



Complete Summary

GUIDELINE TITLE

Recommendations for the use of Lyme disease vaccine.

BIBLIOGRAPHIC SOURCE(S)

Recommendations for the use of lyme disease vaccine recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 1999 Jun 4; 48(RR07): 1-17. [80 references]

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- METHODOLOGY - including Rating Scheme and Cost Analysis
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SCOPE

DISEASE/CONDITION(S)

Lyme disease

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

- Allergy and Immunology
- Infectious Diseases
- Pharmacology
- Preventive Medicine
- Rheumatology

INTENDED USERS

- Allied Health Personnel
- Health Care Providers

Patients
Public Health Departments

GUIDELINE OBJECTIVE(S)

- 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.
- To guide clinical practice and policy development related to administration of the Lyme disease vaccine.

TARGET POPULATION

Persons aged 15-70 years residing in Lyme disease-endemic areas of the northeastern and north-central United States.

INTERVENTIONS AND PRACTICES CONSIDERED

Recombinant outer-surface protein A (rOspA) Lyme disease vaccine (LYMERix™)

*Note from the National Guideline Clearinghouse (NGC) and the Centers for Disease Control and Prevention (CDC): As of February 25, 2002 the manufacturer announced that the LYMERix™ Lyme disease vaccine will no longer be commercially available. The recommendations contained within this guideline apply to any vaccine currently in use.

MAJOR OUTCOMES CONSIDERED

Safety and efficacy of LYMERix in persons aged 15 to 70 years in the United States.

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The cost of Lyme disease has been evaluated from both a societal and a third-party-payer perspective. The cost-effectiveness of vaccinating against Lyme disease has also been analyzed from a societal perspective. At an assumed cost of vaccination of \$100/person/year, a vaccine effectiveness of 0.85, a probability of 0.85 of correctly identifying and treating early Lyme disease, and an assumed incidence of Lyme disease of 1,000/100,000 persons/year, the net cost of vaccination to society was \$5,692/case averted and \$35,375/complicated neurologic or arthritic case avoided. Using these same baseline assumptions, the societal cost of vaccination exceeds the cost of not vaccinating, unless the incidence of Lyme disease is greater than 1,973/100,000 persons/year. Of the variables examined, the incidence of Lyme disease had the greatest impact on cost-effectiveness of vaccination. The likelihood of early diagnosis and treatment also has a substantial impact on vaccine cost-effectiveness because of the reduced incidence of sequelae when Lyme disease is diagnosed and patients are treated early in the disease.

Most disease-endemic states and counties report Lyme disease incidence rates that are substantially below 1,000/100,000 persons/year. For example, in 1997, the highest reported state incidence was 70/100,000 persons in Connecticut, and the highest reported county incidence was 600/100,000 population in Nantucket County, Massachusetts. However, some studies document that approximately 10%-15% of physician-diagnosed cases of Lyme disease are reported to state authorities in highly endemic areas. Epidemiologic studies of populations at high risk in the northeastern United States have estimated annual incidence of greater than 1,000/100,000 persons/year in several communities.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

*Note from the National Guideline Clearinghouse (NGC) and the Centers for Disease Control and Prevention (CDC): As of February 25, 2002 the manufacturer announced that the LYMERix™ Lyme disease vaccine will no longer be commercially available. The recommendations that follow apply to any vaccine currently in use.

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 risk for Lyme disease is focally distributed in the United States (refer to the guideline document for a National [U.S.] Lyme disease risk map). Detailed information regarding the distribution of Lyme disease risk within specific areas is best obtained from state and local public health authorities.

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

	Vaccination Recommendation
Persons who reside, work, or recreate in areas of high or moderate risk <ul style="list-style-type: none">• Persons aged 15 to 70 years whose exposure to tick-infested habitat is frequent or prolonged• Persons aged 15 to 70 years who are exposed to tick-infested habitats, but whose exposure is not frequent or prolonged• Persons whose exposure to tick-infested habitat is minimal or none	Should be considered May be considered Not recommended
Persons who reside, work, or recreate in areas of low or no risk	Not recommended

<p>Travelers to areas of high or moderate risk</p> <ul style="list-style-type: none"> Travelers aged 15 to 70 years whose exposure to tick infested habitat is frequent or prolonged 	Should be considered
Children aged less than 15 years	Not recommended
<p>Pregnant women</p> <ul style="list-style-type: none"> Health care providers are encouraged to register vaccinations of pregnant women by calling SmithKline Beecham, toll free, at (800) 366-8900, ext. 5231 	Not recommended
Persons with immunodeficiency	No available data
Persons with musculoskeletal disease	Limited data available
<p>Persons with previous history of Lyme disease</p> <ul style="list-style-type: none"> Persons aged 15 to 70 years with previous uncomplicated Lyme disease who are at continued high risk 	Should be considered
<ul style="list-style-type: none"> Persons with treatment-resistant Lyme arthritis 	Not recommended
<ul style="list-style-type: none"> Persons with chronic joint or neurologic illness related to Lyme disease and persons with second-or third-degree atrioventricular block 	No available data
<p>OTHER RECOMMENDATIONS</p> <p>Vaccine schedule</p> <ul style="list-style-type: none"> Three doses administered by intramuscular injection as follows: <p style="margin-left: 40px;">Initial dose, followed by a second dose 1 month later, followed by a third dose 12 months after the first dose</p> Second dose (year 1) and third dose (year 2) administered several weeks before the beginning of the disease-transmission season, which is usually April 	

Boosters

Existing data indicate that boosters might be needed, but additional data are required before recommendations can be made regarding booster schedules

Simultaneous administration with other vaccines

- Additional data needed
- If simultaneous administration is necessary, use separate syringes and separate injection sites

Recommendations for Surveillance, Research, Education, and Program Evaluation Activities

- Determine safety, immunogenicity, and efficacy of Lyme disease vaccine in children.
- Determine optimal vaccine dosage schedules and timing of administration.
- Determine the need for and spacing of booster doses.
- Determine safety and efficacy of the vaccine in persons aged greater than 70 years.
- Develop additional serodiagnostic tests that discriminate between infection and vaccine-induced antibody production.
- Develop a program of Lyme disease vaccine education for care providers and prospective vaccine clients.
- Develop an information sheet to be distributed to prospective vaccine recipients or to persons at the time of vaccine administration.
- Conduct surveillance for rare or late-developing adverse effects of vaccination.
- Establish postlicensure epidemiologic studies of safety, efficacy, prevention effectiveness, cost-effectiveness, and patterns of use.
- Develop a program to monitor vaccine use at the local, state, and national levels and to measure its public health and economic impact.
- Develop population-based studies to assess the impact of vaccine use on incidence of Lyme disease in communities.
- Continue to develop maps of geographic distribution of Lyme disease with improved accuracy and predictive power.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is primarily a phase III randomized, controlled trial.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Lyme disease vaccine, as an adjunct to other preventive measures (such as personal protection), might prevent Lyme disease. Results of a large-scale, randomized, controlled (Phase III) trial indicate that the vaccine is safe and efficacious when administered on a three-dose schedule of 0, 1, and 12 months. Using an intention-to-treat analysis, 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%). Efficacy in protecting against asymptomatic infection (no recognized symptoms, but with Western immunoblot (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.

POTENTIAL HARMS

Adverse reactions to vaccination

From a large-scale, randomized, controlled trial of LYMERix, 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 less than 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 less than 0.001). Myalgia, influenza-like illness, fever, and chills were more common among vaccine recipients than placebo recipients (p less than 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 less than 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 incidence of adverse events more than 30 days after receiving a dose, and no episodes of immediate hypersensitivity among vaccine recipients were noted.

Effect of vaccination on the serologic diagnosis of Lyme disease

Care providers and laboratorians should be advised that vaccine-induced anti-recombinant outer-surface protein A (rOspA) antibodies routinely cause false-positive enzyme-linked immunosorbent assay (ELISA) results for exposure to *Borrelia burgdorferi*. Experienced laboratory workers, through careful interpretation of the results of immunoblots, can usually discriminate between *B. burgdorferi* infection and previous rOspA immunization. Although vaccination is expected to elicit antibody to OspA only, natural infection results in the production of antibody to additional diagnostic antigen bands in immunoblots.

QUALIFYING STATEMENTS

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1. Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.
2. As of publication of this report, only LYMERix has been licensed by the U.S. Food and Drug Administration for use in the United States; therefore, these recommendations apply only to the use of that vaccine. Additional statements will be provided as other Lyme disease vaccines are licensed.
3. Information regarding vaccine safety and efficacy beyond the transmission season immediately after the third dose is not available. Thus, the duration of protective immunity and need for booster doses beyond the third dose are unknown. The safety and immunogenicity of alternate dosing schedules are currently being evaluated.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Jun

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Advisory Committee on Immunization Practices

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [Centers for Disease Control and Prevention Web site](#).

Print copies: Available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on December 1, 1999. The information was verified by the guideline developer as of April 7, 2000.

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