



In Pursuit of a Lyme Disease Vaccine: Why We Need It and What It Has the Potential to Do

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While preventative measures, including applying insect repellent and checking for ticks¹, are recommended to help with personal protection, there's limited evidence that they're having an impact on reducing the annual number of cases of Lyme disease, according to Raphael Simon, PhD, Senior Director of Vaccine Research and Development at Pfizer.

Lyme disease is the most common vector-borne illness in the United States.² And yet, the actual cases are vastly underreported. The U.S. Centers for Disease Control and

Prevention (CDC) says that state health departments only report around 30,000 cases each year. However, the CDC, to account for underreporting, uses methods beyond self-reporting to estimate that approximately 476,000 people in the US get Lyme disease annually.³

In other words, the estimated number of cases of Lyme disease in the U.S. seems to be much higher than what is being reported.

“The prevalence of this disease remains high, despite a growing awareness,” Dr. Simon says. In areas where this disease is endemic (constantly present), up to half of surveyed ticks can carry the *Borrelia* bacteria,” he says.

Understanding the Risks

Borrelia burgdorferi, which causes Lyme disease, is a spiral-shaped bacterium. It’s spread through bites from infected *Ixodes* ticks.⁵ A bullseye-shaped rash called erythema migrans,⁴ which occurs at the site of the bite, is the most common sign of infection and can be accompanied by symptoms including headache, fever, and fatigue. However, a rash is not always evident or seen. If the early signs are missed, the infection can progress in the absence of prompt antibiotic treatment, and it can result in arthritis, cardiovascular, and neurological complications.⁵

Each encounter with an infected tick carries the risk of developing Lyme disease.⁵ While antibiotics like doxycycline are the recommended treatment option, there is a growing need for preventative measures.⁶ Research published in *BMC Infectious Diseases* shows that a single dose of antibiotics, if administered early, decreased the likelihood of developing Lyme disease following a tick bite compared to placebo.⁵ However, early intervention is crucial as, if left untreated because of a missed diagnosis, chronic outcomes can develop, which are unresponsive to typical Lyme disease treatment.⁴

The Lyme Disease Footprint is Expanding

The uptick in cases may also be linked to an expanded geographic range for ticks. Changes to land use patterns, such as suburban development, have led to a greater number of encounters between people and ticks. Climate change may also play a role.⁶

“Ticks require a certain type of environment at the right temperature and right humidity in order to thrive and that can change as the climate changes,” Dr. Simon explains.

With both the prevalence and geographic range of Lyme disease increasing, vaccination could help prevent the disease and ease its burden.

Hope on the Horizon—A Human Vaccine Candidate for Lyme Disease

In 2020, Pfizer announced a collaboration with Valneva, a European company specializing in vaccines, to codevelop and commercialize a vaccine candidate against Lyme disease. The investigational product, VLA15, is a multivalent protein subunit vaccine that targets OspA, an outer surface protein expressed by the *Borrelia* bacteria when it is inside the tick.⁷

The vaccine has a unique mechanism, according to Dr. Simon. Once vaccinated, the recipient generates antibodies against the OspA protein and, after receiving a tick bite, the antibodies go into the feeding tick along with the blood meal and neutralize the *Borrelia* bacteria, preventing it from being transmitted to the host and causing Lyme disease, he says.

A single type of *Borrelia* causes almost all of the Lyme disease in the U.S.; however, in Europe, there is a broader range of variants (which includes the U.S. species).⁸ VLA15 has been designed to offer coverage for the most common circulating types of *Borrelia* bacteria that cause Lyme disease in both regions.⁷

In Phase 2 clinical trials, results showed that VLA15 was safe and well-tolerated, and generated strong anti-OspA immune responses in adults and pediatric volunteers.^{9,11} A Phase 3 clinical study, Vaccine Against Lyme for Outdoor Recreationists (VALOR) (NCT05477524), investigating the efficacy, safety and immunogenicity of VLA15 was initiated in August 2022.¹⁰

As of October 2022, VLA15 was the sole active vaccine candidate program in clinical development aimed at preventing the spread of the disease.¹¹ Preclinical experiments in animal models found that the vaccine candidate was able to effectively prevent transmission of North American and European *Borrelia* strains from infected Ixodes ticks.¹¹ If it is found to be similarly successful in people, Dr. Simon says, it could provide an important tool to reduce the disease burden resulting from the expanding geographic distribution of ticks and increasing diagnoses of Lyme disease.

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