

FisherFocus

Fall 2021

NEWS FROM THE SHERRILYN AND KEN FISHER CENTER FOR ENVIRONMENTAL INFECTIOUS DISEASES

Dedicated to the clinical research of environmental pathogens which improves the diagnosis and treatment of these infections.

Is a New Lyme Vaccine on the Way?

We have heard the advice over and over. To prevent tick bites, wear long sleeves and pants, treat clothing with permethrin, and apply DEET bug spray. We are careful to check ourselves, children and pets for ticks. Yet the geographic tick range is expanding, and Lyme disease rates have increased, with estimated ranges of 300,000-450,000 cases per year. New prevention strategies are necessary.

Lyme disease Vaccine in Development

Vaccine studies for prevention of Lyme disease are currently underway. The French vaccine firm Valneva has partnered with Pfizer on VLA15, a vaccine candidate that targets the outer surface protein A (OspA) of the *Borrelia* bacteria that causes Lyme disease. Phase 2 (testing for safety and efficacy) trials are nearly completed in North America and Europe. Early results, released to the public in September 2021, showed that VLA15 elicited high antibody responses one month after vaccination. By 18 months after vaccine administration, antibody levels declined but remained above baseline, confirming the need for a booster shot. When boosters were given, they elicited a strong response, with increased antibody levels compared to the first vaccine doses. A phase 3 (how well it works in a larger group) trial with a placebo control is expected to start in 2022.

Wasn't There an Earlier Lyme disease Vaccine That Failed?

In the 1990s, two vaccines against *Borrelia burgdorferi* were developed. A Lyme

disease vaccine, ImuLyme, developed by Pasteur Mérieux Connaught, demonstrated protection in Phase III clinical trials. Despite this success, the company decided against seeking regulatory approval.

The other vaccine, LYMERix, developed by SmithKline Beecham (now GlaxoSmithKline), was FDA approved in 1998. After three vaccine doses, LYMERix reduced new *Borrelia burgdorferi* infections in vaccinated adults by nearly 80%, making it a highly effective vaccine. The vaccine, which also used an OspA antibody basis, was approved for people 15-70 years of age at high risk of exposure to ticks. Approximately 1.4 million doses of the vaccine were distributed, with the most common side effects being pain and reaction at the injection site.

After FDA approval and distribution, all vaccines are monitored for safety by reports to the Vaccine Adverse Events Reporting System (VAERS). As an open system, VAERS accepts reports from vaccine manufacturers, health practitioners, vaccine recipients, and attorneys; essentially, anyone may enter a report. VAERS can help identify rare side effects found only with a wider distribution. Regarding LYMERix, 905



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MESSAGE FROM THE DIRECTOR



The pandemic has focused many of us on our health and family health, from an occasional thought to a daily occurrence. While many give little thought at all, others may face frequent decisions such as whether to go to a wedding, eat in a restaurant indoors, visit family, travel by air or wear a mask.

The torrent of scientific knowledge and clinical trials generated in response to the pandemic has led to frequent changes in recommended practices. Some have co-opted the political term “flip flop” to reflect these changes, but perhaps more rightfully should be viewed as knowledge building. America is an innovative society, so embracing what is new is not usual, but the speed of change when so much is upended in our community and lives is upsetting.

A look backward in my own experience may offer some useful perspectives. New medications and vaccines are often slow to be adopted by either healthcare practitioners or patients alike. I recollect that when my children were a young age, the chickenpox vaccine was launched, in 1995. At the time, my wife and I decided to wait for our oldest child, who was one year old, to receive the vaccine since it was brand new. What happened? Predictably, he got chickenpox, but it also involved his eye—a serious, potentially sight-threatening infection. Luckily, he healed well without any permanent damage, but it gave us a scare. We subsequently got our second child into the pediatrician’s office straight away to get the vaccine.

The original meaning of xenophobia is the fear of the unknown, although, in modern usage, it has generally been used to denote the fear of strangers. Unknown worries tend to be considered more strongly than risks we think we know. Many hesitant to get a COVID vaccine may be unduly voicing concerns about the vaccine’s theoretical and likely negligible long-term effects, compared to the risks of developing COVID-19 infection, including the potential for post-COVID conditions.

I don’t wish to underplay fear of the unknown. Some psychologists believe it is the fundamental fear. However, when we decided not to immunize our son, I did not consider all the facts. Neither did I know that at the time that chickenpox caused 9,000 hospitalizations and 100 deaths annually, nor did I read about the safety shown in the vaccine’s clinical trials or that it had been used safely in Japan and South Korea since the 1980s. It was a causal decision based on a decision to wait and see because the vaccine was new.

Children five years and older can now get a COVID vaccine, a lower ten microgram dose of the Pfizer/BNT vaccine. Many parents have voiced concerns there has not been enough experience with the vaccine in children and that the risks for COVID-19 in this age range are slight. While true, there are known dangers of COVID-19.

Children do remain at risk for severe infection even if they are healthy. Rates of hospitalized children are increasing. Moreover, one-third of children who are admitted to the hospital need ICU care. Some children develop a severe late inflammatory condition called MIS-C or post-COVID problems such as chronic fatigue, brain fog and pain. The impact of COVID on children and adolescents is not yet fully understood since aspects of the pandemic have other effects such as mask wearing, virtual learning and less socialization.

Before making a decision, look at what we know. The significant risk with a vaccine such as the Pfizer/BNT vaccine appears to be heart inflammation (myocarditis) in adolescents and younger adults, more in males. It is usually mild and completely reversible. COVID-19 causes myocarditis too, but at a rate that is substantially higher than vaccine-induced changes.

Though unknowns exist, parents and older children should legitimately weigh the experience of the vaccines so far in many millions of doses given that offer protection from infection, hospitalization, post-infectious problems and death versus theoretical or unknown risks. When asked if I would give the vaccine to my children, now a much older and perhaps wiser parent but honestly only a potential grandparent, I answer strongly yes.

A handwritten signature in black ink, appearing to read "Todd Santoro". The signature is fluid and cursive, written on a light-colored background.

Is a New Lyme Vaccine on the Way?

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reports were made to VAERS, with 66 classified as serious. In particular, there were press reports that the vaccine could cause arthritis, and a class-action lawsuit was filed. After investigation, an FDA panel found no association between vaccine administration and the development of arthritis.

In 2002 the manufacturer voluntarily withdrew LYMERix from the market, but not for safety issues. Instead, the company decided to no longer market the vaccine due to decreasing demand. The media attention, including the class-action lawsuit with no solid scientific grounding, led the company to believe that fewer than 10,000 people would seek the vaccine annually. The company found that it was not economical to continue vaccine manufacturing.

The new Lyme disease vaccine VLA15 under study uses a different series of antibody-provoking motifs called epitopes that avoid the theoretical concern raised twenty years ago about stimulating arthritis with the LYMERix vaccine.

Why Get a Lyme Disease Vaccine?

Gardeners, those that live near wooded areas, and children may be at most risk for tick bites. Although most tick bites do not transmit diseases, such as Lyme disease, those at risk may consider a Lyme disease vaccine when available. When asked his thoughts on a potential Lyme vaccine, a patient stated, "I get tick bites all the time, especially in the spring when working in the garden. I have never had Lyme disease but am concerned about getting it. If a vaccine were reasonably priced or covered by my insurance, I would get it."

The pharmaceutical company, Pfizer, has selected Johns Hopkins as a site for a phase 3 Lyme vaccine trial. The Fisher Center's Director, Paul Auwaerter, MD, will serve as the Principal Investigator, working with the Johns Hopkins

Center for Immunization Research. Beginning in the spring of 2021, the Center will start recruiting volunteers to participate in this exciting research.

IN THE MEANTIME, PREVENTION IS KEY...

Prevent Tick Bites on People

- Treat clothing with permethrin
- Use insect repellent with DEET or picaridin
- Avoid high grass and leaf litter
- Walk in the center of trails
- Shower soon after being outdoors
- Check your body for ticks

Prevent Tick Bites on Pets

- Talk to your vet about prevention products and the Lyme disease vaccine approved for dogs

- Examine your pet after time outdoors

Prevent Ticks in the Yard

- Keep the yard free of leaf litter and brush

- Maintain a barrier of wood chips or rock between the forest and lawn

- Grow deer-resistant plants



For further guidance, visit
the CDC website:

<https://www.cdc.gov/lyme/prev/index.html>

Why I Give

Mr. Robert Bank



For Mr. Robert Bank and his family, there are many connections to Johns Hopkins University. Bob received his Master of Arts in Teaching in American History in 1971 from the Krieger School. His father, Howard M. Bank, received a Bachelor of Arts in the mid 1930's and his mother, Harriet Bank, graduated from Johns Hopkins Medicine with a degree in Nutrition, coming back to teach at Hopkins in the early 1940's. In the mid-70's, Bob and his two brothers started the Howard Bank Fund in the division of rheumatology in memory of their late father, Howard Bank, to support rheumatoid arthritis research. Bob has many reasons to give; he chooses to support the Fisher Center Discovery Program because of the extraordinary care from his doctor, Dr. Paul Auwaerter. Bob said,

I support Dr. Auwaerter. He is a great doctor, a wonderful scientist and the important work he is doing in the Fisher Center is having global reach.

BreakOut

Farewell



Since the inception of the Fisher Center in 2012, Yvonne Higgins, MAS, MS, has served as the Center's Senior Research Program Manager. Yvonne was instrumental in the development and management of the Fisher Center Discovery Program, has actively participated in research, and has served as writer and editor of the Fisher Focus. In February 2022, she will join her husband in retirement. Fisher Center Director Paul Auwaerter credits Yvonne for the significant impact that the Center has produced over the last decade. "Yvonne's superb organizational and analytical skills have helped both me and so many researchers and educators advance our knowledge and care of infectious diseases. We will greatly miss Yvonne's productive support and good humor, but happy to know that she and her husband Bob will enjoy many years together traveling the US in their RV."

Yvonne writes, "It is with mixed emotions that I retire from the Fisher Center. My years here have been professionally fulfilling. I am particularly grateful to the Fishers for supporting the Fisher Center Discovery Program, as I have seen its genuine impact on the research of early-career investigators within the Johns Hopkins community. As a catalyst for research, supporting under-funded areas of interest, the Fisher Discovery Program is a model for true innovation in clinical research support. Thank you for letting me serve."

From Bench to Business

Universities are increasingly aware of the prospect of developing technology transfer organizations or partnering with established technology transfer organizations to leverage research into commercial reality. The Fisher Center is proud to have had a small hand in assisting one such transfer.

In 2015 the Fisher Center Discovery Program awarded Professor **Kieren Marr, MD**, a grant to evaluate a prototype diagnostic test for Histoplasmosis, one of the most common environmentally-acquired fungal infections in the United States. While long noted to be a world-wide expert in fungal infections, Dr. Marr and her team are no strangers to business development. In 2004 her team generated data to support an FDA submission of another diagnostic assay, currently in commercial use to diagnose aspergillosis, another environmental fungal infection. Dr. Marr worked with the Johns Hopkins Accelerated Translational Incubator Pilot (ATIP) program and the Johns Hopkins University Carey Business School's Discovery 2 Market program. It was a natural outgrowth then for Dr. Marr to start MycoMed Technologies. In March 2018, MycoMed Technologies was awarded a US patent for a rapid lateral flow device to detect *Aspergillus* antigens in urine. Again, in May 2019, MycoMed was awarded a US Patent related to methods for detecting *Aspergillus fumigatus*. MycoMed Technologies LLC is located in the FastForward Accelerator Building near the Johns Hopkins East Baltimore campus.



Kieren Marr, MD

As Vice-Chair for the Department of Medicine's Innovation in Healthcare Implementation, Dr. Marr worked with faculty and the Johns Hopkins Technology Ventures to foster a culture of innovation. She helped to create pathways to turn the scholarly activity of scientists and clinician-scientists into products that touch our patients through technology licensing and/or entrepreneurial activities. As a product of her successful scientific and business endeavors, Dr. Marr recently announced she would step down as Vice Chair and transition to adjunct faculty in the Division of Infectious Diseases, effective year end. However, her commitment to fostering better products to treat fungal diseases

continues. Dr. Marr will become the co-founder and chief medical officer of Sfunga Therapeutics, a new Deerfield-backed antifungal company and will continue her work with the Johns Hopkins spin-off company, MycoMed.

As the inaugural medical director for the JHU Transplant and Oncology ID Program, Dr. Marr built a world-class academic center of excellence for transplant and oncology infectious diseases. Since 2008, the program has become one of the nation's best in clinical research and clinical care of solid organ transplant and oncology patients.

We wish Dr. Marr continued success in her new ventures, and thank her for leadership in clinical care, research, and business entrepreneurship.

FUNDING OUR FUTURE

Thanks so much to the generous donors who support the research efforts in the Fisher Center. We are grateful.

WE THANK THE GENEROUS CONTRIBUTORS THAT HELP SUPPORT THE FISHER CENTER PROGRAM

Sherrri Fisher

Healthnetwork Foundation

Robert B. and Susan R. Bank

Thomas L. Owsley

IF YOU HAVE ANY QUESTIONS ABOUT GIVING, PLEASE CONTACT DONNA BOLIN AT 410-336-5761 OR BY EMAIL AT DBOLIN1@JHMI.EDU.

If you would like to support the fisher center, please make an online gift here:

<https://secure.jhu.edu/form/infdis>

To send a donation by mail, please use this address:

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+ RECENT PRESENTATIONS

Auwaerter, P. (October 2021). Medicine in Ancient Egypt. Chief Executives Organization (CEO.org).

Auwaerter, P. (October 2021). Lankenau Medical Center, Department of Medicine Grand Rounds. Lyme disease Update. Lankenau, PA.

Auwaerter, P. (October 2021). COVID-19 Update. Grand Rounds, Department of Medicine, Union Memorial Hospital, Baltimore, MD.

Auwaerter, P. (October 07, 2021). Treatment Considerations for Pregnant Women With COVID-19. Medscape Infectious Diseases, Commentary [online video]. Medscape Infectious Diseases.

Auwaerter, P. (September 2021). Variants and the Pandemic. Department of Medicine Grand Rounds, Louisville, KY.

Auwaerter, P. (August 2021). COVID-19 Therapeutics, India, USAID RISE seminar series - Session 4: COVID-19.

Auwaerter, P. (July 2021). Pandemic, Variants and Vaccines: COVID-19. Kentucky COVID-19 Task Force, University of Louisville, KY (virtual).

Auwaerter, P. (May 2021). COVID-19 Therapeutics, Department of Medicine Grand Rounds/Tumulty Topics of Medicine, Baltimore, MD.

+ RECENT PUBLICATIONS

Hughes MT, Auwaerter PG, Ehmann MR, Garibaldi BT, Golden SH, Lorigiano TJ, O'Connor KJ, Kachalia A, Kahn. Opinion: The importance of offering vaccine choice in the fight against COVID-19. *J. Proc Natl Acad Sci U S A*. 2021 Oct 26;118(43):e2117185118. doi: 10.1073/pnas.2117185118. PMID: 34670839 No abstract available.

Kessler R, Auwaerter P. Strategies to improve human papillomavirus (HPV) vaccination rates among college students. *Am Coll Health*. 2021 Sep 1:1-8. doi: 10.1080/07448481.2021.1965146. Online ahead of print. PMID: 34469255

Auwaerter PG. The Race to Understand Post-COVID-19 Conditions. *Ann Intern Med*. 2021 Oct;174(10):1458-1459. doi: 10.7326/M21-3072. Epub 2021 Aug 31. PMID: 34461032

Wright WF, Mulders-Manders CM, Auwaerter PG, Bleeker-Rovers CP. Fever of unknown origin—a call for new research standards and updated clinical management. *Am J Med* 2021, Aug 24:S0002-9343(21)00526-X

Auwaerter PG, Kobayashi T, Wormser GP. Guidelines for Lyme disease are updated. *Am J Med* 2021, Aug 3:S0002-9343(21)00492-7.

Lantos PM, Tsao J, Janko M, Arab A, von Fricken ME, Auwaerter PG, Nigrovic LE, Fowler V, Ruffin F, Gaines D, Broyhill J, Swenson JJ. Environmental Correlates of Lyme Disease Emergence in Southwest Virginia, 2005-2014. *Med Entomol*. 2021 Jul 16;58(4):1680-1685. doi: 10.1093/jme/tjab038. PMID: 33825903

Wormser GP, Strle F, Shapiro ED, Auwaerter PG. Comparison of the clinical practice guidelines for Lyme disease from the Infectious Diseases Society of America: 2000, 2006, and 2020. *Diagn Microbiol Infect Dis*. 2021 Oct;101(2):115446. doi: 10.1016/j.diagmicrobio.2021.115446. Epub 2021 Jun 4. PMID: 34256207 No abstract available.

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