CD Summary

June 22, 1999
Vol. 48, No. 13

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CENTER FOR DISEASE PREVENTION & EPIDEMIOLOGY • OREGON HEALTH DIVISION

ACIP RECOMMENDATIONS FOR USE OF LYME DISEASE VACCINE

LYME DISEASE, caused by the spirochete *Borrelia burgdorferi* and transmitted by the bite of *Ixodes* ticks, is currently the most common arthropod-borne infection in the United States: 14,646 cases were reported to the Centers for Disease Control and Prevention (CDC) during 1998. Last December, the US Food and Drug Administration approved the first vaccine against Lyme Disease (LD) — LYMErix™ (SmithKline Beecham) — for the prevention of LD in persons 15-70 years of age. The Advisory Committee on Immunization Practices (ACIP) recently published its recommendations for use of this vaccine.[1] This issue of the *CD Summary* summarizes those recommendations and opines about use of the vaccine in Oregon. Those interested may earn continuing education credit from CDC.*

LD is a systemic disease with protean manifestations that may include dermatologic, rheumatologic, neurologic, and cardiac abnormalities. The best clinical marker for the disease is the initial skin lesion, erythema migrans (EM), which occurs in 60%-80% of cases. In its early stages, LD can be easily treated with oral antibiotics. If left untreated, some persons with LD may develop chronic arthritis or neurologic sequelae.

THE VACCINE

LYMErix™ is a genetically engineered vaccine that contains recombinant outer-surface protein A (rOspA), an antigen expressed by *B. burgdorferi*. The recommended 0.5-ml dose of LYMErix™ contains 30 µg of purified rOspA lipidated protein adsorbed onto aluminum hydroxide adjuvant; it is administered by injection into the deltoid muscle. A three-dose schedule is being recommended; the first dose is followed by a second dose 1 month later and a third dose 12 months after the first.

In a multicenter, double-blind, randomized trial involving 10,936 persons 15-70 years of age, the 3-dose series induced anti-OspA antibodies in vaccinees and provided 76% protection (95% CI, 58%-86%) against "definite" LD (characteristic symptoms with corroborating culture, PCR, or Western blot serology) and 100% protection (95% CI, 26%-100%) against asymptomatic infection. After 2 doses, vaccine efficacy rates were 49% and 83% respectively.[2] Because it is a new vaccine, long-term efficacy has not been quantified. However, kinetics of anti-OspA antibody titers suggest that boosters beyond the currently recommended 12-month dose might be necessary for continued protection.

In the randomized trial cited above, the most common side effect of the vaccine was soreness at the injection site, reported by 24% of vaccine recipients (versus 8% of placebo recipients). Injection-site redness or swelling, myalgia, influenza-like illness, fever, and chills were each more common among vaccine recipients than among placebo recipients, but occurred in ≤3% of vaccinees.[2] Side effects do not appear to be more serious in persons who have previously had LD.[3]

Are antibodies against OspA a good thing? Following natural exposure to *B. burgdorferi*, persons who express certain major histocompatibility complex molecules are more likely than others to develop chronic, poorly responsive Lyme arthritis associated with high levels of antibody to OspA in serum and synovial fluid. In patients with chronic Lyme arthritis, the levels of antibody to OspA, and especially to the C-terminal epitope of OspA, have been found to correlate directly with the severity and duration of the arthritis. It has been proposed that this arthritis is a consequence of molecular mimicry between the dominant T-cell epitope of OspA and human leukocyte function-associated antigen 1 (hLFA-1). For this reason, the vaccine should not be administered to persons with a history of treatment-resistant Lyme arthritis. In addition, because of a lack of trial data, LD vaccine is not recommended for persons who are <15 years of age, >70 years of age, or pregnant.

WHO IS AT RISK?

Ixodes ticks are not found in all parts of the country, and where they are found, tick infection by *B. burgdorferi* varies from <1% to 50% or more.[4] Not surprisingly, therefore, the risk of LD varies considerably around the country (see map, *verso*); 89% of US cases during 1998 were reported from New England or Mid-Atlantic states. Even within the high-risk areas, persons who never frolic in tick-infested areas remain at low risk. Age groups at highest risk include children <15 years and adults 30-59 years of age. When considering vaccination against LD, the ACIP prudently recommends that would-be vaccinees and their physicians consider the geographic area where exposure to ticks will occur, the age of the person who will be exposed, the frequency or length of exposure to tick habitat, and the time of year when exposure to tick habitat will occur (April-July are peak months in most areas).

For persons 15-70 years old who reside, work, or recreate in areas of "high" or "moderate" risk: LD vaccination should be considered if they engage in activities that result in frequent or prolonged exposure to tick-infested habitat. LD vaccination may be considered if they are exposed to tick-infested habitat, but their exposure is neither frequent nor prolonged. LD vaccination is not recommended if they have minimal or no exposure to tick-infested habitat.

For persons who reside, work, or recreate in areas of low or no risk, LD vaccination is not recommended.

*To receive CME, CEU, or CNE credit, register (http://www2.cdc.gov/cep) and obtain a copy of the *MMWR* June 4, 1999/Vol 48/No.RR-7. You will find the quiz and instructions for submitting your answers by mail, by fax, or electronically.

CD Summary (ISSN 1058-7888) is published biweekly, free of charge, by the Oregon Health Division, a part of the Dept. of Human Resources.
800 NE Oregon St., Portland, Oregon 97232
Periodicals postage paid at Portland, Oregon.
Postmaster—send address changes to:
CD Summary, 800 NE Oregon St., Suite 730, Portland, OR 97232

CD SUMMARY
June 22, 1999
Vol. 48, No. 13

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For travelers to areas of high or moderate risk, LD vaccination should be considered if frequent or prolonged exposure to tick habitat is anticipated.

LYME DISEASE IN OREGON

So what's the risk in Oregon? We do have *Ixodes* ticks. In 1977, a 9-year tick survey was completed, revealing that *I. pacificus* ticks (a.k.a. western black-legged ticks) were present in 21 counties.[5] *I. pacificus* was only found west of the Cascades from Washington State to the California border and along the Columbia Gorge as far east as Wasco County. In 1997-1998, CDC and OHD cultured ticks from Jackson and Josephine Counties and isolated *B. burgdorferi* from 3% of *I. pacificus* adults.[6]

During 1995-1998, 79 cases of LD were reported in Oregon — a rate of 0.6 cases/100,000/year. The area of highest risk has been the southwestern part of the state, with rates of 2.4/100,000/year in Jackson County and 2.7/100,000/year in Josephine County. Rates like these serve only to elevate these counties from the "no risk" to the "low risk" ACIP category.

The low risk of LD that accompanies outdoor pursuits in Oregon can be lessened further by simple precautions. These include: wearing light-colored clothing (ticks are easier to see); tucking long pants into socks to prevent tick bites; avoiding tall grass and shrubby areas whenever possible; and wearing a tick repellent. Repellents containing permethrin or DEET repel 82-100% of ticks. Those intent on recreating in tall grass while scantily clad with dark-colored clothes and no tick repellent can eliminate the risk of LD by checking themselves for ticks following their risky activity. And if all else fails, this disease, after all, is treatable with conventional antibiotics.

BOTTOM LINE FOR OREGONIANS

The ACIP states that "Lyme disease vaccination is not recommended for persons who reside, work or recreate in areas of low risk." All of Oregon is classified as either "low" or "no" risk. You complete the syllogism.

If your Oregon patient is traveling to an area of high or moderate risk, "consider" vaccination if frequent or prolonged exposure to tick habitat is anticipated. Do your considering far in advance: to get optimal protection, you have to start the series a year before the excursion.

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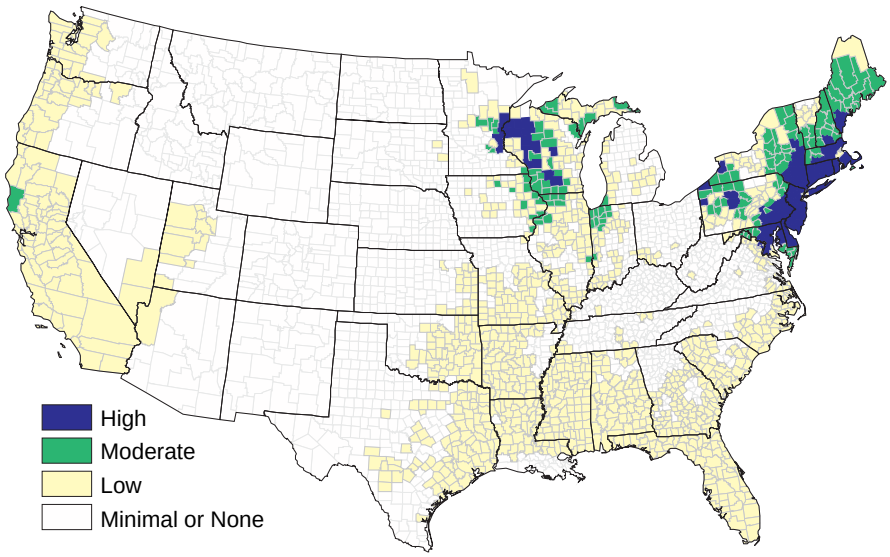
County-by-County Lyme Disease Risk in the Lower 48 [1]



Map file courtesy of Carrie Howard, Yale University School of Medicine