Acceptability of 4-Poster Deer Treatment Devices as a Communitywide Method for Reducing Ticks Important to Human Health in CT and NY

Sponsored by:

Bacterial Diseases Branch

Division of Vector-Borne Diseases (DVBD)

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

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PROTOCOL SUMMARY

Title: Acceptability of 4-Poster Deer Treatment Devices as a Communitywide Method for Reducing Ticks Important to Human Health in CT and NY

Objectives: The primary objective of this study is to evaluate the acceptability of 4-Poster Deer Treatment Devices (4-poster devices) as a communitywide method for reducing ticks important to human health in high Lyme disease incidence (LDI) counties of CT and NY. Specifically, we will use this survey to 1) assess the willingness of respondents to have a 4-poster device placed on their properties and in their communities, 2) identify reasons respondents do not support placement of a device in these settings, and 3) evaluate whether acceptance is correlated with geographic region, respondent household characteristics, concern for and experience with tickborne diseases, or opinions on community tick control.

Design: Using a cross-sectional design, we will conduct a survey of at least 1500 persons from CT and NY (500 from CT; and 500 from each of two regions in NY) in the spring of 2020. We will conduct descriptive analyses of survey results to determine respondents' acceptance of 4-poster devices as a method for community tick control and primary reasons respondents find 4-poster devices unacceptable. We will evaluate associations, if any, between respondent willingness to have a 4-poster device placed on his/her property or in his/her community and geographic region, respondent and household characteristics, concern for and experience with tickborne diseases, and opinions on community tick control.

Population: Survey invitations will be sent to a random sample of households in select high LDI counties in CT and NY (8 counties in CT; 8 counties in NY). High LDI counties are defined as counties with a five-year average (2013-2017) LDI $\geq$ 10 cases per 100,000 persons. In NY, the population will be stratified based on history of 4-poster device implementation in the community (Suffolk County compared to Hudson Valley counties). One adult over the age of 18 from each residence will be asked to respond to the survey.

Study Duration: Recruitment, enrollment, and survey completion will occur in March-April 2020, so that collection of information from all respondents will take place just before tickborne disease season (typically from April-October). Statistical analysis and dissemination of results will be completed in the 12 months following data collection.

Study Procedures: An invitation postcard will be used for recruitment. This postcard will contain a web link, QR code, and unique access code for completing the survey online. Respondents will be informed that they may contact their state study coordinator to take the survey over the phone if preferred.

Endpoints: Results of this survey will inform whether future efforts to evaluate the impact of 4-poster devices on human tick encounters and tickborne disease and to utilize devices as a form of community tick control in high LDI communities are warranted. Additionally, it will identify areas of high acceptance where conducting a future 4-poster device intervention to evaluate impacts on human tick encounters and tickborne disease may be feasible.

INVESTIGATORS/COLLABORATORS

This activity involves collaboration between CDC investigators in the Bacterial Diseases Branch (Fort Collins, CO), Division of Vector-Borne Diseases (DVBD), the Connecticut Emerging Infections Programs, and the New York State Emerging Infections Programs.

CDC investigators

Alison Hinckley	Epidemiologist, Principal Investigator for TickNET studies. Responsible for providing technical assistance/scientific consult to TickNET in the development of project design and protocol, evaluating conduct, data storage, data management, and analysis. As Project Officer, provides oversight for all of the individual cooperative agreements with TickNET.
Courtney Nawrocki	Epidemiology ORISE Fellow. Responsible for assisting with protocol development, preparing IRB materials, developing the data analysis plan, and drafting the project report.
Lars Eisen	Research Entomologist. Responsible for providing entomological expertise and scientific consultation in the development of project design, implementation of the protocol, analysis of the results, and manuscript preparation and dissemination.
Erik Foster	Research Entomologist. Responsible for providing entomological expertise and scientific consultation in the development of project design, implementation of the protocol, analysis of the results, and manuscript preparation and dissemination.
Brad Biggerstaff	Mathematical Statistician. Responsible for consulting on sampling design, providing support for statistical analysis, and assisting with final study analyses, presentation of results, and manuscript preparation.

TickNET investigators

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Kristen Howard, Graduate Student Assistant
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The investigators at the CT and NYS EIP sites will work collaboratively with CDC scientists on scientific aspects

of study design and analysis, including development of the study protocol, interview instrument design, and study conduct. In addition, they are responsible at their individual sites for: 1) meeting human subjects research requirements; 2) data storage and management; 3) statistical aspects of study design and analysis

The Centers for Disease Control and Prevention is funding this study. There are no known conflicts of interest.

LIST OF ABBREVIATIONS AND ACRONYMS

CDC	Centers for Disease Control and Prevention
CT	Connecticut
DIN	Density of infected nymphs
EIP	Emerging Infections Program
EM	Erythema migrans
LDI	Lyme disease incidence
MSG	Marketing Systems Group
NEATCP	Northeast Area-wide Tick Control Project
NY	New York
IRB	Institutional Review Board
USDA	United States Department of Agriculture

BACKGROUND AND OVERVIEW

History and Purpose of TickNET

TickNET is a collaborative effort between three separate CDC branches working on tickborne diseases and four Emerging Infections Program (EIP) sites in Connecticut, Maryland, Minnesota, and New York. The EIP is a network of state health departments and their collaborators in local health departments, academic institutions, other federal agencies, and public health and clinical laboratories. Major strengths of this partnership include the ability to evaluate multiple tickborne pathogens simultaneously, support for localized efforts, access to a large study population, and collaborative development of instruments and methods. The ultimate goals of TickNET are to foster greater collaboration among CDC programs working on tickborne diseases, to enhance and integrate surveillance for tickborne diseases in partnership with states, and to facilitate applied research projects that address key public health questions regarding tickborne diseases. Through these efforts, CDC aims to better understand the burden of tickborne diseases and to develop tools to control their increasing incidence.

Tickborne Diseases in the United States

In 2010, tickborne diseases were collectively the 2nd and 3rd most common nationally notifiable conditions in the New England and Mid-Atlantic states, with over 15,000 cases of human illness reported (MMWR 2009). Tickborne diseases in these areas result primarily from pathogens cycling among animals. Ticks require a blood meal at each of three life stages (larva, nymph and adult) and generally feed on a different host for each stage. In general, larval ticks may acquire pathogens by feeding on infected rodents (particularly the white footed mouse, *Peromyscus leucopus*). Infections are retained as larvae become nymphs, and as nymphs become adult ticks. Humans acquire tickborne diseases incidentally, and most often through the bite of infected nymphs or adults.

Lyme disease is the most common vector-borne disease in the United States, where it is caused by infection with the bacteria *Borrelia burgdorferi* and less commonly, *Borrelia mayonii*. *B. burgdorferi* is transmitted by the *Ixodes scapularis* tick (also known as the blacklegged, or “deer” tick) in the Northeastern, Upper Midwest, and Mid-Atlantic states. Connecticut and New York are considered high Lyme disease incidence (LDI) states, with average annual incidence rates of 58.7 and 17.3 per 100,000 population, respectively (Schwartz 2017). Lyme disease is most often characterized in early illness by an erythema migrans (EM) rash. Without treatment, the infection disseminates, and patients can develop multiple secondary annular skin lesions, and/or overt rheumatologic, cardiac, or neurologic symptoms (Steere 2005). Anaplasmosis, caused by the bacterium *Anaplasma phagocytophilum*, and babesiosis, caused from infection with parasites of the *Babesia* genus, are other tickborne diseases transmitted by *I. scapularis*, and can become severe, especially if left untreated. *Ehrlichia chaffeensis* and *Ehrlichia ewingii* (which cause human ehrlichiosis) *Francisella tularensis* (which causes tularemia), Heartland virus, and Bourbon virus are other disease-causing pathogens and are transmitted by the *Ambloymma americanum*, or lone star tick, along the eastern U.S.

Surveillance systems can be used to describe the general epidemiology of these diseases. However, due to the lack of funding for large-scale studies of tickborne diseases, it has been difficult to evaluate the efficacy of disease prevention methods for humans.

Prevention of Tickborne Diseases

Current recommendations for tickborne disease prevention focus on personal protection strategies (*e.g.*, repellents, tick checks, protective clothing, acaricide-treated clothing). These are simple measures that can be used to minimize the risk of tick bite and pathogen exposure, although effectiveness relies heavily on consistency of practice (Piesman and Eisen 2008). There is also a wide array of environmental prevention tools available (*e.g.*, applications of acaricide on properties, natural product pesticides, biological control agents). However, implementation of many of these methods is the responsibility of the household; barriers such as cost and lack of awareness of tickborne disease risk can lead to inconsistent practice within communities (Piesman and Eisen 2008). Given these barriers to effective implementation of prevention measures, the incidence of tickborne disease is steadily increasing and its geographic scope expanding.

4-Poster Deer Treatment Devices

Heavily forested areas border many communities in the northeastern United States, creating numerous opportunities for non-domestic hosts of human-biting ticks to transport these vectors into the peridomestic environment. One such host is the white-tailed deer (*Odocoileus virginianus*), a primary source of blood for adult blacklegged ticks and lone star ticks. White-tailed deer and blacklegged tick populations have been linked in both abundance and small-scale geographical distribution in the U.S. (Piesman 1979; Anderson and Magnarelli 1980; Shulze 1984, 2001; Wilson 1985, 1990b; Daniels 1993; Stafford 1993; Duffy 1994; Daniels and Fish 1995; Ginsberg and Zhioua 1999; Rand 2003; Ginsberg 2004; Jordan and Schulze 2005; Werden 2014; Kugeler 2015).

The 4-Poster Deer Treatment Device (4-poster device) was designed to topically treat white-tailed deer for *I. scapularis* and *A. amblyomma* ticks as the deer feed from bait bins. The 4-poster device consists of two vertical, acaricide-impregnated applicator rollers on either side of a central bait bin filled with whole kernel corn. As deer consume the corn, the sides of the head, neck, and ears, where ticks typically feed, are rubbed against the applicators and treated with acaricide (permethrin). Because 4-poster devices target adult ticks prior to female egg laying, significant reductions in the abundance of *I. scapularis* and *A. amblyomma* nymphs are generally not observed until at least three years post-deployment (Pound 2009a). For this reason, devices are intended to be operated for several consecutive years and must remain in operation during seasons of peak tick activity for continuous control.

Due to the geographical range of white-tailed deer, 4-poster devices have the benefit of providing protection to a much larger area than other environmental controls such as rodent bait boxes or yard applications of acaricides; this means that entire communities can benefit from several well-placed devices. In a high-density deployment of devices, one device can provide protection for approximately 21 hectares of land (Pound 2009b). Treating deer topically with acaricide also directly affects the life cycles of ticks without eliminating the host or spraying large volumes of acaricide into the environment, both of which may be somewhat controversial in some communities (Piesman 2006).

Previous 4-poster interventions have evaluated control of *I. scapularis* and *A. americanum* populations in a variety of settings, with the majority showing moderate to high reductions in the abundance of host-seeking nymphs (Solberg 2003; Carroll. 2002, 2009a, b; Grear 2014; Schulze 2009; Daniels 2009; Miller 2009, Stafford 2009; Pound 2009b). Small-scale initial studies showed a 69-91% overall reduction in the abundance of host-seeking *I. scapularis* nymphs after 2-3-year intervention periods (Carroll 2002; Solberg 2003). On a larger scale, five 4-poster intervention studies conducted concurrently from 1997-2002 as part of the United States Department of Agriculture (USDA) Northeast Area-wide Tick Control Project (NEATCP) found a 71% collective reduction in *I. scpaularis* nymphal density following the intervention (Pound 2009b; Brei 2009).

Though indices of entomological risk (e.g. density of nymphs, density of infected nymphs (DIN), and nymphal infection prevalence) are often spatially correlated with tickborne diseases on national, regional, and state scales, they are not considered reliable predictors of human disease at finer scales, such as in endemic communities and neighborhoods (Connally 2006). For example, a recent intervention prospectively measuring the impacts of a single, residential barrier acaricide spray on human-tick encounters found that a reduction in host-seeking nymphal abundance did not correlate with a reduction in human-tick encounters (Hinckley 2016). A follow-up study to the 4-poster intervention at the CT NEATCP site found that the intervention may not have reduced the mean incidence of EM rash in the treatment area or compared to the original control area (Garnett 2011). As such, a large-scale, randomized controlled trial is needed to directly and prospectively assess the ability of a communitywide 4-poster device intervention to reduce human-tick encounters and tickborne disease.

Justification for an Acceptability Survey

The ability of 4-poster devices to reduce human tick exposure in a community is limited by the willingness of residents to host devices on their property or support placement of devices on other lands in their community. Of the studies mentioned above, few had treatment sites in residential settings, and no data exist on the public's acceptance of 4-poster devices as part of a communitywide tick management system in Lyme disease endemic

areas. Understanding the acceptability of 4-poster devices as a method for community tick control in high LDI regions and reasons for lack of acceptance is critical before implementing an intervention to assess impacts of 4-poster devices on human outcomes.

Objectives of the Survey

The primary objective of this survey is to evaluate the acceptability of 4-Poster Deer Treatment Devices (4-poster devices) as a communitywide method for reducing ticks important to human health in high LDI areas of CT and NY. Specifically, this survey will be used to:

- Assess the willingness of respondents to have a 4-poster device placed on their properties and in their communities
- Identify reasons respondents do not support placement of a 4-poster device in these settings
- Examine the relationships or lack thereof between willingness of respondents to have a 4-poster device placed on their property or in their community and geographic region, respondent household characteristics, concern for and experience with tickborne diseases, and opinions on community tick control

Hypotheses

We expect that respondent willingness to have a 4-poster device placed on their property or in their community will be related to concern for and experience with tickborne diseases, opinions on community tick control, and previous experience with 4-poster devices in the community. As with many other tickborne disease prevention measures, we hypothesize that acceptance and support for 4-poster devices as a communitywide tick control method increases with perceived risk of tickborne disease and previous infection with a tickborne disease.

Intended Use of Study Findings

We will use results of the survey to:

- Inform whether future efforts to utilize devices as a form of community tick control in high LDI counties are warranted based on willingness of respondents to have a device placed on their properties or in their communities and primary reasons for lack of willingness
- Assess the feasibility of conducting a 4-poster intervention study in high LDI counties in CT and NY to assess impacts on human-tick encounters and tickborne disease
- Identify specific communities with high levels of acceptance where a future 4-poster intervention study could potentially be conducted

Timeline

March-April 2020

- Initiate survey recruitment activities
- Enroll survey respondents
- Survey respondents complete web-based survey

May 2020-August 2020

- Data cleaned and analyzed
- Manuscript of findings prepared

STUDY DESIGN

Using a cross-sectional design, we will conduct a population-based survey among residents of high LDI counties in CT and NY from March-April of 2020. We will conduct descriptive analyses of survey results to determine respondents' acceptance of 4-poster devices as a means of community tick control, and evaluate associations, if any, between respondent willingness to have a 4-poster device placed on their properties or in their communities

and respondent and household characteristics, concern for and experience with tickborne diseases, and opinions on community tick control.

STUDY POPULATION

We will send survey invitations to a random sample of residences in select high LDI counties in CT and NY (Appendix A). One adult over the age of 18 years from each residence will be asked to respond to the survey. Random selection of addresses will be proportional to county population in CT. In NY, random selection of addresses will be stratified to allow for comparison between Suffolk County, where 4-poster devices have been deployed in several towns since 2008, and seven high LDI Hudson Valley counties with no previous exposure to 4-poster devices in the community (the pooled populations of Westchester, Rockland, Putnam, Orange, Dutchess, Ulster, and Sullivan counties). We aim to recruit at least 1500 individuals for this study (at least 500 respondents in CT and at least 500 respondents from each of two regions in NY).

- Target population: adult residents of all eight counties in CT (all counties meet LDI criteria), residents of seven high LDI counties in Hudson Valley, NY (Westchester, Rockland, Putnam, Orange, Dutchess, Ulster, Sullivan) and one high LDI county in Long Island, NY (Suffolk)
- Sampling frame: 1500 randomly selected households (500 in CT; 1000 in NY) in all 8 counties in CT and 8 counties in NY
- Sampling unit: households
- Observation unit: an individual over the age of 18 within a household

Inclusion Criteria

Survey respondent must be adults ≥ 18 years of age.

Recruitment and Enrollment

We will randomly recruit from among all residents living at residential addresses on file with the U.S. Postal Service (USPS) in all 8 counties in CT and 8 high LDI counties in NY. USPS updates this list monthly based on change of address submissions; this list is not available directly from USPS, but addresses from this list can be purchased from marketing companies. In this case, we will use an existing purchased list of addresses from a company we have worked with for other studies, Marketing Systems Group (MSG). This company will randomly select addresses for identified high LDI counties in CT and NY. The number of addresses selected per county will be proportional to county size in CT and proportional to the pooled population of the 7 Hudson Valley counties in NY. The number of addresses selected in Suffolk County, NY will allow for comparisons to be made between responses from residents of Suffolk County to those of the 7 Hudson Valley counties (see Estimated Number of Respondents).

With a minimum necessary sample of 500 respondents in CT and 1000 in NY and an anticipated response rate of 5% (a conservative estimate based on the response rate from a recent TickNET convenience sample survey), we will identify a random selection of 10,000 addresses in CT and 20,000 in NY (10,000 across all included Hudson Valley counties and 10,000 from Suffolk County) for recruitment, for a total of 30,000 addresses.

Once selected, per above, CT and NY EIP sites will then mail survey invitations in the form of postcards (Appendix B) to eligible respondents. This postcard will:

- explain the purpose of the study, scope of respondent involvement, and compensation for respondents' time
- define eligibility criteria
- give the respondent the link to the survey (via a typed link as well as scannable QR code) with a unique access code
- tell the respondent the survey expiration date (~4 weeks from receipt of invitation)
- ask the respondent to take the web-based survey if interested in participating
- give study website (Appendix H) and EIP site contact information in case of questions, in case the respondent would prefer to take the survey over the phone, or in case the respondent would like to

withdraw.

Duration of Respondent Involvement

In this study, respondents will complete one web-based survey (Appendix D), which may be taken over the phone with an EIP site study coordinator if so desired by the respondent. The survey will take 10 minutes or less to complete. The surveys will expire roughly four weeks from the time respondents receive the survey invitations or after reaching a maximum of 2000 respondents. Potential respondents will receive an additional postcard (Appendix C) reminding them to take the survey two weeks after the initial postcard.

After completion of the survey, respondents will be mailed a thank you letter (Appendix F) with a $10 gift card.

Estimated Number of Respondents

This study will require a sample size of 500 respondents in CT and 1000 in NY for a total of 1500 respondents.

Our sample size calculation is based on the following inputs:

- Expected response of 50% of respondents likely to support placement of a 4-poster device on their own property (this is a conservative estimate, as acceptability of 4-poster devices has not previously been assessed)
- 95% CI
- Acceptable error rate of +/- 5%
- Stratification by state to allow for comparisons to be made between CT and NY
- Stratification by previous experience with 4-poster devices in NY (500 respondents from Suffolk County and 500 respondents across the 7 Hudson Valley counties to allow for detection of differences between these two groups)

METHODS, DATA COLLECTION and STUDY INSTRUMENTS

Survey Instrument and Administration

The survey (Appendix D) will be developed and administered using the Research Electronic Data Capture software (REDCap). Each randomly selected address from MSG will be assigned a coded recruitment ID generated by each study site. The recruitment IDs will be loaded into REDCap and assigned unique access codes generated by REDCap. These addresses, recruitment IDs, and access codes will be linked and stored in a separate spreadsheet, outside of the REDCap database. Each access code will be included in the survey invitation postcard (Appendix B) and will be required to access the survey, whether taken by the respondent online or over the phone with a study coordinator.

The survey will offer respondents the option to either watch a video via a link in the survey (Appendix E) to learn about 4-poster devices or read three short background pages contained within the survey. Both the video and the background pages contain the exact same information. Respondents cannot proceed with the survey unless they select an options to either watch the video or read the background pages.

Variables

The following variables will be collected from survey responses (Appendix D)

- Concerns and experiences related to tickborne diseases in general (e.g., concern about getting LD, history of tickborne disease diagnosis among household members)
- What entities the respondent feels should be responsible for tick control on private properties (e.g., homeowners, homeowner associations, local government, state government)
- Whether the respondent had ever heard of 4-poster devices prior to taking the survey
- Whether the respondent would support placement of a 4-poster device on their property, other private properties in their neighborhood, or public lands in their community

- Reasons for the respondent not supporting placement of a 4-poster device on their property, other private properties in their neighborhood, or public lands in their community
- Additional demographics (gender of the person about whom information will be collected, whether they rent or own their property, approximate property size, number of household members, whether any of the household members are children under the age of 18)
- Whether the address the postcard was sent to is the respondent's mailing address and if not, what the correct mailing address is for the respondent

DATA ANALYSIS PLAN and SUMMARY

Descriptive analyses of survey responses will be conducted to describe the proportion of respondents who would support placement of a 4-poster device on their property, on other private lands in their neighborhood, and on public lands in their community, and primary reasons for not supporting device placement in these locations. Additionally, respondent and household characteristics, concern for and experience with tickborne diseases, and opinions on community tick control will be described. Analytic statistical methods will be used to evaluate the association (if any) between respondent willingness to have a 4-poster device placed on their property or in their community and respondent and household characteristics, concern for and experience with tickborne diseases, opinions on community tick control, and potential for device placement on property based on ownership of property, property size, and residence in an area classified as suburban or rural. In NY, we will compare responses to all questions between Suffolk County (where 4-poster devices have previously been used for tick control) and the 7 Hudson Valley counties. Lastly, we will evaluate any differences in this association by state.

DATA MANAGEMENT PLAN

Information Management and Analysis Software

For this study, REDCap, Microsoft Access, Microsoft Excel, and R will be used for data entry, management, and analysis.

Data management and storage related to recruitment, participation, and study organization will be maintained at the EIP sites. Responsibility for maintaining confidentiality regarding respondent information and survey data lies within the respective EIP site. The study data will be stored in separate, secured REDCap databases for each site, maintained by Yale's REDCap administrators. Only coded data without direct personal identifiers will be stored in the REDCap databases and subsequently shared with CDC for data analysis. Copies of electronic and paper files will be kept at the EIP sites. All respondent tracking and follow-up will be completed at the EIP sites.

Quality Control/Assurance

Data will be collected and stored in REDCap on a secure partition of the Yale network with limited user access. All data will be kept confidential to the extent allowed by local, state, and federal law. All data will be coded in REDCap using the recruitment ID. On a site-specific spreadsheet (not stored in the REDCap database or on the CDC server), each survey access code will be linked to the mailing addresses from MSG. Once a respondent completes the survey, s/he will be assigned a coded study ID. Only the EIP sites will have links to the identifiable data; CDC will receive and store only coded study data. To maintain confidentiality, all data, forms, reports, and other records will be identified by the study ID number only. All computer entry and networking programs will utilize only coded numbers. Study documentation will be maintained according to the respective EIP's IRB file management and retention policy. Links to personally identifiable information will be destroyed following the study, according to the respective EIP's IRB policy. For example, some participating IRBs may require links to be preserved for a certain time period after study completion.

Bias in Data Collection, Measurement and Analysis

There is potential for selection bias in our study in the form of non-response bias. The most likely scenario would involve those who do not perceive themselves to be at risk for tickborne diseases (related to the exposure); therefore, this group may differentially not respond to the survey because they are not interested in the topic. In

this scenario, any associations we find between risk perception and support of 4-poster device placement either on the respondent's own property or in his/her community may be biased towards no association. We will attempt to mitigate non-response by sending a reminder to take the survey two weeks after the initial survey invitation. We will not be able to assess tickborne disease risk perception for non-responders, but we will be able to understand some aspects of their actual risk based on their address and corresponding disease incidence in their county

On the other hand, we may encounter self-selection bias. Those who perceive themselves to be at risk and support placement of a 4-poster device on their own property or in their community may be the most likely group to respond to the survey because they are passionate about the topic, which would artificially strengthen our measurement of association. Additionally, those who have had previous experiences with 4-poster devices in their community (specifically in NY, where devices have been used in Suffolk County) may be more likely to take the survey because they have previous knowledge or strong opinions about 4-poster devices. We attempt to mitigate self-selection bias in NY by stratifying households based on whether they reside in a county that has used 4-poster devices for tick control previously (Suffolk County compared to the 7 Hudson Valley counties). Other biases that we may encounter are due to the limitations that we are only recruiting English-speaking adults with permanent addresses. Due to this sampling strategy, we will miss representation from minors under the age of 18, populations experiencing homelessness, non-native residents, households without access to the internet or phone services, as well as residents of "low risk" counties in each respective state. Therefore, while the recruitment strategy of the study has been designed to target residences with the highest risk for tickborne disease, the sampled populations will likely not be generalizable to each state's population.

ETHICS and RESEARCH INTEGRITY

Response to New or Unexpected Findings

We do not anticipate new or unexpected findings from this survey to prompt an immediate response to study respondents.

Identifying, Managing, and Reporting Adverse Events

We do not anticipate any adverse events with this survey.

Internal and External Reviews and Approvals

This study will be reviewed by each participating institution in accordance with their own institutional procedures. We believe this study qualifies for exemption under 45 CFR 46.104(d)(2) and is therefore not subject to the single IRB mandate at §46.114.

Informed Consent

Respondents will be informed about the nature and purpose of the survey through the recruitment postcard and survey introduction. Respondents will not be requested to sign a consent document, as their deliberate navigation to the survey link and subsequent completion of the survey demonstrates their consent to participate.

Protocol Modifications

Any change or modification to the protocol will require a formal amendment to the protocol. Such amendments will be agreed upon by the CDC Principal Investigator and EIP co-investigators and reviewed and approved by each participating institution in accordance with their own institutional procedures. Administrative changes will be documented in the study file and shared with reviewers at each institution in accordance with institutional procedures.

Risks

The risks to a person from being in this study are small. The possibility exists that respondents may find certain questions from the surveys objectionable. However, topics covered in the survey should not be considered sensitive. Questions covering such topics as demographics and health history are typical components of medical

examinations. Questions regarding attitudes about tick control methods and tickborne disease risk perception would not be considered sensitive. Respondents will be told that they may terminate participation at any time. If a subject asks to be withdrawn from the study, the subject's name and the study data will be destroyed.

Privacy and Confidentiality

As a CDC-funded research activity involving the collection of identifiable (including coded) sensitive information, as defined in section 301(d) of the Public Health Service (PHS) Act, this study is covered by a Certificate of Confidentiality.

Therefore, CDC and any of its collaborators, contractors, grantees, or investigators that receive such information from this study are prohibited from:

- Disclosing or providing, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of an individual or any information about the individual that was created or compiled for purposes of the research, unless given consent by the individual to whom the information pertains; or
- Disclosing or providing to any other person not connected with the research the name of an individual or any information about such an individual that was created or compiled for purposes of the research.

Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Made with the consent of the individual to whom the information pertains; or
- Made for the purposes of other scientific research that is compliant with applicable Federal regulations governing the protection of human subjects in research.

CDC and its collaborators and contractors conducting this research have established and will maintain effective procedures to ensure that this research complies with the above requirements.

We will ensure:

1) that any investigator or institution not funded by CDC who receives a copy of identifiable (including coded) information protected by this Certificate, understands that it is also subject to the requirements of subsection 301(d) of the PHS Act; and
2) that any sub-recipient that receives CDC funds to carry out part of this research involving a copy of identifiable (including coded) information protected by a Certificate understands that it is subject to subsection 301(d) of the PHS Act.

Additionally, all study staff have received training on the importance of protecting the confidentiality of human research subjects and of personal information acquired. Each site involved in this study has methods in place to ensure confidentiality of respondents, as they perform multiple, individual-based research studies and conduct routine disease surveillance. Identifiable information will not be shared between TickNET sites or with CDC.

Survey respondents will be informed that their information will be held in strict confidence.

Study Discontinuation

The study may be discontinued at any time by CDC, the IRBs, or the EIP sites as part of the duty of ensuring that research subjects are protected.

Benefits

There will be no direct benefit from participation in this study.

Financial Remuneration

Respondents will be reimbursed $10 in the form of gift cards to a local store as compensation for the time necessary to complete the survey. Respondents may choose to skip questions and will still receive reimbursement for their time and effort. If respondents complete the first eligibility questions but are ineligible, they will not continue with the survey or receive gift cards as compensation for their time.

Costs

There are no costs to respondents for this study. Potential respondents will be informed in their invitation letter that they will not need to pay anything for being in this study.

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APPENDIX MATERIALS

Appendix A: High Lyme disease Incidence Counties Used for Recruitment in Study

Appendix B: Survey Invitation Postcard

Appendix C: Survey Reminder Postcard

Appendix D: Survey

Appendix E: Video to Accompany Survey

Appendix F: Thank You Letter

Appendix G: CDC Study Website