



VIRGINIA EPIDEMIOLOGY BULLETIN

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Recommendations for the Use of Lyme Disease Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP)

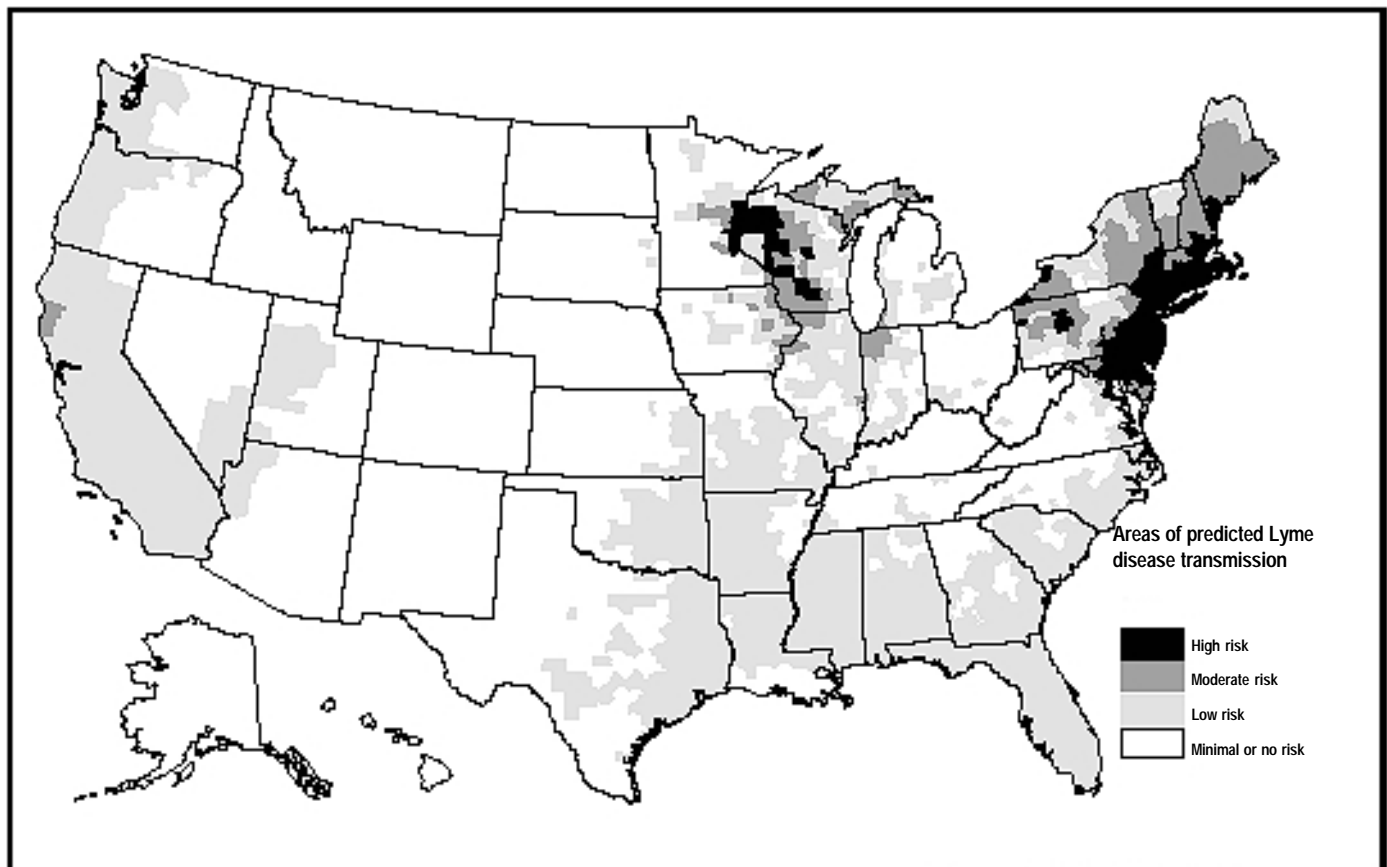
Summary

This report provides recommendations for use of a newly developed recombinant outer-surface protein A Lyme disease vaccine (LYMERix,™ SmithKline Beecham Pharmaceuticals) for persons aged 15-70 years in the United States. The purpose of these recommendations is to provide health-care providers, public health authorities, and the

public with guidance regarding the risk for acquiring Lyme disease and the role of vaccination as an adjunct to preventing Lyme disease. The Advisory Committee on Immunization Practices recommends that decisions regarding vaccine use be made on the basis of assessment of individual risk, taking into account both geographic risk and a person's activities and behaviors relating to tick exposure.

The following is adapted from the MMWR article with the above title (1999;48[No. RR-7]:1-17). If you would like to receive a copy of the entire MMWR article, you may call the Office of Epidemiology at 804/786-6261 or visit the Centers for Disease Control and Prevention (CDC) web site at <http://www.cdc.gov>.

National Lyme disease risk map with four categories of risk



Lyme Disease Vaccine

Description

LYMERix is made from lipidated recombinant outer-surface protein A (rOspA) of *Borrelia burgdorferi*. The rOspA protein is expressed in *Escherichia coli* and purified. Each 0.5-mL dose of LYMERix contains 30 mg of purified rOspA lipidated protein adsorbed onto aluminum hydroxide adjuvant. The rOspA vaccine elicits antibodies that kill Lyme disease spirochetes within the tick gut while the tick is feeding.

Route of Administration, Vaccination Schedule, and Dosage

LYMERix is administered by intramuscular injection, 0.5 mL (30 mg), into the deltoid muscle. Three doses are required for optimal protection. The first dose is followed by a second dose 1 month later and a third dose administered 12 months after the first dose. Vaccine administration should be timed so that the second dose of the vaccine (year 1) and the third dose (year 2) are administered several weeks before the beginning of the *B. burgdorferi* transmission season, which usually begins in April. The safety and immunogenicity of alternate dosing schedules are currently being evaluated.

Vaccine Performance

Safety

A total of 10,936 subjects aged 15-70 years living in Lyme disease-endemic areas were recruited at 31 sites and randomized to receive three doses of vaccine or placebo (Phase III clinical trial). The subjects were then followed for 20 months. Soreness at the injection site was the most frequently reported adverse event, which was reported without solicitation by 24.1% of vaccine recipients and 7.6% of placebo recipients ($p < 0.001$). Redness and swelling at the injection site were reported by less than 2% of either group but were reported more frequently among vaccine recipients than among those who received placebo ($p < 0.001$). Myalgia, influenza-like illness, fever, and chills were more common among vaccine recipients than placebo recipients ($p < 0.001$), but none of these was reported by more than 3.2% of subjects. Reports of arthritis were not significantly different between vaccine and placebo recipients, but vaccine recipients were significantly ($p < 0.05$) more likely to report arthralgia or myalgia within 30 days after each dose. No statistically significant differences existed between vaccine and placebo groups in the in-

cidence of adverse events more than 30 days after receiving a dose, and no episodes of immediate hypersensitivity among vaccine recipients were noted.

Safety in Patients with Previously Diagnosed Lyme Disease

The safety of three different dosage strengths of rOspA vaccine with adjuvant was evaluated in 30 adults with previous Lyme disease in an uncontrolled safety and immunogenicity trial. Doses were administered at 0, 1, and 2 months. Follow-up of subjects was conducted 1 month after the third dose. No serious adverse events were recorded during the study period.

In the randomized controlled Phase III trial, the incidence of adverse events among vaccinees who were seropositive at baseline was similar to the incidence among those who were seronegative. Among vaccinees, 20% of persons who self-reported a history of Lyme disease experienced early (within 30 days of vaccination) musculoskeletal symptoms compared with 13% of persons with no history of Lyme disease ($p < 0.001$). By comparison, a history of self-reported Lyme disease did not affect the incidence of early musculoskeletal symptoms in the placebo group (13% vs 11%, $p = 0.24$). In both the vaccine and placebo groups, there was an increased incidence of late (>30 days post-vaccination) musculoskeletal symptoms in subjects with a history of Lyme disease compared with persons without a history of Lyme disease. No statistically significant difference existed in the incidence of late musculoskeletal adverse events between vaccine and placebo recipients with a self-reported previous history of Lyme disease (33% vs 35%, $p = 0.51$).

Possible Immunopathogenicity of rOspA Vaccine

In chronic Lyme arthritis patients, the levels of antibody to OspA have been found to correlate directly with the severity and duration of the arthritis. The Phase III trial did not detect differences in the incidence of neurologic or rheumatologic disorders between vaccine recipients and their placebo controls during the 20 months after the initial dose. However, because the association between immune reactivity to OspA and treatment-resistant Lyme arthritis is poorly understood, the vaccine should not be administered to persons with a history of treatment-resistant Lyme arthritis.

Efficacy

The vaccine efficacy in protecting against "definite" Lyme disease after two doses was

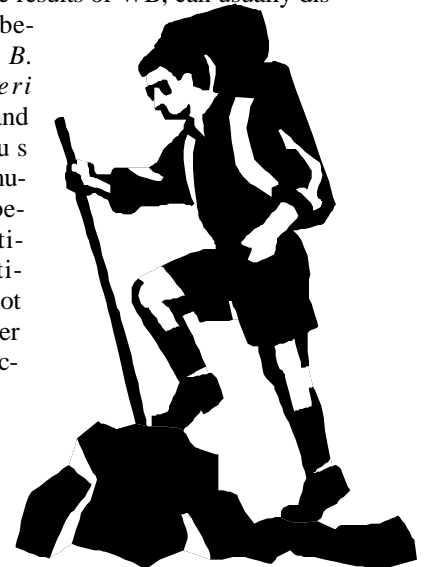
49% (95% confidence interval [CI] = 15%-69%) and after three doses was 76% (95% CI = 58%-86%). (In this study, "definite" Lyme disease was defined as the presence of erythema migrans or objective neurologic, musculoskeletal, or cardiovascular manifestations of Lyme disease, plus laboratory confirmation of infection by culture, polymerase chain reaction [PCR] positivity, or Western immunoblot [WB] seroconversion.) Efficacy in protecting against asymptomatic infection (no recognized symptoms, but with WB seroconversions recorded in year 1 or year 2) was 83% (95% CI = 32%-97%) in year 1 and 100% (95% CI = 26%-100%) in year 2.

Immunogenicity

A subset of adult subjects enrolled in the Phase III clinical trial was studied for the development of OspA antibodies at months 2, 12, 13, and 20. At month 2, one month after the second injection, the geometric mean antibody titer (GMT) of IgG anti-OspA antibodies was 1,227 enzyme-linked immunosorbent assay (ELISA) units/mL. Ten months later, the GMT had declined to 116 ELISA units/mL. At month 13, one month after the third injection, a marked anamnestic response resulted in a GMT of 6,006 ELISA units/mL. At month 20, the mean response had decreased to 1,991 ELISA units/mL. An analysis of antibody titers and the risk for developing Lyme disease concluded that a titer greater than 1,200 ELISA units/mL correlated with protection.

Effect of Vaccination on the Serologic Diagnosis of Lyme Disease

Care providers and laboratorians should be advised that vaccine-induced anti-rOspA antibodies routinely cause false-positive ELISA results for Lyme disease. Experienced laboratory workers, through careful interpretation of the results of WB, can usually discriminate between *B. burgdorferi* infection and previous rOspA immunization, because anti-OspA antibodies do not develop after natural infection.



Assessing the Risk for Lyme Disease

The decision to administer Lyme disease vaccine should be made on the basis of an assessment of individual risk, which depends on a person's likelihood of being bitten by tick vectors infected with *B. burgdorferi*. This likelihood is primarily determined by the following:

- density of vector ticks in the environment, which varies by place and season;
- prevalence of *B. burgdorferi* infection in vector ticks; and
- extent of person-tick contact, which is related to the type, frequency, and duration of a person's activities in a tick-infested environment.

Assessing risk should include consideration of the geographic distribution of Lyme disease. The areas of highest Lyme disease risk in the United States are concentrated within some northeastern and north-central states (see Map). The risk for Lyme disease differs not only between regions and states and counties within states, but even within counties and townships. Detailed information regarding the distribution of Lyme disease risk within specific areas is best obtained from state and local public health authorities.

Activities that place persons at high risk are those that involve frequent or prolonged exposure to the habitat of infected ticks at times of the year when the nymphal stages of these ticks are actively seeking hosts, which in most endemic areas is April-July. Typical habitat of *Ixodes* ticks are wooded, brushy, or overgrown grassy areas that are

favorable for deer and the ticks' rodent hosts. Outdoor activities such as recreation, property maintenance, and occupational pursuits that are carried out in tick habitat can be risky activities.

Recommendations and Contraindications for Use of Lyme Disease Vaccine

Lyme disease vaccine does not protect all recipients against infection with *B. burgdorferi* and offers no protection against other tickborne diseases. Vaccinated persons should continue to practice personal protective measures against ticks and should seek early diagnosis and treatment of suspected tickborne infections. Because Lyme disease is not transmitted person-to-person, use of the vaccine will not reduce risk among unvaccinated persons. Decisions regarding the use of vaccine should be based on individual assessment of the risk for exposure to infected ticks and on careful consideration of the relative risks and benefits of vaccination compared with other protective measures, including early diagnosis and treatment of Lyme disease.

The following recommendations are made regarding use of Lyme disease vaccine:

- **Persons Who Reside, Work, or Recreate in Areas of High or Moderate Risk**

Lyme disease vaccination should be considered for persons aged 15-70 years who engage in activities that

Remembering Our Past - Looking to Our Future APIC - Virginia's 25th Annual Educational Conference

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result in frequent or prolonged exposure to tick-infested habitat.

Lyme disease vaccination may be considered for persons aged 15-70 years who are exposed to tick-infested habitat but whose exposure is neither frequent nor prolonged. The benefit of vaccination beyond that provided by basic personal protection and early diagnosis and treatment of infection is uncertain.

Lyme disease vaccination is not recommended for persons who have minimal or no exposure to tick-infested habitat.

- **Persons Who Reside, Work, or Recreate in Areas of Low or No Risk**

Lyme disease vaccination is not recommended for persons who reside, work, or recreate in areas of low or no risk.

- **Travelers to Areas of High or Moderate Risk**

Because of the limited time of exposure, travelers to Lyme disease-endemic areas within the United States are generally expected to be at lower risk for Lyme disease than those who permanently reside in endemic areas. Vaccination should be considered for travelers to areas of high risk if frequent or prolonged exposure to tick habitat is anticipated.

Travelers can obtain some protection from two doses of vaccine but will not achieve optimal protection until the full series of three doses has been administered. All travelers to high- or moderate-risk areas during Lyme disease transmission season should practice personal protection measures and seek prompt diagnosis and treatment if signs or symptoms of Lyme disease develop. Lyme disease is endemic in some temperate areas of Europe and Asia; however, considerable heterogeneity of expression exists in the Eurasian strains of *B. burgdorferi* that infect humans, and whether the rOspA vaccine licensed for use in the United States would protect against infection with Eurasian strains is uncertain.

(continued on page 5)

Tick Vectors of Lyme Disease

Ixodes scapularis, the black-legged or deer tick, is the vector in the eastern United States; *I. pacificus*, the western black-legged tick is the vector in the western United States. *I. scapularis* is also a vector for human granulocytic ehrlichiosis and babesiosis. In their nymphal stage, these ticks feed predominantly in the late spring and early summer. The majority of Lyme disease cases result from bites by infected nymphs. In highly enzootic areas of the United States, approximately 15%-30% of questing *I. scapularis* nymphs and up to 14% of *I. pacificus* nymphs are infected with *B. burgdorferi*. However, in the southern United States, the prevalence of infection in *I. scapularis* ticks is generally 0%-3%. This low prevalence may be due in part to the feeding habits of southern *I. scapularis* larvae and nymphs that prefer skinks and lizards, instead of the *B. burgdorferi* reservoir rodents. The risk for acquiring Lyme disease in the United States varies with the distribution, density, and prevalence of infection in vector ticks.

During the past several decades, the distribution of *I. scapularis* has spread slowly in the northeastern and upper north-central regions of the United States. Although deer are not competent reservoirs of *B. burgdorferi*, they are the principal maintenance hosts for adult black-legged ticks, and the presence of deer appears to be a prerequisite for the establishment of *I. scapularis* in any area. The explosive repopulation in the eastern United States by white-tailed deer during recent decades has been linked to the spread of *I. scapularis* ticks and of Lyme disease in this region. The future limits of this spread are not known.

A Primer on Lyme Disease and Considerations for Using the Vaccine in Virginia

Suzanne R. Jenkins, VMD, MPH, Director, Zoonotic Disease Control

Introduction

The availability and widespread marketing of the first human vaccine for the prevention of Lyme disease (LYMERix, SmithKline Beecham) is raising questions for both public and private health care providers about the most appropriate use for such a vaccine. Lyme disease is caused by *Borrelia burgdorferi*, a tick-borne spirochete. In this country, more than 90% of the reported cases occur in the Northeast, Mid-Atlantic area (which does not include Virginia) and upper Midwest, with the highest incidence in persons who live, work or recreate in grassy or wooded areas. The tick vector in these areas is *Ixodes scapularis*, the deer tick. Transmission of the spirochete from the tick requires attachment of the tick for at least 36 to 48 hours.

Disease

Lyme disease most often presents with a characteristic rash, erythema migrans (EM), that occurs at the site of the bite and expands to >5cm with central clearing, or annular clearing if there is local reaction to the bite. The rash may be accompanied by nonspecific symptoms such as fever, malaise, fatigue, headache, myalgia and arthralgia. The incubation period can range from a few days to a month, but is usually between one and two weeks. EM is recognized in 85% or more of the patients. A small percentage of infected individuals have no recognizable illness.

Signs of early disseminated infection usually occur days to weeks after the appearance of a single EM lesion and may include multiple EM lesions, neurologic manifestations (lymphocytic meningitis; cranial neuropathy, especially facial nerve palsy; and radiculoneuritis), musculoskeletal manifestations (migratory joint and muscle pains with or without joint swelling), or rarely, cardiac manifestations (transient atrioventricular blocks of varying degrees).

Untreated infection may progress to late disseminated disease weeks to months after infection. The most common clinical picture is intermittent arthritis of one or more joints, particularly the knee. Less commonly, patients

develop chronic axonal polyneuropathy or encephalopathy with subtle cognitive disorders, sleep disturbance, fatigue and personality changes. An ill-defined post-Lyme disease syndrome has been described for some persons following treatment for the disease. Lyme disease is rarely, if ever, fatal.

Diagnosis

Patients who present with EM should be treated without serologic testing. Serologic testing may be useful for persons with endemic exposure, signs of disseminated disease, and no EM. Negative test results help rule out Lyme disease for persons with symptoms compatible with disseminated or late-stage infection. The proportion of false positive results increases as the likelihood of exposure decreases so serologic testing is not recommended for persons who do not have endemic exposure.

When serologic testing is indicated, the Centers for Disease Control and Prevention (CDC) recommends testing initially with a sensitive test, either an enzyme-linked immunosorbent assay (ELISA) or an indirect fluorescent antibody test, followed by testing with the more specific Western immunoblot (WB) test to corroborate equivocal or positive results obtained with the first test. Although antibiotic treatment in early-localized disease can blunt or abrogate the antibody response, patients with early disseminated or late-stage disease usually have strong serologic reactivity and demonstrate expanded WB immunoglobulin G (IgG) banding patterns to diagnostic *B. burgdorferi* antigens.

Antibodies often persist for months or years after successfully treated or untreated infection. Thus, seroreactivity alone cannot be used as a marker of active disease. Neither positive serologic test results nor a history of previous Lyme disease ensures that a person has protective immunity. Repeated infection with *B. burgdorferi* has been reported.

B. burgdorferi can be cultured from 80% or more of biopsy specimens taken from early EM lesions. However, the diagnostic usefulness of this procedure is limited because of the need for a special bacteriologic me-

dium (i.e., modified Barbour-Stoenner-Kelly medium) and protracted observation of cultures. Polymerase chain reaction (PCR) has been used to amplify genomic DNA of *B. burgdorferi* in skin, blood, cerebrospinal fluid, and synovial fluid, but PCR has not been standardized for routine diagnosis of Lyme disease.

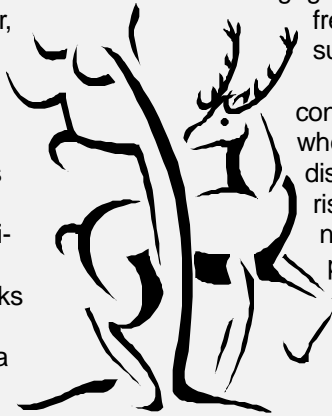
Treatment

Early and uncomplicated infection, including infection presenting with isolated cranial nerve palsy, almost always responds to treatment with orally administered antibiotics. Parenteral antibiotics are recommended for treating meningitis, later stage neurologic Lyme disease and complicated arthritis. Late, complicated Lyme disease may respond slowly or incompletely, and more than one treatment course may be required to eliminate active infection. Refractory Lyme disease arthritis is associated with the HLA-DR4 haplotype and may require anti-inflammatory agents and surgical synovectomy for relief. The minority of patients reporting persistent or recurrent symptoms following appropriate antibiotic therapy (chronic Lyme disease, Post-Lyme disease syndrome) may have symptoms due to some other cause.

Considerations for Vaccine Use

The risk of acquiring Lyme disease should be assessed based on density of vector ticks, prevalence of infected ticks (which requires infected rodent reservoirs), reported rates of human cases, and extent of contact that an individual has with the vector ticks. In Virginia, *I. scapularis* is most prevalent on the Eastern Shore. There are also higher populations on the Peninsula and possibly in the Potomac River basin. As you move west through the Piedmont Plateau and into the mountains, the *I. scapularis* densities fall off. These ticks may be found sporadically in these areas, but are not well established. West of the Blue Ridge Mountains the American Dog Tick, *Dermacentor variabilis*, predominates. The Lone Star Tick, *Amblyomma americanum*, the one with the white spot on its back, is more likely than the deer tick to be found on humans in Virginia.

Studies conducted in the early 1990s by Dr. Daniel Sonenshine of Old Dominion University detected infected populations of *I. scapularis* and rodents on the Eastern Shore and near Williamsburg. However the rates of infection on the Peninsula were lower than those on the Eastern Shore, which were well below those found in known highly endemic areas such as Long Island, New York and New England. In addition, the military has found the tick vector for Lyme disease to be established at the following sites: Fort A.P. Hill, Fort Belvoir, Fort Eustis, and Quantico. Although ticks and rodents have not been sampled in most other areas, the locations that were studied were selected because ecologically they were the most likely to have infected ticks and rodents. We concur with the CDC that Virginia



is a “low risk” state for Lyme disease.

In Virginia, an annual average of 1.3 Lyme disease cases per 100,000 population were reported during 1993-1997 versus a national average of 5.5 per 100,000. Some states have rates as high as 15 to 40 per 100,000. As indicated, some areas in Virginia pose a higher risk than others, so it is important to know what is being seen in your community. The extent of contact with ticks should be evaluated by determining whether or not the person engages in activities that result in

frequent or prolonged exposure to tick-infested habitats.

There are additional considerations when deciding whether to use the Lyme disease vaccine. Individuals at risk for tick exposures still need to be stringent in their personal protection measures. Rocky Mountain Spotted Fever and ehrlichiosis are both very real risks in Virginia.

Lastly, as with any new vaccine, a number of issues still need to be settled. There are the questions about use in children and the elderly, what the optimal dosing and scheduling should be, the need for and spacing of booster doses, the potential for rare or late-developing adverse effects, and the cost effectiveness of the vaccine. Efficacy is reported to be about 50% after two doses and 76% after three doses.

Summary

It is unlikely that very many Virginians are at risk for acquiring Lyme disease given the restricted areas in which the tick is commonly found, the low rates of infection in ticks and rodents, and the availability of a treatment when symptoms are recognized. When considering whether to recommend the vaccine, the low risk for disease must be weighed against what is known about the efficacy of the vaccine and what is unknown about its long-term effects.

(continued from page 3)

• **Children Aged < 15 Years**

Until the safety and immunogenicity of rOspA vaccines in children have been established, this vaccine is not recommended for children aged less than 15 years. Currently, LYMERix is licensed for use in persons aged 15-70 years only.

• **Persons Aged > 70 Years**

The safety and efficacy of LYMERix have not been established for persons aged greater than 70 years.

• **Pregnant Women**

Because the safety of rOspA vaccines administered during pregnancy has not been established, vaccination of women who are known to be pregnant is not recommended.

No evidence exists that pregnancy increases the risk for Lyme disease or its severity. Acute Lyme disease during pregnancy responds well to antibiotic therapy, and adverse fetal outcomes have not been reported in pregnant women receiving standard courses of treatment. A vaccine pregnancy registry has been established by SmithKline Beecham Pharmaceuticals. In the event that a pregnant woman is vaccinated, health-care providers are encouraged to register this vac-

ination by calling (800) 366-8900, ext. 5231.

• **Persons with Immunodeficiency**

Persons with immunodeficiency were excluded from the Phase III safety and efficacy trial, and no data are available regarding Lyme disease vaccine use in this group.

• **Persons with Musculoskeletal Disease**

Persons with diseases associated with joint swelling (including rheumatoid arthritis) or diffuse musculoskeletal pain were excluded from the Phase III safety and efficacy trial, and only limited data are available regarding Lyme disease vaccine use in such patients.

• **Persons with a Previous History of Lyme Disease**

Vaccination should be considered for persons with a history of previous uncomplicated Lyme disease who are at continued high risk.

Persons who have treatment-resistant Lyme arthritis should not be vaccinated because of the association between this condition and immune reactivity to OspA.

Persons with chronic joint or neurologic

illness related to Lyme disease, as well as second- or third-degree atrioventricular block, were excluded from the Phase III safety and efficacy trial, and thus, the safety and efficacy of Lyme disease vaccine in such persons are unknown.

• **Boosters**

Whether protective immunity will last longer than 1 year beyond the month-12 dose is unknown. Data regarding antibody levels during a 20-month period after the first injection of LYMERix indicate that boosters beyond the month-12 booster might be necessary. Additional data are needed before recommendations regarding vaccination with more than three doses of rOspA vaccine can be made.

• **Simultaneous Administration with Other Vaccines**

The safety and efficacy of the simultaneous administration of rOspA vaccine with other vaccines have not been established. If LYMERix must be administered concurrently with other vaccines, each vaccine should be administered in a separate syringe at a separate injection site.

Cases of Selected Notifiable Diseases Reported in Virginia*

Total Cases Reported, May 1999

Regions

**Total Cases Reported Statewide,
January through May**

Disease	State	Regions					Total Cases Reported Statewide, January through May		
		NW	N	SW	C	E	This Year	Last Year	5 Yr Avg
AIDS	56	2	8	24	11	11	295	343	450
Campylobacteriosis	77	9	11	21	19	17	180	193	183
<i>E. coli</i> O157:H7	9	2	0	1	1	5	18	11	6
Giardiasis	31	5	12	7	3	4	127	141	122
Gonorrhea	730	18	75	113	237	287	3847	2441	3871
Hepatitis A	13	0	6	0	4	3	54	115	77
B, acute	11	3	3	3	0	2	40	45	48
C/NANB, acute	2	0	2	0	0	0	8	3	8
HIV Infection	59	8	12	10	11	18	268	364	411
Lead in Children [†]	18	1	1	4	7	5	126	194	233
Legionellosis	4	0	1	2	0	1	10	7	7
Lyme Disease	12	1	2	0	6	3	15	10	9
Measles	0	0	0	0	0	0	3	2	1
Meningococcal Infection	5	0	2	1	1	1	24	20	28
Mumps	1	0	0	0	0	1	8	4	10
Pertussis	1	0	0	0	0	1	13	6	10
Rabies in Animals	72	11	25	7	17	12	207	261	213
Rocky Mountain Spotted Fever	0	0	0	0	0	0	0	0	1
Rubella	0	0	0	0	0	0	0	0	<1
Salmonellosis	72	5	18	19	8	22	239	301	311
Shigellosis	8	1	6	0	0	1	29	54	150
Syphilis, Early [§]	22	0	3	10	3	6	163	189	395
Tuberculosis	21	0	10	0	5	6	108	121	136

Localities Reporting Animal Rabies This Month: Accomack 2 raccoons; Alexandria 1 bat; Alleghany 1 raccoon; Amelia 2 raccoons; Arlington 1 raccoon; Botetourt 1 skunk; Charles City 1 raccoon; Chesapeake 1 raccoon; Chesterfield 1 dog, 3 raccoons; Culpeper 1 cat; Dinwiddie 1 dog; Fairfax 4 foxes, 9 raccoons; Frederick 1 raccoon; Gloucester 1 raccoon; Halifax 1 skunk; Hanover 1 bat, 1 fox; Henrico 1 bat; Isle of Wight 1 raccoon; King George 2 raccoons, 1 skunk; Loudoun 1 bat, 2 foxes, 5 raccoons; Mathews 1 raccoon; Middlesex 1 skunk; Northampton 1 raccoon; Page 1 raccoon; Pittsylvania 1 raccoon; Powhatan 1 fox, 1 raccoon; Prince George 1 raccoon; Prince William 1 fox, 1 raccoon; Pulaski 1 raccoon; Richmond City 2 raccoons; Rockingham 2 raccoons; Russell 1 fox; Scott 1 skunk; Stafford 1 raccoon, 1 skunk; Suffolk 2 raccoons; Wythe 1 raccoon; York 2 raccoons.

Occupational Illnesses: Asbestosis 51; Carpal Tunnel Syndrome 51; Carbon Monoxide Exposure 1; De Quervain's Syndrome 1; Hearing Loss 36; Lead Exposure 15; Mercury Exposure 1; Pneumoconiosis 5.

*Data for 1999 are provisional. †Elevated blood lead levels $\geq 10\mu\text{g}/\text{dL}$.

§Includes primary, secondary, and early latent.

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