

# A Lyme disease vaccine doesn't exist, but a yearly antibody shot shows promise at preventing infection

June 4 2020, by Mark Klempner

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Ticks can carry bacteria that causes Lyme Disease. Credit: CDC

Lyme disease has become an insidious epidemic in the United States. Caused by bacteria transmitted by an infected tick bite, [symptoms can include](#) arthritis, cardiac and neurological problems if left untreated. It is the most common tick-borne illness in the United States, and the Centers for Disease Control and Prevention estimates that [around 300,000 people](#) likely contract the disease each year.

Scientists, doctors and ecologists have worked for decades to slow the spread of Lyme and the blacklegged, or deer, ticks that carry the [disease-causing bacteria](#). However, the ticks' range continues to expand. Today, [over 50% of the American population lives in an area](#) where these ticks are found.

The U.S. Food and Drug Administration approved a [vaccine](#) against Lyme in 1998, but it was met by controversy and [pulled from the market three years later](#). Efforts continue today to create a human vaccine as well as stop the spread of Lyme by other means, including using [gene-editing to immunize mice](#) that can transmit the bacteria to ticks, [killing deer](#) and using [pesticides](#) to control ticks.

My colleagues and I have been working on a different kind of prevention: a yearly injection. I am an [infectious diseases physician-scientist](#) and have been studying and working toward preventing Lyme disease for much of my career. I also oversee [UMass Medical School's MassBiologics](#), the only nonprofit, FDA-licensed manufacturer of vaccines and biologics in the United States.

Our method, known as Lyme PrEP, delivers a single anti-Lyme antibody directly to a person rather than triggering the patient's own immune system to make many [antibodies](#) as vaccines do. It is designed to be a seasonal shot that people can get once a year before tick season begins. We have published several peer-reviewed articles on this methodology, [including its success in mice](#) and nonhuman primates. Later this year, we are scheduled to begin our first human phase 1 trial.

## **A vaccine's cautionary tale**

In 1998, the FDA approved a [Lyme vaccine](#) composed of protein antigens from the surface of the Lyme bacteria, *Borrelia burgdorferi*.

A vaccine works by introducing proteins from the disease-causing agent into the body to trigger the body's immune response, which includes making antibodies against bacterial proteins. Antibodies have been used to prevent and treat infectious diseases for over a century. In the case of the Lyme vaccine it can take many months for the body to build up the necessary level of immunity to prevent infection. It also means that some of the antibodies induced by the vaccine can have "off-target" effects, or [side effects](#).

The vaccine, known as LYMErix, largely reduced infections but was [withdrawn from the market after three years](#) because of limitations and controversy.

It needed to be administered by multiple injections over a year before immunity developed. Uncertainty about the length of immunity from the vaccine also raised questions of whether a booster shot would be regularly needed. Further, [publicity about side effects](#) such as arthritis, reported by some who had been vaccinated, contributed to its decline in popularity.

Today, a French biotech company, in collaboration with Pfizer, is [attempting to develop a Lyme vaccine](#) that is currently in clinical trials.

## **A different approach**

Unlike a vaccine, Lyme PrEP uses a single human antibody, or blood protein, to kill the bacteria in the tick's gut while it takes its blood drink, before the bacteria can get into the human host.

Through our research, we realized that just one of the antibodies that the human body developed after multiple injections of the LymeRx vaccine was sufficient to prevent infection. So we identified which antibody led to immunity and tested it in animals where [it proved 100% effective](#).

These animal studies show Lyme PrEP gives protection immediately upon injection, as it circulates through the blood. Unlike a vaccine which induces many antibodies that may not contribute to protection but can cause side effects, this approach uses a single, defined antibody, thus reducing the risk of side effects.

Initial tests of a single injection of Lyme PrEP protected mice for several weeks.

Humans, however, need to be protected longer, likely for the nine-month season when over 90% of cases occur. We have developed the Lyme PrEP antibody to extend its protective effects to cover this amount of time. Yet, the actual duration of protection will have to be determined during clinical trials.

Our goal for the phase 1 clinical trial later this year is to test for the treatment's safety and determine how long it lasts in the bloodstream in humans.

For the phase 1 trial we want to avoid testing the Lyme PrEP antibody on volunteers who may have already been exposed to the Lyme bacteria and have developed responses to the bacteria that could confuse the results. For that reason, initial testing will take place in volunteers who have not been exposed to Lyme disease.

If all goes well, phase 1 [clinical trials](#) would be completed in 2021. The phase 2 trial to test for safety and efficacy in a small group of volunteers would follow and then be followed by a phase 3 trial to test the efficacy on many volunteers. We hope to complete these larger studies in late 2022 or 2023.

The COVID-19 pandemic has put in sharp focus the need to prevent infections and the old adage, "An ounce of protection is worth a pound

of cure."

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