

The Epidemiology of Lyme Disease and the LYMERix™ Experience

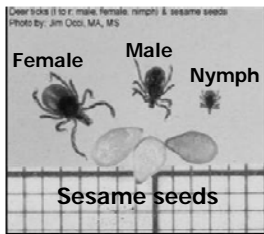
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Lyme Disease

- Caused by *Borrelia burgdorferi* (Bb) sensu lato
 - *Borrelia burgdorferi* sensu stricto
 - *Borrelia afzelii*
 - *Borrelia garinii*
- Transmitted by *Ixodes scapularis*
- Symptoms 3-30 days post-tick bite
 - Erythema migrans \geq 5 cm in diameter
 - Flu-like symptoms
- Early / timely treatment is very effective
- Untreated symptoms can lead to disseminated infection
 - Musculoskeletal
 - Neurologic
 - Cardiac

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Ixodes Scapularis

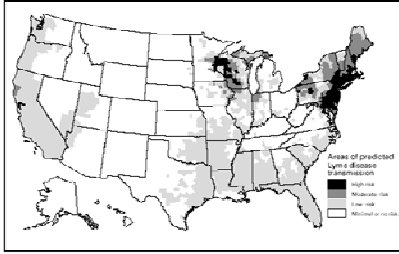


- Life cycle is 2 years
- 3 feeding stages
- Acquires Bb from White-footed mouse
- Must be attached for > 36 hours to transmit pathogen
- Abundance determined by deer population
- Bb infection rate varies
- Endemic in 21 counties in New Jersey

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Distribution of Lyme Disease

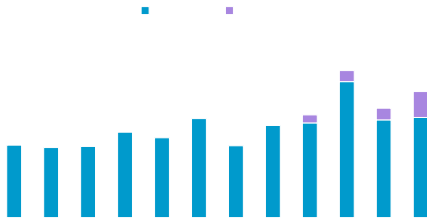
National Lyme disease risk map with four categories of risk



Note: This map demonstrates an approximate distribution of predicted Lyme disease risk in the United States. The true relative risk in any given county compared with other counties might differ from that shown here and might change from year to year. Risk categories are defined in the accompanying text. Information on risk distribution within states and counties is best obtained from state and local public health authorities.

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Frequency of Lyme Disease New Jersey, 2000-2011



Source: 2000-2004 NJDHSS electronic files containing aggregate data; 2005-2011 NJDHSS CDRSS historical reports limited to DHSS approved cases.

Note: In 2008, the NJDHSS / CDC surveillance case definition changed to include confirmed and probable cases. 5

Traditional Prevention Measures

- Avoid tick-infested areas
- Use insect repellent
- Wear light-colored clothing
- Tuck socks into long pants
- Perform daily tick checks
- Landscape management
- Application of acaricides
- Deer management
- Post-exposure prophylaxis

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LYMERix™ Ascends

- SmithKlineBeecham
- Phase III clinical trial in 1990s
- Licensed in December 1998
- Recombinant *Borrelia burgdorferi* OspA
 - Bb sensu stricto ZS7
- Transmission-blocking vaccine
- Administered in 3 doses
- For use in individuals 15-70 years of age

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LYMERix™ Descends

- Immediate limitations
 - 20% not covered
 - Excludes highest risk group
 - Requires 3 doses over 1 year
 - Boosters may be required
 - Only effective against North American strain
- Media coverage and “Vaccine Victims”
- Class action lawsuit
- DR4+ hypothesis
- Rotavirus vaccine experience

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LYMERix™ Investigation

- FDA re-examined Phase III data
- VAERS
 - 905 adverse events reported
 - 7.4% classified as “serious”
 - 56% occurred after first dose
- Phase IV trial
 - Case-control study
 - Follow outcomes for 4 years
 - Discontinued after 2 years
- FDA panel in January 2001
- Vaccine voluntarily withdrawn February 2002

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Next Steps for a New Vaccine

- Safety, efficacy, cost
- Induce high and sustained duration of protections
- Approved for use in highest risk groups
- Protect against other tick-borne pathogens
- Protect against other genospecies
- Endorsed by public health and healthcare providers
- Educate general public to increase confidence

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