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Understanding consumer and clinician perceptions of a potential Lyme disease vaccine

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Abstract

Each year, over 450 000 Lyme disease diagnoses are estimated to occur in the United States, and current preventive measures have been insufficient to stem the rising incidence. An effective human Lyme disease vaccine could be a powerful intervention for population-level impact. In advance of new Lyme disease vaccines coming to market, this study explored barriers to acceptability and motivations for the uptake of a new Lyme disease vaccine. Researchers conducted 9 online focus groups among consumers who may potentially benefit from the vaccine and 30 in-depth interviews among clinician groups who may provide the vaccine. All participants were recruited from three US regions of high Lyme disease incidence. Researchers found that participants shared common motivators to either recommend (clinicians) or accept (consumers) a Lyme disease vaccine, largely driven by perceived benefits of the vaccine, the lack of current effective preventive measures and a greater peace of mind. The concern about the challenges associated with diagnosing and treating Lyme disease is a primary motivator for clinicians to recommend the vaccine, while the concern about getting Lyme disease is a primary motivator for consumers to desire the vaccine.

Introduction

Reported cases of tick-borne diseases more than doubled from 2004 to 2016—from 22 000 to 48 000 cases [1]. Lyme disease represented 82% of those 48 000 cases. However, due to underreporting, the US Centers for Disease Control and Prevention (CDC) estimates that the true number of diagnosed and treated infections is approximately 476 000 annually [2]. The Lyme disease bacterium, *Borrelia burgdorferi*, is spread through the bite of infected blacklegged ticks (or deer ticks), primarily in the Northeast, Mid-Atlantic and Upper Midwest regions of the United States [3]. Lyme disease is a multisystem disease causing varied clinical manifestations, including erythema migrans, arthritis, facial palsy

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Conflict of interest statement

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and carditis [4]. The myriad clinical presentations of Lyme disease, limitations of current diagnostic testing and ubiquitous misinformation [5-8] can make science-informed diagnosis and treatment for Lyme disease difficult for clinicians, patients and parents [9].

Human development in the blacklegged tick habitat and the range expansion of the tick put more people at risk for Lyme disease [10]. Personal and yard-based prevention measures have not proven sufficient to lower disease incidence [11], and as per a nationally representative survey, nearly half of the respondents in high Lyme disease incidence states reported not using any personal prevention methods [12]. In the absence of other validated prevention methods, an effective human Lyme disease vaccine may be the only intervention able to substantially reduce the disease incidence.

A safe and effective vaccine for Lyme disease, LYMERix, was available for persons aged 15–70 years from 1998 until 2002 in the United States [13, 14]. In February 2002, it was voluntarily discontinued by the manufacturer, GlaxoSmithKline Pharmaceuticals, citing poor sales [15]. However, several factors have been highlighted as reasons contributing to low demand, including complex recommendations for the use of the vaccine; the lack of approval for the use of the vaccine in children, the group at highest risk; unvalidated claims of the vaccine causing Lyme arthritis and the coincident rise of general anti-vaccination sentiment among the public [16-21].

Almost two decades have passed since the LYMERix vaccine was withdrawn, but there are currently vaccine candidates being evaluated in clinical trials, with potential availability for the general population, including children, in the next several years [22-26]. However, it is unclear how consumers most at risk for the disease and clinicians perceive future Lyme disease vaccines. Although there is little research published on this topic, consumer studies found that increased Lyme disease knowledge and increased perceived susceptibility are associated with the likelihood to engage in non-vaccine preventive behaviors [27]. Additionally, two recent surveys showed that a majority of adults in Connecticut and Maryland and Asian American college students in New York would be willing to receive vaccination against Lyme disease, if available [28, 29].

In advance of Lyme disease vaccines coming to market, this research explores what barriers and supports exist for clinicians to recommend vaccination and what factors encourage or inhibit consumers at high risk for the disease from embracing a vaccine to protect against Lyme disease.

Methods

Study sample

Clinicians—Clinician participants were recruited through a clinician-specialized market research firm from three US regions of high Lyme disease incidence: Northeast (Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island and Vermont), Mid-Atlantic (Delaware, Maryland and Virginia) and Upper Midwest (Minnesota and Wisconsin). The market research firm maintains a national database that clinicians opt into to participate in studies for which they are eligible;

clinicians who responded to the initial call for participants for this study then underwent additional screening for eligibility. Recruited clinicians included a range of specialties likely to diagnose and treat Lyme disease patients (Table I). Inclusion criteria were: (i) pediatricians, family practice and internal medicine physicians and physician assistants/nurse practitioners (PA/NPs) who see at least one Lyme disease patient per week, on average, in summer months; (ii) occupational medicine providers who see patients who spend at least 25% of their time outside in wooded or brushy areas and (iii) clinical retail providers, pharmacists and public health nurses working in the specified regions (no additional criteria). To ensure that clinician participants represented mainstream practice, all clinician participants were screened based on responses to two attitudinal statements about vaccines. Clinicians who strongly disagreed that vaccines are important in keeping patients healthy and that their role included vaccine recommendations were excluded. Participants received honoraria of \$150–\$175, depending on their clinical specialty, for their participation.

Consumers—Consumer participants were recruited through a national market research panel (with a similar opt-in model to the clinician database) across three consumer categories: parents of children aged 5–10 years, adults aged 45–60 years and individuals previously diagnosed with Lyme disease (categories were not mutually exclusive). Individuals with a previous Lyme disease diagnosis were also recruited using online advertising on Google and Facebook, which took consumers to an online screener, and third-party recruiters followed up with eligible participants for confirmation and scheduling. Participants represented one of three regions (Northeast, Mid-Atlantic and Upper Midwest) and a mix of agreement responses to attitudinal statements about the importance of vaccines, perceived susceptibility for getting Lyme disease and current actions to prevent Lyme disease. Individuals who strongly disagreed with the importance of vaccines in general were excluded from the study to minimize skewed opinions that may not reflect the opinions of the general population. Participants received incentives of \$75 for their participation.

Study procedure

Investigators received an institutional review board exemption under 45 CFR 46.101(b)(2) from the CDC Human Research Protection Office. Semi-structured in-depth interviews among clinicians and online focus groups among consumers were conducted during August–September 2018, using a web conferencing platform. Participants provided verbal informed consent before the discussions began. Interview questions explored clinicians' perceptions about and experience treating patients with Lyme disease; focus group questions examined consumers' awareness, knowledge and personal experience with Lyme disease and both interview and focus groups discussions explored participants' attitudes and beliefs about a potential vaccine to prevent Lyme disease.

Analysis

Interviews and focus groups were recorded and transcribed. Using the applied thematic analysis framework [30] and Dedoose qualitative analysis software [31], two members of the research team reviewed the transcripts to identify common themes among participants, areas of consensus and areas where participants differed in their perspectives and experiences.

Researchers organized excerpts using a codebook, including emergent and *a priori* codes, categorized into barriers and facilitators that could influence the uptake of a Lyme disease vaccine. Two researchers independently coded the data, resolved coding disagreements and refined coding frames [32]. Interrater reliability was evaluated by percent agreement and Cohen's kappa.

Results

In coding the data, investigators achieved an interrater reliability of 96.8% agreement [33] and a 0.64 pooled Cohen's kappa, which met goals of 80% agreement and 0.61–0.80 Cohen's kappa based on standards set by previous studies [34, 35].

Interviews with clinicians

Thirty clinicians were interviewed; interviews lasted 24–65 min (mean = 42 min). Clinician types included pediatricians ($n = 6$), family practice or internal medicine physicians ($n = 6$), PAs/NPs ($n = 6$), healthcare providers working in retail clinical settings ($n = 3$), pharmacists ($n = 3$), public health nurses ($n = 3$) and occupational medicine providers ($n = 3$). Two clinicians were from specialized Lyme disease clinics/academic research centers, and one participant self-identified as a Lyme-literate physician (not an official designation that requires certification), although this was not a standard interview question. Participant characteristics are detailed in Table I.

Facilitators for clinician recommendation of a Lyme disease vaccine—

Clinicians were generally receptive and enthusiastic about a Lyme disease vaccine; facilitators included high incidence of Lyme disease, high level of patient and clinician concern and high perceived benefits of the vaccine. Twenty-six clinicians (87%) reported they would be very likely to recommend a Lyme disease vaccine to their patients, while four (13%) reported being somewhat likely to recommend the vaccine. Over half of the clinicians deemed a Lyme disease vaccine as more valuable than other preventive measures due to a potential vaccine's effectiveness, convenience and safety and the added layer of protection beyond potentially ineffective personal preventive behaviors. Most clinicians ranked the importance of a Lyme disease vaccine as equal to or greater than other vaccines, contingent on Lyme disease incidence, patients' risk of exposure and potential severity of the disease. More than one-third of the clinicians reported that their patient population would be receptive to a Lyme disease vaccine and that some patients may be more receptive to a Lyme disease vaccine than to other vaccines. Table II summarizes factors that clinicians reported as influencing their decision to recommend the vaccine to patients.

Patient–provider interactions regarding Lyme disease.: Clinicians suggested that patient awareness of Lyme disease incidence in their regions leads to fear and concerns, especially among parents. As such, clinicians reported seeing many more patients with 'suspected' Lyme disease than confirmed cases, usually in the context of a tick exposure or non-specific symptoms. One-third of the clinicians attributed patient fear to a lack of knowledge about disease transmission and symptoms.

Clinicians reported challenges when discussing Lyme disease with patients due to uncertain diagnoses, high prevalence of misinformation and patient resistance to certain treatment options (e.g. antibiotics). More than half of the clinicians said that they often must combat misinformation that patients receive about Lyme disease from friends and family, advocacy groups and online sources. These clinicians also shared that they must combat ‘miseducation’ from other providers who do not follow accepted guidelines and evidence-based protocols (e.g. diagnostic tests and treatments).

I feel like I’m countering a lot of misinformation all the time, and just having patients understand how we’re testing, why we’re testing, when we’re testing, interpreting the test results is sometimes very challenging. I’ve had patients who just absolutely will not accept it, and they’ve gone to see a different doctor, and they’ve gotten the answer they want and have gotten treatment, even though their test is very clearly negative.

(Family practice physician, Mid-Atlantic)

Most clinicians reported frequently discussing Lyme disease prevention with patients, most often during the summer months, as a part of their regular wellness discussions with patients. Clinicians discussed performing regular tick checks, wearing protective clothing, using insect repellent, properly removing ticks and avoiding tick-prone areas.

Clinician concerns about Lyme disease.: Clinicians reported that they were primarily concerned about Lyme disease due to challenges related to diagnosis and treatment. All but one clinician expressed frustration with diagnostic tests and some reported that limitations of diagnostic tests and uncertainty of test results often lead to over-prescription of antibiotics. Over half of the clinicians reported facing challenges in treatment outcomes, particularly after delayed diagnosis, complex symptoms or when treating children. Other clinician concerns included high levels of risk in some of their patient populations (e.g. hunters and outdoor workers), lack of patient knowledge about Lyme disease (e.g. transmission and treatment) and undesirable or ineffective preventive methods.

Perceived benefits of a Lyme disease vaccine.: Clinicians cited primary benefits of a Lyme disease vaccine as protection for at-risk populations, reduction in disease burden and peace of mind for both patients and themselves:

Fear has a lot to do with the way things get managed, right? So, what ends up happening is, if a patient comes in and they have a fear of Lyme disease, you end up sometimes putting them on antibiotics without any reason. Sometimes you end up drawing blood and doing additional testing without any reasons. Sometimes you’re kind of stuck in this Lyme route.

(Pediatrician, Mid-Atlantic)

Almost half of the clinicians said that the vaccine would provide an added layer of protection when used with other preventive measures (e.g. insect repellent and protective clothing). One-quarter suggested that a Lyme disease vaccine would reduce costs for patients and the healthcare system. A few clinicians expressed that a vaccine could reduce the demand for unnecessary antibiotics.

Barriers to clinician recommendation of a Lyme disease vaccine—The interviews illuminated several potential barriers to a strong clinician recommendation of Lyme disease vaccination. A few clinicians across specialties and regions reported not including prevention recommendations as part of routine discussions with patients. Reasons cited were lack of clinical priority, lack of time and/or the perception that prevention discussions are outside of the clinician's scope of work. Over half of the clinicians also identified patient misinformation as a barrier to effective discussions about Lyme disease prevention.

A quarter of the clinicians argued that a Lyme disease vaccine would be less important than other routine vaccines because Lyme disease can be prevented through other measures, cannot be transmitted person-to-person, is not widespread throughout the United States and has a lower disease burden than other vaccine-preventable diseases. Two clinicians speculated that patients may not perceive the vaccine as a priority; for example, patients have other prevention options against Lyme disease, and other vaccines may take precedence. The most commonly presumed barriers to vaccine uptake were patient concerns about cost and safety and anti-vaccine sentiment.

Five clinicians expressed concern that a vaccine might promote a false sense of security against Lyme disease and other vector-borne diseases. These and other clinicians said they would encourage patients to continue to take measures to prevent other possible infections associated with a tick bite. Additionally, when diagnosed and treated in a timely manner, clinicians recognized that Lyme disease can be mild, which may decrease motivation to recommend the vaccine.

Focus groups with consumers

Thirty-five members of the general public participated in the study, and focus groups lasted 46–91 min (mean = 67 min). Eleven (35%) represented parents of children aged 5–10 years; 14 (40%) represented adults aged 45–60 years and 10 (29%) represented people previously diagnosed with Lyme disease by a physician (Table I).

Facilitators to consumer uptake of a Lyme disease vaccine—Over half of the consumer participants said that they would be very likely to get a Lyme disease vaccine for themselves or their children or families, citing high awareness, perceived susceptibility and perceived severity of Lyme disease and preference for a vaccine over other preventive measures. Most consumers expressed a positive initial reaction to information about the new vaccine in development; all were still interested, if not more so, at the end of the discussions and were eager to learn more. Table III summarizes factors consumers reported as influencing their decision to get a Lyme disease vaccine for themselves and/or their families.

Nearly two-thirds of the consumers suggested that having a vaccine to prevent Lyme disease would be more effective, easier or more convenient than other preventive behaviors, such as wearing protective clothing and performing tick checks. About half of the consumers ranked the importance of a Lyme disease vaccine as equal to or greater than other vaccines due to the disease burden on populations at risk and the potential for long-term health

consequences of the disease. Four consumers reported that they often opt out of other vaccines (e.g. influenza) but would be more inclined to get a Lyme disease vaccine:

So, I've not done a flu shot. I've not done the chicken pox. I think it's higher [importance] just because I'm exposed to it, and I've seen the devastation with getting a tick bite and getting Lyme disease.

(Adult, Upper Midwest)

When discussing the vaccine itself, almost half of the consumers mentioned that a Lyme disease vaccine would be of significant interest to others in their community, largely due to high incidence of the disease and risk factors (e.g. time spent outside).

Knowledge and awareness of Lyme disease.: Adults in the Northeast most often recognized Lyme disease as a common risk in their region and, therefore, had a heightened level of concern. The reported incidence, perceived susceptibility and level of concern varied more among those in the Mid-Atlantic and the Upper Midwest. Consumers suggested that tick populations are so abundant in parts of the Northeast and the Upper Midwest that people are susceptible to tick bites wherever they are, not just when in the woods or rural areas.

All consumer participants were generally aware of how Lyme disease is spread through tick bites and that ticks had to be attached for a certain amount of time to transmit the disease. Fewer participants specifically mentioned deer ticks, that not all ticks carry the disease or that Lyme disease is a bacterial infection.

All consumer participants were aware of at least one way to prevent Lyme disease, with many citing multiple preventive measures, including covering exposed skin, wearing light-colored clothing, using insect repellent, performing regular tick checks and prompt and proper tick removal and taking environmental measures (e.g. keeping grass short and treating lawns).

Most consumers—except those with a previous Lyme disease diagnosis—had limited knowledge of the diagnosis and treatment of Lyme disease. Two-thirds of the consumers associated delayed diagnosis and treatment of Lyme disease with life-long health issues. Four consumers commented that even when treated, Lyme disease can cause significant negative, long-term health issues, suggesting that treatment may not always alleviate symptom longevity or severity. This sentiment was also reflected in some of the personal experiences of those who had been previously diagnosed with Lyme disease, with 7 out of 10 reporting delays in diagnosis for months or years and lingering issues.

Perceived benefits of a Lyme disease vaccine.: In discussing disease prevention as a key benefit, almost half referenced the high burden of Lyme disease in their area and the associated degradation in the quality of life:

Here in Maine, we've become like the number one state for Lyme disease. So, it's a real common thing here, and I know quite a few people that have gotten Lyme.... And a lot of them, seeing the pain they're in, knowing that, if there had been a vaccine and they had taken it, their lives might be very different today.

(Adult, Northeast)

Almost half of the consumers shared that having a vaccine to prevent Lyme disease would ease their worry about getting the disease while being outside and doing activities they enjoy. Over half expressed that a vaccine would be one more tool in their preventive toolbox, with several stating that they would likely continue the other preventive behaviors to protect against other vector-borne diseases:

My thing is, there's no guarantee that I am going to be able to pick every tick off my child because some are so tiny, and some are bigger... It doesn't matter if I put long pants on my child, spray him, or check. There's no guarantee, whereas if there's a vaccine, there's a backup plan.

(Parent, Mid-Atlantic)

When thinking about who would most benefit from a Lyme disease vaccine, consumers often listed those who spend lots of time outside (recreationally or by occupation), children, those in high incidence areas, people with pets and those with compromised immune systems.

Barriers to consumer uptake of a Lyme disease vaccine—About a third of the consumers were undecided about getting the vaccine for themselves or their families. Fewer reported that it would be unlikely for them or their families to be vaccinated, usually due to the lack of perceived susceptibility, competing medical priorities or disinterest or distrust of vaccines in general. One-third of the consumers suggested that a Lyme disease vaccine would be less important than other vaccines because Lyme disease is not transmitted person-to-person and not every tick carries the Lyme disease pathogen.

Four consumers expressed concerns about side effects, with most others assuming it would have minimal risks. Three consumers suggested that potential side effects may make a vaccine more risky than other preventive behaviors. Four consumers shared that they prefer to avoid vaccines in general. Two consumers also mentioned generally that anti-vaccine sentiment in their communities might be a barrier for vaccine acceptance more broadly. Finally, two consumers mentioned that the vaccine could create a false sense of security among recipients if the vaccine was not completely protective against Lyme disease.

While consumers generally perceived Lyme disease to be moderate to severe, three consumers characterized the disease as mild if detected and treated early, which may reduce interest in a Lyme disease vaccine. Four consumers mentioned that they do not feel enough at risk for Lyme disease to necessitate vaccination.

Discussion

Most consumers and clinicians in areas of high Lyme disease incidence were supportive of a vaccine and would either highly recommend it (clinicians) or be likely to receive it (consumers). Participants in areas with high Lyme disease incidence shared common motivators to either recommend (clinicians) or accept (consumers) a Lyme disease vaccine, largely driven by perceived benefits of the vaccine, lack of current effective preventive

measures and greater peace of mind. Clinicians in this study also expressed concern about their capacity to diagnose and treat Lyme disease in an efficient, evidence-based manner and would be less concerned about misdiagnoses if patients were vaccinated.

Clinicians seeing a key benefit to Lyme disease vaccination in avoiding challenges related to diagnosis and treatment of the complex disease is a novel finding and unique among provider vaccine recommendations, which are often grounded in benefits to the patient. Removing Lyme disease from the sometimes-long list of differential diagnoses for illnesses with more generalized symptoms can ease patient discussions and improve the time to an accurate diagnosis.

Additionally, that most clinicians would strongly recommend the vaccine is meaningful. Previous human papilloma virus (HPV) vaccine research has shown that patients who receive a strong provider recommendation for the HPV vaccine are 9–35 times more likely to start the series [36, 37], and provider recommendation to parents and caregivers is the strongest predictor of HPV vaccination among adolescents [38, 39]. Recent studies have also shown that provider recommendations would increase consumers' willingness to get a COVID-19 vaccine [40], potentially working to overcome consumers' concerns regarding the newness of a vaccine.

While other studies have examined non-vaccine prevention perceptions around Lyme disease in the United States [12, 27, 41–45] and vaccine intentions among targeted adult populations [12, 28, 29], this is the first study that specifically explores the perceived benefits of a new vaccine among a variety of clinicians and three at-risk segments of adults across endemic regions. These results indicate that both clinicians and consumers in high incidence areas might have a greater sense of protection and peace of mind compared to other prevention methods. Similar studies concerning perceptions about a potential Zika virus vaccine found associations between vaccine acceptability and perceived disease susceptibility. At-risk populations preferred a potential Zika vaccine to other preventive behavioral strategies, such as the application of a repellent, that are challenging to implement consistently [46, 47].

Similar to other research related to the HPV, H1N1 influenza and early childhood vaccines [48–50], our findings align with the Health Belief Model, which suggests that six main constructs (perceived susceptibility, severity, benefits, barriers, cues to action and self-efficacy) influence an individual's decision about whether to take preventive actions [51]. Our results suggest the need for health promotion and messaging to patients in areas of high risk or with high perceived susceptibility that highlight the benefits of Lyme disease vaccination over barriers, such as concerns about vaccine safety (particularly for a new vaccine) and logistical barriers (e.g. cost).

While this effort establishes a supportive foundation to understand clinician and consumer supports, and barriers to Lyme disease vaccine acceptability and uptake, additional work is needed to (i) understand the perceptions and role of the Lyme disease patient advocacy community in influencing clinician and consumer acceptance of a vaccine and (ii) develop and evaluate appropriate messaging for vaccine promotion.

Limitations

The focus groups and in-depth interviews (IDIs) comprised a relatively small sample size, and the recruiting methods did not generate a representative sample, as is typical of qualitative research. Additionally, the exclusion of participants who strongly disagreed that vaccines are important to protect public health limits the generalizability of our results. However, this exclusion criterion was justified, given that a strong anti-vaccine sentiment is exceptionally difficult to change (Collier, 2017).

Implications for practice

Exploring vaccine perceptions from both consumer and clinician perspectives provides a more holistic view of the factors that might influence vaccine success and can inform communications and education efforts that target both audiences. Public health education efforts can leverage public awareness about Lyme disease to position vaccination as a prevention behavior, which may alleviate fear and uncertainty in both consumers and clinicians.

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References

1. Rosenberg R, Lindsey NP, Fischer M et al. Vital signs: trends in reported vectorborne disease cases —United States and territories, 2004–2016. *MMWR Morb Mortal Wkly Rep* 2018; 67: 496–501. [PubMed: 29723166]
2. Kugeler KJ, Schwartz AM, Delorey MJ, et al. Estimating the frequency of Lyme disease diagnoses, United States, 2010–2018. *Emerg Infect Dis* 2021; 27: 616–9. [PubMed: 33496229]
3. Centers for Disease Control and Prevention. Lyme Disease Transmission. Available at: <https://www.cdc.gov/lyme/transmission/index.html>. Accessed: 12 March 2021.
4. Wormser GP, Dattwyler RJ, Shapiro ED et al. The clinical assessment, treatment, and prevention of Lyme disease, human granulocytic anaplasmosis, and babesiosis: clinical practice guidelines by the Infectious Diseases Society of America. *Clin Infect Dis* 2006; 43: 1089–134. [published correction appears in *Clin Infect Dis* 2007; 45: 941]. [PubMed: 17029130]
5. Marques AR. Laboratory diagnosis of Lyme disease: advances and challenges. *Infect Dis Clin North Am* 2015; 29:295–307. [PubMed: 25999225]
6. Lantos PM, Rumbaugh J, Bockenstedt LK et al. Clinical practice guidelines by the Infectious Diseases Society of America, American Academy of Neurology, and American College of Rheumatology: 2020 guidelines for the prevention, diagnosis, and treatment of Lyme disease. *Neurology* 2021; 96: 262–73. [published correction appears in *Neurology* 2021; 96: 296]. [PubMed: 33257476]
7. Weitzner E, McKenna D, Nowakowski J et al. Long-term assessment of post-treatment symptoms in patients with culture-confirmed early Lyme disease. *Clin Infect Dis* 2015; 61:1800–6. [PubMed: 26385994]

8. Marques A. Chronic Lyme disease: a review. *Infect Dis Clin North Am* 2008; 22: 341–60. [PubMed: 18452806]
9. Auwaerter PG, Bakken JS, Dattwyler RJ et al. Antiscience and ethical concerns associated with advocacy of Lyme disease. *Lancet Infect Dis* 2011; 11: 713–9. [PubMed: 21867956]
10. Eisen RJ, Eisen L, Beard CB. County-scale distribution of *Ixodes scapularis* and *Ixodes pacificus* (Acari: Ixodidae) in the continental United States. *J Med Entomol* 2016; 53: 349–86. [PubMed: 26783367]
11. Hinckley AF, Meek JI, Ray JA et al. Effectiveness of residential acaricides to prevent Lyme and other tick-borne diseases in humans. *J Infect Dis* 2016; 214: 182–8. [PubMed: 26740276]
12. Nawrocki CC, Hinckley AF. Experiences with tick exposure, Lyme disease, and use of personal prevention methods for tick bites among members of the U.S. population, 2013–2015. *Ticks Tick Borne Dis* 2021; 12: 101605. [PubMed: 33217712]
13. Recommendations for the use of Lyme disease vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* 1999; 48: 1–25. [published correction appears in *MMWR Morb Mortal Wkly Rep* 1999 Sep 24; 48(37): 833].
14. Poland GA, Jacobson RM. The prevention of Lyme disease with vaccine. *Vaccine* 2001; 19: 2303–8. [PubMed: 11257352]
15. Shen AK, Mead PS, Beard CB. The Lyme disease vaccine—a public health perspective. *Clin Infect Dis* 2011; 52: s247–s52. [PubMed: 21217171]
16. Aronowitz RA. The rise and fall of the Lyme disease vaccines: a cautionary tale for risk interventions in American medicine and public health. *Milbank Q* 2012; 90: 250–77. [PubMed: 22709388]
17. Ball R, Shadomy SV, Meyer A et al. HLA type and immune response to *Borrelia burgdorferi* outer surface protein a in people in whom arthritis developed after Lyme disease vaccination. *Arthritis Rheum* 2009; 60: 1179–86. [PubMed: 19333928]
18. Lathrop SL, Ball R, Haber P et al. Adverse event reports following vaccination for Lyme disease: December 1998–July 2000. *Vaccine* 2002; 20: 1603–8. [PubMed: 11858868]
19. Nigrovic LE, Thompson KM. The Lyme vaccine: a cautionary tale. *Epidemiol Infect* 2007; 135: 1–8. [PubMed: 16893489]
20. Plotkin SA. Correcting a public health fiasco: the need for a new vaccine against Lyme disease. *Clin Infect Dis* 2011; 52: s271–s5. [PubMed: 21217175]
21. Plotkin SA. Need for a new Lyme disease vaccine. *N Engl J Med* 2016; 375: 911–3. [PubMed: 27602662]
22. Lyme Disease – VLA15. Valneva. Available at: <https://valneva.com/research-development/lyme-disease/>. Accessed: 12 March 2021.
23. Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate VLA15. Valneva. Available at: <https://valneva.com/press-release/valneva-announces-positive-initial-results-for-second-phase-2-study-of-lyme-disease-vaccine-candidate-vla15/>. Accessed: 12 March 2021.
24. Flaherty B. Can a new Lyme disease vaccine overcome a history of distrust and failure? *STAT* 2019.
25. Wang Y, Esquivel R, Flingai S et al. Anti-OspA DNA-encoded monoclonal antibody prevents transmission of spirochetes in tick challenge providing sterilizing immunity in mice. *J Infect Dis* 2019; 219: 1146–50. [PubMed: 30476132]
26. Wang Y, Kern A, Boatright NK et al. Pre-exposure pro-phylaxis with OspA-specific human monoclonal antibodies protects mice against tick transmission of Lyme disease spirochetes. *J Infect Dis* 2016; 214: 205–11. [PubMed: 27338767]
27. Fogel J, Chawla GS. Susceptibility, likelihood to be diagnosed, worry and fear for contracting Lyme disease. *J Infect Public Health* 2017; 10: 64–75. [PubMed: 27026135]
28. Niesobecki S, Hansen A, Rutz H et al. Knowledge, attitudes, and behaviors regarding tick-borne disease prevention in endemic areas. *Ticks Tick Borne Dis* 2019; 10: 101264. [PubMed: 31431351]
29. Fogel J, Kusz M. Intentions to receive a potentially available Lyme disease vaccine in an urban sample. *Ther Adv Vaccines* 2016; 4: 3–14. [PubMed: 27551427]

30. Fereday J, Muir-Cochrane E. Demonstrating rigor using thematic analysis: a hybrid approach of inductive and deductive coding and theme development. *Int J Qual Methods* 2006; 5: 80–92.
31. SocioCultural Research Consultants. *Dedoose Mixed Methods and Qualitative Research Software*. 2018.
32. Guest G, MacQueen KM, Namey EE. *Applied Thematic Analysis*. Los Angeles, CA: Sage Publications, 2012.
33. Miles MB, Huberman AM, Saldana J. *Qualitative Data Analysis: An Methods Sourcebook*, 3rd edn. Thousand Oaks, CA: Sage Publications, 2013.
34. Cohen J. A coefficient of agreement for nominal scales. *Educ Psychol Meas* 1960; 20: 37–46.
35. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977; 33: 159–74. [PubMed: 843571]
36. Gerend MA, Shepherd MA, Lustria ML, et al. Predictors of provider recommendation for HPV vaccine among young adult men and women: findings from a cross-sectional survey. *Sex Transm Infect* 2016; 92: 104–7. [PubMed: 26297720]
37. Gilkey MB, Calo WA, Moss JL, et al. Provider communication and HPV vaccination: the impact of recommendation quality. *Vaccine* 2016; 34: 1187–92. [PubMed: 26812078]
38. Gargano LM, Herbert NL, Painter JE et al. Impact of a physician recommendation and parental immunization attitudes on receipt or intention to receive adolescent vaccines. *Hum Vaccin Immunother* 2013; 9: 2627–33. [published correction appears in *Hum Vaccin Immunother*. 2014; 10(9): 2631]. [PubMed: 23883781]
39. Reiter PL, McRee AL, Pepper JK, et al. Longitudinal predictors of human papillomavirus vaccination among a national sample of adolescent males. *Am J Public Health* 2013; 103: 1419–27. [PubMed: 23763402]
40. Reiter PL, Pennell ML, Katz ML. Acceptability of a COVID-19 vaccine among adults in the United States: How many people would get vaccinated? *Vaccine* 2020; 38: 6500–7. [PubMed: 32863069]
41. Gould LH, Nelson RS, Griffith KS et al. Knowledge, attitudes, and behaviors regarding Lyme disease prevention among Connecticut residents, 1999–2004. *Vector Borne Zoonotic Dis* 2008; 8: 769–76. [PubMed: 18637724]
42. Herrington JE. Risk perceptions regarding ticks and Lyme disease: a national survey. *Am J Prev Med* 2004; 26: 135–40. [PubMed: 14751325]
43. Herrington JE Jr, Campbell GL, Bailey RE et al. Predisposing factors for individuals' Lyme disease prevention practices: Connecticut, Maine, and Montana. *Am J Public Health* 1997; 87: 2035–8. [PubMed: 9431299]
44. McKenna D, Faustini Y, Nowakowski J, et al. Factors influencing the utilization of Lyme disease-prevention behaviors in a high-risk population. *J Am Acad Nurse Pract* 2004; 16: 24–30. [PubMed: 15008035]
45. Shadick NA, Daltroy LH, Phillips CB, et al. Determinants of tick-avoidance behaviors in an endemic area for Lyme disease. *Am J Prev Med* 1997; 13: 265–70. [PubMed: 9236962]
46. Fraiz LD, de Roche A, Mauro C et al. U.S. pregnant women's knowledge and attitudes about behavioral strategies and vaccines to prevent Zika acquisition. *Vaccine* 2018; 36: 165–9. [PubMed: 29157958]
47. Painter JE, Plaster AN, Tjersland DH, et al. Zika virus knowledge, attitudes, and vaccine interest among university students. *Vaccine* 2017; 35: 960–5. [PubMed: 28069360]
48. Coe AB, Gatewood SB, Moczygemba LR, et al. The use of the health belief model to assess predictors of intent to receive the novel (2009) H1N1 influenza vaccine. *Innov Pharm* 2012; 3: 1–11. [PubMed: 22844651]
49. Donadiki EM, Jiménez-García R, Hernández-Barrera V et al. Health Belief Model applied to non-compliance with HPV vaccine among female university students. *Public Health* 2014; 128: 268–73. [PubMed: 24529635]
50. Smith PJ, Humiston SG, Marcuse EK et al. Parental delay or refusal of vaccine doses, childhood vaccination coverage at 24 months of age, and the Health Belief Model. *Public Health Rep* 2011; 126: 135–46. [PubMed: 21812176]

51. National Cancer Institute. Theory at A Glance: A Guide for Health Promotion Practice, 2nd edn. Bethesda, MD: US Dept. of Health and Human Services, National Institutes of Health, National Cancer Institute, 2005.
52. Collier R. Facts not enough to change minds about health myths. CMAJ 2017; 189: E1430. [PubMed: 29158461]

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Table 1.
Number of clinician IDI and consumer focus group participants by segment and region

Audience segment	Number of participants by region				Total
	Northeast	Mid-Atlantic	Upper Midwest	Total	
Clinician IDI participants					
Pediatricians	2	2	2	6	
Family practice or internal medicine physicians who see adult patients	2	2	2	6	
Physician assistants/nurse practitioners	2	2	2	6	
Healthcare providers working in retail clinical settings	1	1	1	3	
Pharmacists	1	1	1	3	
Public health nurses at local health centers	1	1	1	3	
Occupational medicine providers	1	1	1	3	
Total	10	10	10	30	
Consumer focus group participants					
Adults aged 45–60 years	5	4	5	14	
People previously diagnosed with Lyme disease by a physician	2	3	5	10	
Parents of children aged 5–10 years	4	4	3	11	
Total	11	11	13	35	

Table II.

Factors that influence clinician recommendation of a Lyme disease vaccine

Vaccine benefits

- Protection for at-risk populations
- Decreased disease burden
- Decreased patient worry
- Added layer of protection
- Decreased healthcare costs
- Decreased clinician worry

Vaccine risks

- Side effects
- False sense of security

Facilitators for vaccine recommendation

- Guidelines from professional/scientific body
- Patient receptiveness
- Insurance coverage
- Patient awareness

Barriers to vaccine administration

- Cost
- Anti-vaccine sentiment
- Patient concern about vaccine safety
- Clinician confusion about contraindications

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Table III.

Factors that influence consumer acceptance of a Lyme disease vaccine

Vaccine benefits

- Protection for at-risk populations
- Added layer of protection
- Reduced disease burden
- Decreased worry

Vaccine barriers

- ‘Newness’ of the vaccine
- Lack of perceived risk/not a priority vaccine
- Anti-vaccine sentiment

Factors informing vaccine decision

- Side effects and long-term safety
- Cost and insurance coverage
- Effectiveness
- Dosage
- Indications/contraindications
- How it works
- Convenience
- Stakeholders and beneficiaries

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