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C.M.G. Buttery, M.D., M.P.H., Commissioner
Grayson B. Miller, Jr., M.D., Epidemiologist
Editor: Carl W. Armstrong, M.D.

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Update on Hepatitis B Prevention

Introduction

Hepatitis B virus (HBV) infection is a major cause of acute and chronic hepatitis, cirrhosis, and primary hepatocellular carcinoma in the United States and worldwide. Since 1982, a safe and effective hepatitis B (HB) vaccine manuactured from human plasma has been available in the United States. This vaccine has been recommended as preexposure prophylaxis for persons at high or moderate risk of HBV infection (*1*). In addition, the combination of HB vaccine and hepatitis B immunoglobulin (HBIG) has been recommended for postexposure prophylaxis in susceptible persons who have perinatal or needle-stick exposure to known HBV-positive persons or their blood.

This statement provides an update on HB vaccine usage and on its impact on disease incidence in the 5 years following its licensure. In addition, it provides both recommendations for using a new HB vaccine produced in yeast by recombinant DNA technology and an assessment of the need for HB vaccine booster doses for persons who have received the initial three-dose regimen. Basic recommendations on preexposure and postexposure usage of HB vaccine and on prevaccination serologic testing for susceptibility to hepatitis B are unchanged. Previous recommendations should be consulted for a complete discussion of the usage of HB vaccine (*1*).

Plasma-Derived HB Vaccine

Patterns of Usage to Date

Since the plasma-derived HB vaccine became available in June 1982, 4,400,000 doses have been distributed in the United States, and an estimated 1,400,000 persons have completed the three-dose series (Merck Sharp & Dohme, unpublished data). During this 5-year period, vaccination programs and overall vaccine usage have focused primarily on three risk groups—persons who work in health-care professions and have exposure to blood, staff and clients of institu-

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tions for the developmentally disabled, and staff and patients in hemodialysis units. Although no precise figures are available, it is estimated that more than 85% of distributed vaccine has been used for these groups.

Development of vaccination programs for health-care workers has progressed steadily since vaccine licensure. Several surveys of hospitals in 1985 showed that between 49% and 68% of hospitals had established HB vaccination programs and that the number has increased steadily each year (CDC, unpublished data). Large hospitals (>500 beds) were most likely to establish programs (90%). However, by June 1985, 60% of hospitals with fewer than 100 beds also had begun vaccination programs. In 75% of the programs, vaccination was recommended for high-risk health-care workers (as defined by the hospital), and, in 77%, the hospital paid for these vaccinations. In addition, 70% of states had established programs for vaccinating health-care workers under state jurisdiction (CDC, unpublished data).

In spite of these programs, the actual use of vaccine in high-risk health-care professions has been modest. One statewide survey showed that, in hospitals with HB vaccine programs, only 36% of persons at high risk had actually received vaccine (CDC, unpublished data). In one survey in three large cities, only 24% of physicians had received vaccine (CDC, unpublished data). National surveys have shown higher rates of vaccination among dentists (44% in early 1986) and hemodialysis staff (an estimated 44% in 1985); however, even these rates fall well short of optimal coverage (CDC, unpublished data).

Development of vaccination programs has also progressed for several other groups at high risk of HBV infection. By mid-1985, 94% of states had established vaccination programs for the developmentally disabled in institutions under state jurisdiction, and 75% had programs for staff of such facilities (CDC, unpublished data). By 1986, an estimated 27% of the developmentally disabled had received HB vaccine (Merck Sharp & Dohme, unpublished data). In addition, wide-scale programs directed at vaccinating all susceptible persons were established in 1981 for Alaskan Natives and in 1985 for the population of American Samoa.

Nevertheless, there has been little progress in developing vaccination programs for other major risk groups, including parenteral drug abusers, homosexual men, and heterosexually active persons with multiple partners. Few states have established programs for offering vaccine to any of these groups, and private usage of vaccine among these groups is believed to be limited.

Impact on Disease Incidence

The incidence of reported hepatitis B has increased steadily over the last decade. Hepatitis B is now the most commonly reported type of hepatitis in the United States. In 1978, 15,000 cases of clinical hepatitis B were reported to CDC, for an incidence rate of 6.9/100,000 population. At that time, CDC estimated that there were actually 200,000 persons with HBV infection and that 50,000 of these had clinically confirmed cases with jaundice. The incidence rate of reported disease increased 33%, to 9.2/100,000, in 1981, the year prior to vaccine availability. It continued to increase during the initial 4 years of vaccine availability, reaching a rate of 11.5/100,000 in 1985 (*2*). Based on a comparison with the overall infection rate estimated in 1978, the incidence of HBV infection in the United States is now estimated at over 300,000 cases per year.

The apparent lack of impact of HB vaccine on the incidence of hepatitis B is attributable to several factors. First, the majority of acute hepatitis B cases now occur in three groups: homosexual men, parenteral drug abusers, and persons acquiring disease through heterosexual exposure (*3*). None of these groups is being reached effectively by current HB vaccine programs. In contrast, fewer than 10% of cases occur in health-care workers, the institutionalized developmentally disabled, and other groups currently accounting for the bulk of vaccine usage. Finally, up to 30% of patients deny any of the recognized risk factors, even after careful questioning. No effective strategy has been devised to prevent disease among this group, although some are probably undisclosed members of the three major risk

groups.

A reduction in the incidence of hepatitis B can be expected only if significant proportions of persons at high risk receive vaccine. Increased efforts are needed to develop programs to vaccinate persons in all high-risk groups and to increase compliance among those who are susceptible in areas where programs are established. To have any effect on the incidence of hepatitis B, use of HB vaccine in the United States must extend beyond the current groups of recipients.

New Recombinant DNA HB Vaccine

Formulation

In July 1986, a new, genetically engineered HB vaccine (Recombivax HB®; Merck Sharp & Dohme) was licensed by the U.S. Food and Drug Administration. This vaccine, as formulated, has an immunogenicity comparable to that of the currently available plasma-derived vaccine (Heptavax B®; Merck Sharp & Dohme). The two vaccines are also comparably effective when given with HBIG to prevent perinatal HBV transmission. The new vaccine provides an alternative to the plasma-derived HB vaccine for almost all groups at risk of HBV infection.

The recombinant vaccine is produced by *Saccharomyces cerevisiae* (common baker's yeast) into which a plasmid containing the gene for the Hepatitis B surface antigen (HBsAg) subtype adw has been inserted (*4*). HBsAg is harvested by lysing the yeast cells and is separated from yeast components by hydrophobic interaction and size-exclusion chromatography. The purified HBsAg protein undergoes sterile filtration and treatment with formalin prior to packaging. The vaccine is packaged to contain 10μg HBsAg protein per ml, absorbed with 0.5 mg/ml aluminum hydroxide; a 1:20,000 concentration of thimerosal is added as a preservative.

The recombinant HBsAg takes the form of 17-25 nm spherical particles, similar in appearance to human plasma-derived HBsAg. The recombinant particles differ in that the HBsAg is not glycosylated, whereas up to 25% of plasma-derived HBsAg is glycosylated. The vaccine contains more than 95% HBsAg protein. Yeast-derived protein can constitute up to 4% of the final product, but no yeast DNA is detectable in the vaccine.

Immunogenicity and Efficacy

The immunogenicity of the recombinant HB vaccine is comparable to that of the plasma-derived product (*5*). When given in a three-dose series (10μg per dose), recombinant HB vaccine induces protective antibodies (anti-HBs*) in over 95% of healthy adults 20–39 years of age. Studies comparing antibody responses of healthy adults show equal rates of seroconversion following the three doses of either the recombinant vaccine (10μg per dose) or the plasma-derived vaccine (20μg per dose). However, the geometric mean titers (GMT) of antibodies developed by recipients of the recombinant vaccine have ranged from equal to

30% as high as those developed by recipients of the plasma-derived vaccine. The recombinant vaccine, like the plasma-derived vaccine, produces a somewhat lower antibody response in older adults than in younger adults (*5*).

In studies using three 5-μg doses of recombinant vaccine for children <12 years of age, over 99% of the recipients have developed protective levels of antibodies. Hemodialysis patients develop a poorer response to the recombinant vaccine than do healthy adults. For example, in one study using three 40-μg doses of recombinant HB vaccine, only 64% of vaccine recipients developed protective levels of antibodies.

The recombinant HB vaccine has been shown to prevent HBV infection of vaccinated chimpanzees challenged intravenously with HBV of either adw or ayr subtypes. In studies of infants born to HBsAg-and HBeAg-positive mothers, the combination of HBIG (0.5 cc at birth) and recombinant HB vaccine (5μg in each of three doses) protected 94% of infants from developing the chronic carrier state, an efficacy equalling that of HBIG plus plasma-derived HB vaccine (*6*). The simultaneous administration of HBIG did not interfere with induction of anti-HBs antibody response by the recombinant HB vaccine.

There have been no large-scale efficacy trials of recombinant vaccine in adults. Nevertheless, the immunogenicity studies, the challenge studies using chimpanzees, and the efficacy trials of the HB vaccine and HBIG in infants born to mothers who are carriers of HBV strongly suggest that the efficacy of recombinant HB vaccine in adults is comparable to that of the plasma-derived product.

Safety

Because only the portion of the HBV viral genome that codes for the surface coat of the virus (HBsAg) is present in the recombinant yeast cells, no potentially infectious viral DNA or complete viral particles can be produced. No human or animal plasma or other blood derivative is used in the preparation of recombinant HB vaccine.

During prelicensure trials, approximately 4,500 persons received at least one dose, and 2,700 persons completed the vaccine series (*5*). Reported side effects were similar in extent and variety to those following administration of the plasma-derived vaccine. Seventeen percent of those vaccinated experienced soreness at the injection site, and 15% experiences mild systemic symptoms (fever, headache, fatigue, and nausea). To date, no severe side effects have been observed nor have significant allergic reactions been reported. Although yeast-derived proteins may constitute up to 4% of the protein in

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**Greater than 10 milli-International Units (mIU)/ml of anti-HBs, approximately equal to 10 sample ratio units by radioimmunoassay or positive by enzyme immunoassay.*

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the vaccine, no adverse reactions that could be related to changes in titers of antibodies to yeast derived antigens occurred during clinical trials.

Early concerns about safety of plasma-derived HB vaccine, especially the concern that infectious agents such as human immunodeficiency virus (HIV) present in donor plasma pools might contaminate the final product, have proven to be unfounded (*7*). There are no data to indicate that the recombinant vaccine is potentially or actually safer than the currently licensed plasma-derived product.

Dosage and Schedule

The recombinant HB vaccine is given in a series of three doses over a 6-month period. The second dose is administered 1 month after the first, and the third dose, 5 months after the second. For normal adults and children >10 years of age, the recommended dose is 10µg (1 ml) intramuscularly in each of the three inoculations. Children <11 years of age should receive a 5-µg dose (0.5 ml) by the same schedule. Newborns of mothers who are carriers of HBsAg should receive the three-dose series (5µg per dose) by the same schedule; however, the first dose, which is given at birth should be combined with a single dose of HBIG (0.5) given intramuscularly at another site.

The recommended dose of recombinant HB vaccine for hemodialysis patients or other immunosuppressed persons is 40µg, which is identical to the dose of plasma-derived vaccine recommended for these groups. A specially formulated preparation (40µg HBsAg protein/ml adsorbed with 0.5 mg aluminum hydroxide) is being developed for these patients. At present, it is not advisable to administer the standard formulation of recombinant HB vaccine to these patients because this would require a large volume (4.0 cc), which is inconvenient for injection in the deltoid, muscle, and would contain more aluminum hydroxide (2.0 mg) than currently recommended as an adjuvant in vaccines (1.25 mg per dose). Only plasma-derived vaccine should be used for these patients.

As with plasma-derived vaccine, recombinant HB vaccine should only be given to older children and adults in the deltoid muscle and to neonates or infants in the anterolateral thigh muscle. The vaccine should be stored at 2 C to 6 C (36 F to 43 F) and *should not be frozen;* freezing destroys the potency of this vaccine.

The response to vaccination by the standard schedule using one or two doses of plasma-derived vaccine followed by the remaining doses of recombinant vaccine has not been studied. However, because the immunogenicities of the two vaccines are similar, it is likely that the response will be comparable to that induced by three doses of either vaccine alone. The response to revaccination with the recombinant vaccine following nonresponse to an initial series of plasma vaccine has not been evaluated.

Indications for Use

The indications for use of the recombinant HB vaccine are identical to those for the plasma-derived product, except that the present formulation of the recombinant HB vaccine should not be used for hemodialysis patients or other immunosuppressed persons (Table 1) (*1*). For other groups, including persons with Down's syndrome, there are no data indicating that the recombinant HB vaccine is either superior or inferior to the plasma-derived HB vaccine for any preexposure or postexposure indication.

Precautions

The recombinant HB vaccine contains only noninfectious HBsAg particles; therefore, vaccination of a pregnant woman should entail no risk to either the woman or the fetus. Furthermore, HBV infection in a pregnant woman can result in severe disease for the mother and chronic infection of the newborn. Pregnancy should not be considered a contraindication for women in high-risk groups who are eligible to receive this vaccine.

Need for Vaccine Booster Doses

Long-term Protection by Plasma-Derived HB Vaccine

In short-term efficacy studies, the plasma-derived HB vaccine provided protection against HBV infection for 85%–95% of vaccine recipients, including virtually all those who developed adequate levels of antibodies (see footnote on pg. 355) (*8,9*). A recent evaluation of the long-term protection afforded by this vaccine (>5 years) provides a basis for recommendations concerning the need for booster doses in previously vaccinated persons (*10*).

Currently available data indicate that vaccine-induced antibody levels decline significantly (*10*). Antibody may decrease to low levels for 30%–40% of vaccinated adults who initially develop adequate levels of antibody during the 5 years after vaccination, and it may become undetectable in 10%–15% of them. The duration of antibody persistence is

Table 1. Persons for whom hepatitis B vaccine is recommended or should be considered*

Preexposure

Persons for whom vaccine is recommended:

- Health-care workers having blood or needle-stick exposures
- Clients and staff of institutions for the developmentally disabled
- Hemodialysis patients
- Homosexually active men
- Users of illicit injectable drugs
- Recipients of certain blood products
- Household members and sexual contacts of HBV carriers
- Special high-risk populations

Persons for whom vaccine should be considered:

- Inmates of long- term correctional facilities
- Heterosexually active persons with multiple sexual partners
- International travelers to HBV endemic areas

Postexposure

- Infants born to HBV positive mothers
- Health-care workers having needle-stick exposure to human blood

*Detailed information on recommendations for HB vaccination is available (*1*).

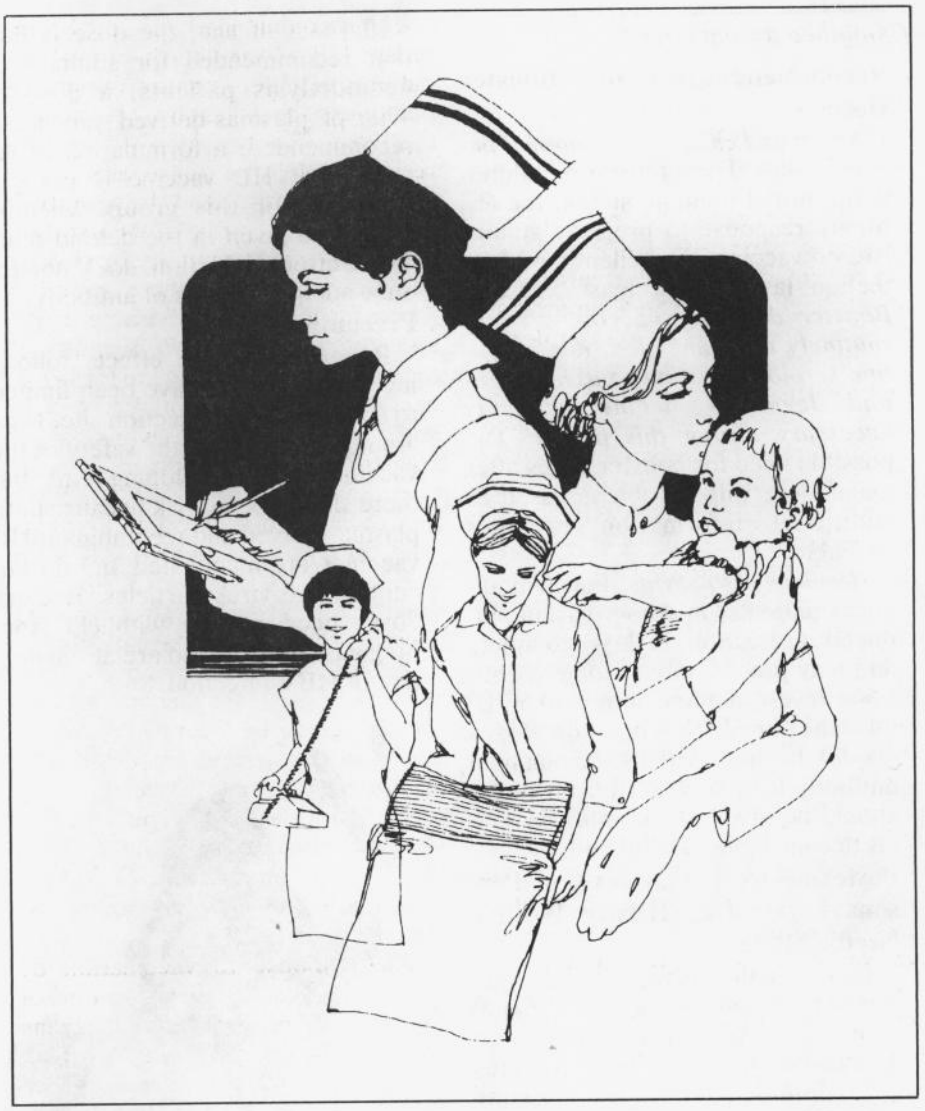
directly related to the peak level achieved after the third dose of vaccine (*11*). The longer persistence of detectable levels of antibody observed in children and young adults (<20 years of age) is consistent with the higher peak response in these age groups.

Studies of the licensed plasma-derived HB vaccine in adults have demonstrated that, in spite of declining levels of antibody, protection against clinical (or viremic) HBV infection persists for >5 years (*10*). Although the risks of HBV infection appear to increase as antibody levels become low or undetectable, the resultant infections are almost always innocuous and do not cause detectable viremia, liver inflammation, or clinical illness. These infections are detected by serologic evidence of an increase of anti-HBs levels associated with the appearance of antibody to the hepatitis B core antigen (anti-HBc). To date, only one transient viremic infection has been recognized in a vaccine responder within 72 months after vaccination. This infection produced mild alanine aminotransferase elevation, but no clinical illness (*10*). Thus, among adults who have responded to the vaccine, protection against clinically significant HBV infection appears to outlast the presence of detectable anti-HBs and can persist for ≥2 years among vaccine recipients whose antibodies have declined to low or undetectable levels.

For infants born to mothers who are carriers of HBV, there are insufficient data to assess duration of antibody persistence and protection against clinically significant HBV infection with the U.S. plasma-derived vaccine. One study, in a developing country (Senegal) and using a different plasma-derived HB vaccine, has demonstrated that protection against viremic HBV infection can decline within 6 years in infants vaccinated between 6 months and 2 years of age (*12*). Firm data on the duration of protection among infants receiving the vaccines licensed in the United States will be necessary before recommendations on booster doses can be made for this group.

Postvaccination Testing of Response to Vaccine

When properly administered, HB vaccine produces anti-HBs in more than 90% of healthy person. Testing for immunity following vaccination has been recommended only for persons in whom suboptimal response to vaccine is anticipated, including persons who received vaccine in the buttock or persons, such as hemodialysis patients, whose subsequent management depends on knowing their immune status (*1*). Revaccination, which has produced adequate antibody in only 30%–50% of persons who have not responded to primary vaccination in the deltoid, is not routinely recommended (*1,10*).



Vaccine program coordinators in hospitals may decide to test vaccine recipients serologically to assess their antibody responses, even though such postvaccination testing is not routinely recommended. Persons electing to do postvaccination testing should be aware of potential difficulties in interpreting the results. Serologic testing within 6 months of completing the primary series will differentiate persons who respond to vaccine from those who fail to respond. However, the results of testing undertaken more than 6 months after completion of the primary series are more difficult to interpret. A vaccine recipient who is negative for anti-HBs between 1 and 5 years after vaccination can be 1) a primary nonresponder who remains susceptible to hepatitis B or 2) a vaccine responder whose antibody levels have decreased below detectability but who is still protected against clinical HBV disease (10).

There is no need for routine anti-HBs testing 1 to 5 years after vaccination unless there has been a decision to provide booster doses for persons who are anti-HBs negative. This strategy is medically acceptable, but costly, and will prevent few additional cases of disease because of the excellent long-term protection already provided by the primary series of vaccine.

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Recommendations for Booster Doses

Adults and children with normal immune status. For adults and children with normal immune status, the antibody response to properly administered vaccine is excellent, and protection lasts for at least 5 years. *Booster doses of vaccine are not routinely recommended, nor is routine serologic testing to assess antibody levels in vaccine recipients necessary during this period.* The possible need for booster doses after longer intervals will be assessed as additional information becomes available.

Hemodialysis patients. For hemodialysis patients, in whom vaccine-induced protection is less complete and may presist only as long as antibody levels remain above 10 mIU/ml, the need for booster doses should be assessed by semiannual antibody testing (*13*). Booster doses should be given when antibody levels decline below 10 mIU/ml.

Postexposure Prophylaxis of Persons Exposed to HBsAg Positive Needle Sticks

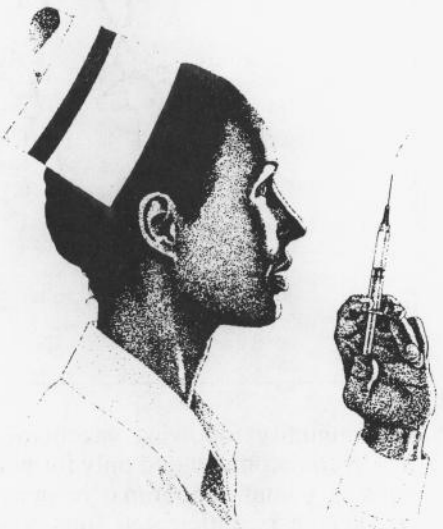
In vaccinated persons who experience percutaneous or needle exposure to HBsAg-positive blood, seroligic testing to assess immune status is recommended unless testing within the previous 12 months has indicated adequate levels of antibody. If the exposed person is tested and found to have an inadequate antibody level, treatment with HBIG and/or a booster dose of vaccine is indicated, depending on whether vaccination has been completed and whether the person is known to have previously responded to HB vaccine. Detailed recommendations on prophylaxis in this situation are provided in the previous recommendations for HB vaccine (*1*).

Dosage

When indicated, HB vaccine recipients can be given booster doses of either plasma-derived or recombinant HB vaccine. Booster doses of either vaccine induce prompt anamnestic responses in over 90% of persons who initially respond to vaccine but subsequently lose detectable antibody (*14,15*). The booster dose for normal adults is 20μg of plasma-derived vaccine or 10μg of recombinant vaccine. For newborns and children <10 years of age, the dose is half that recommended for adults. For hemodialysis patients, a dose of 40μg of plasmas-derived vaccine is recommended; a formulation of recombinant HB vaccine is not yet available for this group. Vaccine should be given in the deltoid muscle. Buttock injection does not induce adequate levels of antibody.

Precautions

Reported adverse effects following booster doses have been limited to soreness at the injection site. Data are not available on the safety of the vaccine for the developing fetus, but there should be no risk because both plasma-derived and recombinant HB vaccines are inactivated and do not contain live virus particles. Booster doses need not be withheld from pregnant women who are at ongoing risk of HBV infection.



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Reprinted from MMWR 1987;36:353-360,366.

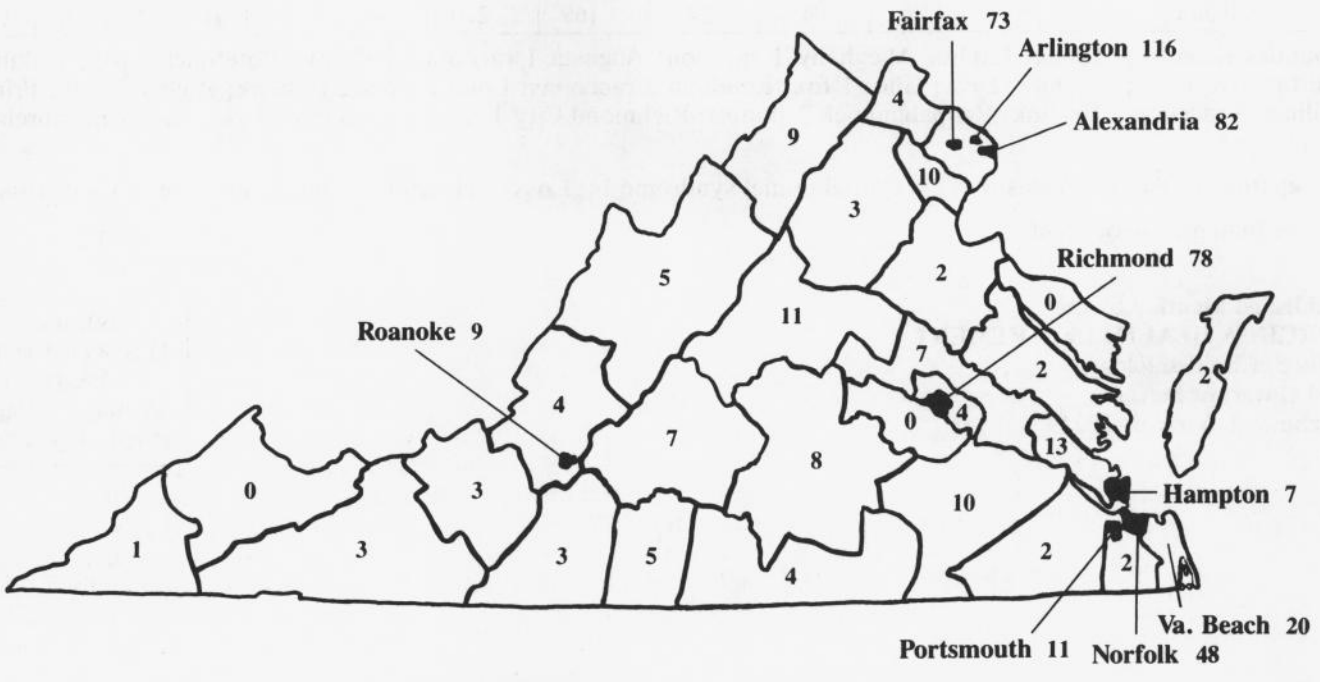
Selected Cases of HIV Infection Now Reportable

The Governor has approved an emergency regulation requiring every physician to report, under special circumstances, those persons identified as infected with human immunodeficiency virus (HIV). The wording of this amendment to the *Regulations for Disease Reporting and Control,* captioned "Diseases to be Reported under Special Circumstances", is as follows:

"Every physician shall report to the local health department those persons identified as infected with HIV when the physician needs the health department's support in patient and contact counseling and epidemiologic tracking. Only individuals who have positive blood tests for HIV antibodies as demonstrated by at least two enzyme-linked immunosorbent assays (done in duplicate at the same time or singly at different times), and another testing procedure such as the western blot are considered to have HIV infection".

Selective testing for HIV antibodies coupled with counseling and testing of contacts of individuals who test positive, may be vital in controlling HIV infection. The Department of Health hopes that the discretion granted to the physicians in this regulation will enhance cooperation among private physicians and public health authorities, an indispensable prerequisite for controlling this disease.

AIDS—To December 1, 1987
Numbers by District



Cases of selected notifiable diseases, Virginia, for the period December 1, through December 31, 1987.

Disease	State					Regions				
			Total to Date		Mean 5 Year To Date	This Month				
	This Month	Last Month	1986	1987		N.W.	N.	S.W.	C.	E.
Measles	0	0	60	1	26	0	0	0	0	0
Mumps	8	7	46	88	39	2	1	2	1	2
Pertussis	6	3	56	58	35	1	1	0	0	4
Rubella	0	0	0	1	3	0	0	0	0	0
Meningitis—Aseptic	19	19	311	279	319	3	6	4	1	5
*Bacterial	27	10	239	185	234	2	2	3	4	16
Hepatitis A (Infectious)	23	14	153	247	153	1	14	1	3	4
B (SERUM)	43	40	540	454	531	3	5	1	5	29
NON-A, NON-B	7	0	77	53	89	0	0	0	1	6
Salmonellosis	113	101	1456	1830	1460	11	25	17	35	25
Shigellosis	35	23	101	248	167	3	14	3	3	12
Campylobacter Infections	50	73	591	639	606	11	10	3	11	15
Tuberculosis	61	26	415	458	514	9	15	9	9	19
Syphilis (Primary & Secondary)	21	30	326	318	451	0	4	0	7	10
Gonorrhea	1021	865	18742	14353	20057	—	—	—	—	—
Rocky Mountain Spotted Fever	1	2	51	22	51	0	0	0	1	0
Rabies in Animals	23	24	200	363	391	9	8	4	1	1
Meningococcal Infections	5	5	79	72	71	0	1	2	0	2
Influenza	10	5	4942	0	1677	0	0	0	10	0
Toxic Shock Syndrome	0	0	9	1	8	0	0	0	0	0
Reye Syndrome	0	0	2	0	4	0	0	0	0	0
Legionellosis	1	3	29	12	28	0	0	0	0	1
Kawasaki's Disease	6	4	25	31	26	2	0	1	1	2
Acquired Immunodeficiency Syndrome	45	34	169	270	—	3	16	6	9	11

Counties Reporting Animal Rabies: Alleghany 1 raccoon; Augusta 1 raccoon, 1 skunk; Botetourt 1 fox, 1 skunk; Fairfax 1 raccoon; Fauquier 1 cat; Giles 1 fox; Loudoun 3 raccoons; Louisa 1 cow, 1 skunk; Page 1 skunk; Prince William 3 raccoons, 1 skunk; Rappahannock 2 skunks; Richmond City 1 raccoon; Stafford 1 raccoon; Westmoreland 1 raccoon.

Occupational Illnesses: Asbestosis 28; Carpal tunnel syndrome 14; Loss of Hearing 8; Pneumoconioses 55; Silicosis 1.

*other than meningococcal

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