involved. Therefore, it is equally important for us to examine the true risks and benefits of this vaccine from a scientific rather than an emotional standpoint.

The efficacy of the vaccine in a high-risk population is in little doubt. Its ability to prevent disease and sero-

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conversions has been clearly demonstrated.[3] However, what is the risk of a nurse or physician developing the disease? Is this risk equal for medical workers of different ethnic origin and sex or, as is more likely, is the risk a function of childhood exposure and length and type of patient care activities?

Neither the attack rate for workers in various patient care occupations nor the attack rate for workers of different ages, sex, race and length of employment is known. Completed studies have looked at the prevalence of hepatitis serum markers and only in a few select groups (eg, dentists) have attack rates been calculated.[4] It may well be appropriate to immunize dentists, dialysis workers and blood banking technicians, but other members of the hospital community may be at much less risk.

How then are we to judge the benefits for those who are at a lesser but as yet undefined risk? This can only be assessed by including an evaluation of the vaccine's potential for serious adverse reactions.

Current production of the vaccine appears to yield a highly purified product. Reactions of an immediate allergic type are unlikely to present a major problem. However, no vaccine can ever be assumed to be entirely safe, and this vaccine cannot be excepted. That it is manufactured from a virus for which there is convincing evidence of oncogenicity in man must raise some concern over long-term exposure and the reimmunization that appears to be necessary.[5]

Unanswered and perhaps unanswerable for years to come are the consequences of administering a vaccine prepared from a human oncogenic virus. Studies in Taiwan have shown that hepatocellular carcinoma is the leading cause of death in men with persistent hepatitis B antigenemia.[5] The mechanism whereby the virus achieves this is not known. There is speculation that the antigenemia must be persistent and present for many years, perhaps from childhood. That repeated exposure to the vaccine could produce such a result is unlikely but the possibility exists. Few vaccines have been introduced without the occurrence of some unforeseen adverse reaction.

The vaccine is extremely difficult and expensive to manufacture by the current process. Initially, it will be in very short supply and great demand. While this will almost certainly lead to other suppliers entering the field, perhaps with new techniques, this too must cause us to review the risks associated with differently manufactured lots.

The cost of an immunization program might be more than equalled by the losses incurred by one or two cases of disease per year in an average sized community hospital. To the very considerable expense of the vaccine, some $100 for a course of the product alone, and the booster immunizations required every few years, must be added the cost of antibody screening of potential recipients. It would seem unwise and expensive to vaccinate those who already are naturally immune. There are some 4.5 million health care workers in the United States. An unselective program to immunize all could cost $450 million for vaccine alone in the first year and $150 million every year thereafter, not considering the usual turnover in the population. Such a program would likely, because of its size, uncover adverse reactions not noted in the smaller clinical trials. This requires that a careful analysis of which health care workers really need the vaccine, and to whom we can afford to give it, must be made.

It is anticipated that the American Committee on Immunization Practices will issue recommendations on the use of the vaccine just prior to its commercial release. These guidelines should address those medical workers known to be at risk and, it is hoped, caution against other indiscriminate use.

These considerations must not undermine our confidence in the vaccine or our resolve to use it appropriately, but encourage us to weigh carefully when and in whom.

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Hepatitis B Vaccine Use in Health Care Professionals

In November 1981, the Food and Drug Administration granted a licensure for an inactivated hepatitis B vaccine. The Centers for Disease Control estimates that in the United States there are approximately 200,000 cases of hepatitis B annually and of these, approximately 10% (20,000) become hepatitis B carriers, this despite the dramatic decrease in the last decade of transfusion-related hepatitis B. In addition there are approximately 4,000 deaths annually due to cirrhosis and 800 deaths due to hepatocellular carcinoma, felt directly related to chronic hepatitis B infection.

The feasibility for the development of a hepatitis B vaccine was demonstrated by Krugman and associates[1] who reported that a heat inactivated serum containing hepatitis B surface antigen (HB_sA_g) was partially protective and noninfectious. The current vaccine was developed by Hilleman and associates[2] and consists of a highly purified, formalin inactivated HB_sA_g particles derived from plasma of chronic carriers.

The vaccine has been found to be highly immunogenic for newborns, children and young adults. Immunocompromised individuals and individuals over age 40 do not respond as well. The vaccine series consists of three

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