Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of December 21, 2022. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on December 21, 2022 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: November 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–25315 Filed 11–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Input on the National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in Humans: Request for Information

AGENCY: Office of the Assistant Secretary for Health (OASH), Office of the Secretary, Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: This Request for information (RFI) invites comments and suggestions on the *National Strategy for the Prevention and Control of Vector-Borne Diseases.* The *Strategy* represents the Federal Government's priorities for addressing vector-borne disease (VBD) threats.

DATES: To be assured consideration, comments must be received via the method provided below, no later than midnight Eastern Time (ET) on December 21, 2022. Submissions received after the deadline will not be reviewed.

ADDRESSES: Comments, including mass comment submissions, must be submitted electronically at *http://www.regulations.gov.* Search for this RFI by typing a keyword in the search field on the homepage. Click on the ''Comment Now'' button on RFI and you can submit your comments including attachments in a window titled, ''Your Information.'' For help finding this RFI and/or submitting comments, please visit *https://www.regulations.gov/help.*

FOR FURTHER INFORMATION CONTACT: Dr. Kristen Honey, Chief Data Scientist and Executive Director of InnovationX, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, *vectorbornedisease@hhs.gov,* (202) 853–7680.

SUPPLEMENTARY INFORMATION: It is important to read this entire RFI notice to ensure an adequate response is prepared and to have a full understanding of how your response will be acknowledged and used. Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Background

The Federal Government is developing a national strategy for the prevention and control of vector-borne diseases (VBD) in humans.

The Federal Government has identified 5 goals and 19 strategic priorities which were developed using the framework of the previously released National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans:

- *Goal 1: Better understand when, where, and how people are exposed to and become sick or die from vector-borne diseases (VBDs).*
  - *Strategic Priority 1:* Better understand vectors, the pathogens they transmit, and the potential effects of a changing climate.
  - *Strategic Priority 2:* Modernize and maintain surveillance systems for vectors, reservoirs, and VBDs.
  - *Strategic Priority 3:* Better understand the risk factors for and effects of VBDs on humans.
- *Goal 2: Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases.*
  - *Strategic Priority 1:* Identify and characterize novel VBD pathogens and their clinical manifestations.
  - *Strategic Priority 2:* Develop, evaluate, and improve diagnostic tests for VBDs.
  - *Strategic Priority 3:* Develop and evaluate evidence-based recommendations and guidelines on VBD diagnosis in humans.
  - *Strategic Priority 4:* Develop, maintain, and distribute non-commercial diagnostic resources to facilitate VBD testing.
- *Goal 3: Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases.*
  - *Strategic Priority 1:* Develop, evaluate, and improve safe and effective VBD prevention tools such as vaccines, vector control strategies, and health communication tools and products that are tailored for communities that are disproportionately affected.
  - *Strategic Priority 2:* Develop and evaluate data-driven and adaptive predictive models and decision support tools for VBDs.
  - *Strategic Priority 3:* Develop and evaluate evidence-based recommendations and guidelines on VBD prevention.
  - *Strategic Priority 4:* Develop and evaluate tools and processes for responding to public health emergencies.
- *Goal 4: Develop and assess drugs and treatment strategies for VBDs.*
  - *Strategic Priority 1:* Identify, develop, and evaluate safe and effective drugs and treatment strategies (regimens) for VBDs.
  - *Strategic Priority 2:* Develop evidence-based recommendations and guidelines on the treatment and management of VBDs.
  - *Strategic Priority 3:* Evaluate drug and treatment use patterns.
- *Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats.*
  - *Strategic Priority 1:* Disseminate evidence-based information about VBD prevention and control, guidelines, and recommendations to partners and the public.
  - *Strategic Priority 2:* Ensure current and future capacity to implement and adequately and equitably scale safe, effective, and publicly accepted VBD prevention and control programs.
  - *Strategic Priority 3:* Monitor and evaluate evidence-based public health programs and tools.
  - *Strategic Priority 4:* Respond to public health emergencies resulting from VBD threats.
  - *Strategic Priority 5:* Clarify, facilitate, and improve processes to bring regulated diagnostic tests, treatment strategies, vaccines, and vector control products to market.

A detailed copy of the goals and strategic priorities of this strategy can be found in the next section of this RFI.

The focus areas listed above are not exhaustive but represent the Federal Government's priorities for preventing and controlling VBDs. Although critical to public health and wellness, healthcare utilization, access to care, and reimbursement or payment for clinical services are outside the scope of this prevention and control strategy.

HHS/OASH recognizes the extensive work of the Tick-Borne Disease Working Group, including the two (2) reports delivered to Congress as of the release of this Request for Information. These reports included 55 recommendations, which have been cross-walked against the Goals and Strategies of the *National Strategy for the Prevention and Control of Vector-Borne Diseases.* This crosswalk reflects the alignment between the TBDWG recommendations and the *Strategy.* A copy of this crosswalk can be found in the last section of this RFI.

II. Information Requested/Questions

HHS/OASH invites input from stakeholders throughout the scientific research, advocacy, and clinical practice communities, as well as the general public, on the proposed national strategy. This input is a valuable component in finalizing the strategy, and the community's time and consideration are appreciated.

HHS/OASH also invites thoughts on preferred strategies for partner engagement as the strategy is further developed and modified over time (*e.g.,* webinars, listening sessions, additional RFIs, etc.).

HHS/OASH encourages organizations (*e.g.,* patient advocacy groups, professional organizations) to submit a single response reflective of the views of the organization/membership as a whole when possible.

III. How To Submit Your Response

Please respond concisely, in plain language, and in narrative format. You may respond to some or all of the topic areas covered in the RFI, and you can suggest other factors or relevant questions. You may also include links to online material or interactive presentations. Clearly mark any proprietary information and place it in its own section or file.

Please note that this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h) (4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. We note that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request.

HHS may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property; they will not be returned, and we may publish some of their non-proprietary content.

Dated: November 15, 2022.

Kristen Honey,

Chief Data Scientist and Executive Director of InnovationX, Office of the Assistant Secretary for Health, Department of Health and Human Services.

National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in Humans

Vision

A nation where vector-borne diseases no longer threaten human health and well-being.

Mission

Protect people from illness, suffering, and death due to vector-borne diseases.

Goal 1: Better understand when, where, and how people are exposed to and become sick or die from vector-borne diseases (VBDs)

STRATEGIC PRIORITY 1—BETTER UNDERSTAND VECTORS, THE PATHOGENS THEY TRANSMIT, AND THE POTENTIAL EFFECTS OF A CHANGING CLIMATE

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Determine how vector-borne pathogens are transmitted to humans:	*DHHS (CDC, NIH).*
• *Sub-objective 1:* Develop animal and vector models for VBD research.	*USDA.*
• *Sub-objective 2:* Identify key animal reservoirs for vector-borne pathogens.	*DOI.*
• *Sub-objective 3:* Identify the factors associated with the ability of vectors to effectively transmit pathogens to humans.	*DOD.*
• *Sub-objective 4:* Determine if co-infections within vectors and animal reservoirs impact transmission to humans.	
Objective 2: Identify the environmental factors associated with vector and animal reservoir populations:	*DHHS (CDC, NIH).*
• *Sub-objective 1:* Identify key factors, such as climate and ecological factors, associated with the distribution and abundance of vectors and animal reservoirs.	*DOD.*
	DOI.
• *Sub-objective 2:* Identify key factors, such as climate and ecological factors, associated with the seasonality of vectors and animal reservoirs.	*NOAA.*
	NASA.
	USDA (APHIS).

STRATEGIC PRIORITY 1—BETTER UNDERSTAND VECTORS, THE PATHOGENS THEY TRANSMIT, AND THE POTENTIAL EFFECTS OF A CHANGING CLIMATE—Continued

Objectives and sub-objectives	Federal entities with accountability
Objective 3: Determine which vectors found outside the United States and its territories pose the greatest near-term risk of becoming established in the United States and its territories: • *Sub-objective 1:* Conduct assessments and develop a list of vectors that pose the highest risk for establishment in the United States and its territories. • *Sub-objective 2:* Develop habitat suitability models for the potential distribution of vectors based on their distribution outside the United States and its territories.	*DHHS (CDC, NIH).* *DOD.* *DOI (USGS, NISC, NPS).* *NOAA.* *USDA (APHIS).*

Goal 1: Better understand when, where, and how people are exposed to and get sick or die from vector-borne diseases

STRATEGIC PRIORITY 2—MODERNIZE [1] AND MAINTAIN SURVEILLANCE SYSTEMS FOR VECTORS, RESERVOIRS, AND VBDS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Evaluate, improve, and maintain surveillance systems for vectors, reservoirs, pathogens, and VBDs in humans and animals: • *Sub-objective 1:* Identify existing complementary public and private surveillance systems. • *Sub-objective 2:* Evaluate existing surveillance systems to identify gaps both within and across systems. • *Sub-objective 3:* Address surveillance gaps within and across existing surveillance systems. • *Sub-objective 4:* Increase usability of surveillance data by expanding data access and timeliness and enhancing data visualizations of data from VBD systems. • *Sub-objective 5:* Evaluate the utility of alternative data sources and tools (*e.g.,* artificial intelligence, citizen science, crowdsourcing, patient registries) and use these evaluations to leverage relevant systems to further inform surveillance.	*DHHS (CDC, NIH).* *USDA.* *DOI (USGS, NPS).*
Objective 2: Increase data integration of and data sharing across surveillance systems: • *Sub-objective 1:* Identify opportunities for and challenges to increase the integration of and data sharing across surveillance systems. • *Sub-objective 2:* Implement steps to increase data integration and interoperability of surveillance systems.	*DHHS (CDC, NIH).* *DOD.* *USDA.* *USGS.*

Goal 1: Better understand when, where, and how people are exposed to and get sick or die from vector-borne diseases

STRATEGIC PRIORITY 3—BETTER UNDERSTAND THE RISK FACTORS FOR AND EFFECTS OF VBDS ON HUMANS

Objectives and sub objectives	Federal entities with accountability
Objective 1: Determine the social, behavioral, and environmental factors for human exposure to VBD pathogens: • *Sub-objective 1:* Determine the social determinants of health [2] and associated with human exposure to VBD pathogens. • *Sub-objective 2:* Determine the environmental factors, including the built environment,[3] associated with human exposure to VBD pathogens. • *Sub-objective 3:* Determine the knowledge, attitudes, and behaviors influencing and impacting human exposure to VBD pathogens, including differences among population groups. • *Sub-objective 4:* Identify, monitor, and evaluate policies and laws that help to reduce risk of human exposure to VBD pathogens.	*DHHS (CDC, NIH).* *NOAA.* *NASA.*
Objective 2: Determine the disease processes, progression, and clinical outcomes of VBDs: • *Sub-objective 1:* Describe the disease processes, progression, and clinical outcomes associated with priority VBDs, including symptom persistence. • *Sub-objective 2:* Describe the frequency and effect of VBD co-infections on diagnosis, treatment, and clinical outcomes. • *Sub-objective 3:* Identify differences in the clinical presentation, disease processes, progression, and clinical outcomes of VBDs associated with specific demographic factors, co-morbidities, and social determinants of health, particularly as they relate to differences across population groups.	*DHHS (CDC, NIH).* *USDA.*
Objective 3: Determine the disease burden of VBDs in the United States, including identifying differences in disease burden across population groups:	*DHHS (CDC).* *USDA (APHIS).*

[1] Data modernization is the result of the nation strengthening data reporting, management, and analytics across public health; conducting proper surveillance; supporting staff in pursuing innovation and building state-of-the-art data science skills; and delivering guidance the public can trust. *https://www.cdc.gov/surveillance/projects/dmi-initiative/.*

[2] Social determinants of health are conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of life-risks and outcomes. *https://www.cdc.gov/socialdeterminants/about.html.*

[3] The built environment includes the physical makeup of where we live, learn, work, and play—our homes, schools, businesses, streets and sidewalks, open spaces, and transportation. *https://www.cdc.gov/nccdphp/dnpao/state-local-programs/built-environment-assessment/index.htm.*

STRATEGIC PRIORITY 3—BETTER UNDERSTAND THE RISK FACTORS FOR AND EFFECTS OF VBDS ON HUMANS—Continued

Objectives and sub objectives	Federal entities with accountability
• *Sub-objective 1:* Describe the epidemiology of VBDs, including social determinants of health.[2] • *Sub-objective 2:* Describe the burden of VBDs, including costs to society and health-related quality of life.	

Goal 2: Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases

STRATEGIC PRIORITY 1—IDENTIFY AND CHARACTERIZE NOVEL VBD PATHOGENS AND THEIR CLINICAL MANIFESTATIONS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Determine a strategy for detecting novel pathogens and variants: • *Sub-objective 1:* Develop and disseminate strategies and algorithms that seek to detect novel VBD pathogens, including the use of new technologies (*e.g.,* machine learning, genomics, emerging tech). • *Sub-objective 2:* Apply the algorithms and strategies to detect novel pathogens; publish a list of novel pathogens that pose a potential risk to human health. • *Sub-objective 3:* Describe the knowledge gaps related to newly identified pathogens that pose a risk to human health. • *Sub-objective 4:* Collaborate with agricultural and other non-health partners to detect novel VBD pathogens in vectors and animals that may pose risk to human health.	*DHHS (CDC, NIH).* *USDA.* *DOD.*
Objective 2: Conduct studies and investigations to address knowledge gaps related to novel pathogens that are potentially vector-transmitted: • *Sub-objective 1:* Investigate potential VBD transmission in people and animals with illness of unknown origin that may be attributed to an emerging vector-borne pathogen. • *Sub-objective 2:* Fill critical knowledge gaps to be prepared for and able to respond to novel VBD emergence events.	*DHHS (CDC, NIH, FDA, BARDA).* *DOD.* *USDA.*

Goal 2: Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases

STRATEGIC PRIORITY 2—DEVELOP, EVALUATE, AND IMPROVE DIAGNOSTIC TESTS FOR VBDS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Develop diagnostic tests for novel pathogens: • *Sub-objective 1:* Determine the specimen types that provide optimal diagnostic performance. • *Sub-objective 2:* Develop pathogen-detection tests, including more rapid tests, within 1 year of identifying a novel pathogen. • *Sub-objective 3:* Develop serologic tests and, when applicable, biomarker tests within 1 year of identifying a novel pathogen. • *Sub-objective 4:* Investigate new methods for pathogen detection as new technologies advance. • *Sub-objective 5:* Make new diagnostic tests available for expanded use and commercialization as public health needs arise.	*DHHS (CDC, NIH, FDA, BARDA).* *DOD.* *USDA.*
Objective 2: Develop and make improved diagnostic tests available for known pathogens: • *Sub-objective 1:* Develop pathogen-detection tests that significantly improve test accuracy, precision, efficiency, performance, and/or speed. • *Sub-objective 2:* Develop serologic tests that significantly improve test accuracy, precision, efficiency, performance, and/or speed. • *Sub-objective 3:* Investigate new methods (*e.g.,* for detecting biomarkers) for detecting existing vector-borne pathogens as new technologies advance. • *Sub-objective 4:* Make new diagnostic tests available for expanded use and commercialization as public health needs arise.	*DHHS (CDC, NIH, FDA, BARDA).* *DOD.*
Objective 3: Compare the performance of new and existing diagnostic tests for people, vectors, animals, and animal reservoirs: • *Sub-objective 1:* Develop, maintain, and disseminate panels for use in evaluations of diagnostic tests. • *Sub-objective 2:* Compare the characteristics and performance of diagnostic tests.	*DHHS (CDC, BARDA, FDA).* *USDA.*

Goal 2: Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases

STRATEGIC PRIORITY 3—DEVELOP AND EVALUATE EVIDENCE-BASED RECOMMENDATIONS AND GUIDELINES ON VBD DIAGNOSIS IN HUMANS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: For novel pathogens, collaborate with external partners to develop guidance, recommendations, or guidelines on clinical and laboratory diagnosis: • *Sub-objective 1:* Establish a surveillance case definition for each VBD caused by a novel pathogen within 1 year of its identification. • *Sub-objective 2:* Develop and disseminate guidance, recommendations, or guidelines on appropriate test methods/procedures, to include interpretation of test results (including lab and clinical parameters).	*DHHS (CDC, NIH).* *DOD.* *USDA.*
Objective 2: Review and revise existing diagnostic guidance, recommendations, or guidelines to incorporate new knowledge: • *Sub-objective 1:* Continuously monitor emerging science that informs the diagnosis of VBDs. • *Sub-objective 2:* Revise and disseminate existing guidance, recommendations, and guidelines for vector-borne diagnosis with new knowledge.	*DHHS (CDC).* *DOD.* *USDA.*

Goal 2: Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases

STRATEGIC PRIORITY 4—DEVELOP, MAINTAIN, AND DISTRIBUTE NON-COMMERCIAL DIAGNOSTIC RESOURCES TO FACILITATE VBD TESTING

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Ensure sufficient supplies of diagnostic resources for VBD pathogens to facilitate research, development, and surveillance: • *Sub-objective 1:* Identify reagents that need to be developed. • *Sub-objective 2:* Identify reagents that require production to complement commercial resources. • *Sub-objective 3:* Inventory supplies of diagnostic resources (*e.g.,* reagents, standards, and biospecimens) available for VBD pathogens of concern. • *Sub-objective 4:* Generate and disseminate sufficient diagnostic resources needed to facilitate research, development, and surveillance and diagnostic testing capacity for priority VBD pathogens.	*DHHS (CDC, NIH).* *USDA.*

Goal 3: Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases

STRATEGIC PRIORITY 1—DEVELOP, EVALUATE, AND IMPROVE SAFE AND EFFECTIVE VBD PREVENTION TOOLS SUCH AS VACCINES, VECTOR CONTROL STRATEGIES, AND HEALTH COMMUNICATION TOOLS AND PRODUCTS THAT ARE TAILORED FOR COMMUNITIES THAT ARE DISPROPORTIONATELY AFFECTED

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Prioritize, develop, and evaluate vaccines against priority VBD pathogens: • *Sub-objective 1:* Design and implement a decision process to prioritize VBDs for vaccine development. • *Sub-objective 2:* Identify key potential challenges to and opportunities for successful development of vaccines. • *Sub-objective 3:* Facilitate partnerships across sectors, including with communities who are disproportionately affected, for vaccine development. • *Sub-objective 4:* Develop, evaluate, and refine vaccines.	*DHHS (CDC, NIH, FDA).* *USDA.*
Objective 2: Identify, develop, prioritize, and evaluate vector control tools and approaches, including engagement with communities who are disproportionately affected as appropriate: • *Sub-objective 1:* Evaluate the factors that make vectors more or less susceptible to vector control tools. • *Sub-objective 2:* Design and implement a decision process to prioritize vector control tools for development. • *Sub-objective 3:* Identify key potential challenges to and opportunities for successful development of novel vector control tools. • *Sub-objective 4:* Facilitate partnerships across sectors for vector control tool development. • *Sub-objective 5:* Identify, develop, evaluate, and refine new and existing vector control tools and approaches.	*DHHS (CDC, NIH).* *DOD.* *USDA.*
Objective 3: Develop and evaluate public health communication tools and products to encourage public acceptance and adoption of prevention and control guidance: • *Sub-objective 1:* Conduct formative research to inform the development of public health communication tools and products. • *Sub-objective 2:* Develop appropriate outreach strategies as informed by formative research.	*DHHS (CDC).* *USDA.*

STRATEGIC PRIORITY 1—DEVELOP, EVALUATE, AND IMPROVE SAFE AND EFFECTIVE VBD PREVENTION TOOLS SUCH AS VACCINES, VECTOR CONTROL STRATEGIES, AND HEALTH COMMUNICATION TOOLS AND PRODUCTS THAT ARE TAILORED FOR COMMUNITIES THAT ARE DISPROPORTIONATELY AFFECTED—Continued

Objectives and sub-objectives	Federal entities with accountability
• *Sub-objective 3:* Evaluate public health communication tools and products to ensure fit within intended communities.	

Goal 3: Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases

STRATEGIC PRIORITY 2—DEVELOP AND EVALUATE DATA-DRIVEN AND ADAPTIVE PREDICTIVE MODELS AND DECISION SUPPORT TOOLS FOR VBDS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Develop predictive models and decision support tools to guide prevention and control activities:	*DHHS (CDC, NIH). USDA. NOAA (NCAR).*
• *Sub-objective 1:* Elicit and prioritize decision-maker needs and requirements for decision-support tools. • *Sub-objective 2:* Prioritize VBDs for the development of predictive models and decision support tools. • *Sub-objective 3:* Develop predictive VBD transmission models and other nowcasting and forecasting tools.	
Objective 2: Evaluate and refine predictive models and decision support tools.	*DHHS (CDC, NIH). NOAA (NCAR).*
• *Sub-objective 1:* Evaluate the accuracy and utility of predictive models and decision support tools. • *Sub-objective 2:* Refine predictive models and decision support tools based on evaluation outcomes.	

Goal 3: Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases

STRATEGIC PRIORITY 3—DEVELOP AND EVALUATE EVIDENCE-BASED RECOMMENDATIONS AND GUIDELINES ON VBD PREVENTION [4]

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Develop and update evidence-based recommendations and guidelines:	*DHHS (CDC, NIH). USDA.*
• *Sub-objective 1:* Regularly update recommendations and guidelines based on the state of the science. • *Sub-objective 2:* Identify and prioritize VBDs for which new recommendations and guidelines are needed. • *Sub-objective 3:* Collaborate with internal and external partners to develop new recommendations and guidelines for priority VBDs, ensuring specific population needs are considered and addressed. • *Sub-objective 4:* Monitor and evaluate the implementation of recommendations and guidelines	

Goal 3: Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases

STRATEGIC PRIORITY 4—DEVELOP AND EVALUATE TOOLS AND PROCESSES FOR RESPONDING TO PUBLIC HEALTH EMERGENCIES

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Ensure national preparedness through the development of national, tribal, state, and territorial preparedness and emergency response plans for vector-borne disease outbreaks:	*DHHS (CDC, NIH). USDA. FEMA.*
• *Sub-objective 1:* Develop, maintain, and exercise preparedness and emergency response plans, including partner engagement strategies. • *Sub-objective 2:* Ensure equitable availability of medical countermeasures and vector-borne disease prevention and control tools, consistent with preparedness and emergency response plans.	

[4] To include vector control and prophylaxis.

[5] To include relevant partners across animal and public health.

STRATEGIC PRIORITY 4—DEVELOP AND EVALUATE TOOLS AND PROCESSES FOR RESPONDING TO PUBLIC HEALTH EMERGENCIES—Continued

Objectives and sub-objectives	Federal entities with accountability
Objective 2: Develop inclusive [5] public health communication plans, products, and tools for responding to vector-borne disease outbreaks that are consistent with and integrated into preparedness and emergency response plans: • *Sub-objective 1:* Develop key messages and tools to effectively communicate health information in a way that is inclusive of all communities. • *Sub-objective 2:* Identify and address challenges to implementation of response communication plans, ensuring equitable accessibility of information.	*DHHS (CDC).* *FEMA.* *USDA.*
Objective 3: Evaluate tools and processes for responding to vector-borne disease emergencies, including reducing associated health inequities: • *Sub-objective 1:* Conduct and support tabletop exercises integrating multiple sectors and community partners as appropriate. • *Sub-objective 2:* Conduct and support after action reviews and develop reports. • *Sub-objective 3:* Evaluate and improve effectiveness of public health communication products and tools.	*DHHS (CDC).* *FEMA.*

Goal 4: Develop and assess drugs and treatment strategies for VBDs

STRATEGIC PRIORITY 1—IDENTIFY, DEVELOP, AND EVALUATE SAFE AND EFFECTIVE DRUGS AND TREATMENT STRATEGIES (REGIMENS) FOR VBDS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Develop new safe and effective drugs, including immunotherapies: • *Sub-objective 1:* Identify and characterize new molecular targets for therapeutics for priority VBDs. • *Sub-objective 2:* Develop effective drugs from newly identified molecular targets including evaluating/comparing clinical efficacy.	*DHHS (NIH, FDA).* *DOD.* *USDA.*
Objective 2: Evaluate or repurpose existing therapeutic strategies for use in the treatment and management of VBDs: • *Sub-objective 1:* Optimize existing therapeutic strategies for VBDs. • *Sub-objective 2:* Optimize therapeutic strategies repurposed for VBDs. • *Sub-objective 3:* Evaluate complementary and integrative health therapies for safety and efficacy. • *Sub-objective 4:* Conduct and disseminate comparative effectiveness studies of existing VBD treatments.	*DHHS (NIH, FDA).*
Objective 3: Advance research on treatment for persistent symptoms associated with VBDs: • *Sub-objective 1:* Assess treatment strategies for extended or long-term symptoms associated with VBDs. • *Sub-objective 2:* Collaborate across fields of medicine to learn about promising therapeutic strategies for persistent symptoms following VBD infections.	*DHHS (NIH).*

Goal 4: Develop and assess drugs and treatment strategies for VBDs.

STRATEGIC PRIORITY 2—DEVELOP EVIDENCE-BASED RECOMMENDATIONS AND GUIDELINES ON THE TREATMENT AND MANAGEMENT OF VBDS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Periodically review the evidence and update *existing* federally developed recommendations and guidelines to treat and manage VBDs: • *Sub-objective 1:* Coordinate expert review of the evidence to inform revisions of federally developed recommendations and guidelines. • *Sub-objective 2:* Update and disseminate existing federally developed recommendations or guidelines on VBD treatment and management.	*DHHS (CDC, NIH).* *USDA.*
Objective 2: Develop *new* guidance for the treatment and management of VBDs when peer-reviewed recommendations or guidelines do not exist: • *Sub-objective 1:* Coordinate expert review of the evidence to inform the development of new federally developed recommendations and guidelines. • *Sub-objective 2:* Disseminate new federally developed recommendations or guidelines on VBD treatment and management.	*DHHS (CDC, NIH).* USDA.

Goal 4: Develop and assess drugs and treatment strategies for VBDs.

STRATEGIC PRIORITY 3: EVALUATE TREATMENT AND MANAGEMENT USE PATTERNS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Describe patterns of treatment and management: • *Sub-objective 1:* Conduct and disseminate studies of drug and treatment use patterns as well as management of VBDs, including conducting surveys and analyzing administrative claims data for surveillance purposes.	*DHHS (CDC, FDA).*
Objective 2: Develop clinician and public advisories pertaining to the treatment and management of VBDs: • *Sub-objective 1:* Disseminate clinician and public advisories pertaining to the treatment and management of VBDs.	*DHHS (CDC, FDA).*

Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats

STRATEGIC PRIORITY 1—DISSEMINATE EVIDENCE-BASED INFORMATION ABOUT VBD PREVENTION AND CONTROL, GUIDELINES, AND RECOMMENDATIONS TO PARTNERS AND THE PUBLIC

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Disseminate evidence-based recommendations and guidelines to key professional audiences (for example, healthcare providers, health departments, veterinarians, and professional societies): • *Sub-objective 1:* Tailor dissemination of products and tools based on audience needs. • *Sub-objective 2:* Develop and implement a dissemination plan to distribute evidence-based recommendations and guidelines.	*DHHS (CDC, FDA). USDA.*
Objective 2: Disseminate health communication products and tools [6] that are tailored for communities and partners: • *Sub-objective 1:* Collaborate with a diverse set of impacted populations, multi-sectoral partners, and community members to co-create dissemination plans to reach communities of focus using traditional and innovative strategies. • *Sub-objective 2:* Implement the dissemination plan to distribute VBD prevention and control information and guidance using appropriate channels, methods, and messages.	*DHHS (CDC). USDA.*

Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats

STRATEGIC PRIORITY 2—ENSURE CURRENT AND FUTURE CAPACITY TO IMPLEMENT AND ADEQUATELY AND EQUITABLY SCALE SAFE, EFFECTIVE, AND PUBLICLY ACCEPTED VBD PREVENTION AND CONTROL PROGRAMS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Equitably support state, tribal, territories and collaborating partners in their efforts to implement VBD programs, to include surveillance, diagnosis and detection, prevention, and control: • *Sub-objective 1:* Provide support to jurisdictions, Tribes, and partners to implement effective VBD programs, including providing staffing support. • *Sub-objective 2:* Provide technical assistance to implementing jurisdictions, Tribes, and partners in their selection, planning, and implementation of programs, tools, collaborations, and innovations.	*DHHS (CDC). USDA.*
Objective 2: Collaborate with partners across levels, sectors, and disciplines to build and sustain implementation capacity: • *Sub-objective 1:* Assess and monitor training needs on evidence-based information, guidelines, and recommendations. • *Sub-objective 2:* Provide trainings on evidence-based information, guidelines, and recommendations. • *Sub-objective 3:* Provide funding and technical assistance to partners to build, expand, and diversify the Public Health workforce.	*DHHS (CDC). USDA.*

Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats

STRATEGIC PRIORITY 3—MONITOR AND EVALUATE EVIDENCE-BASED PUBLIC HEALTH PROGRAMS AND TOOLS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Monitor and evaluate Public Health implementation efforts in communities: • *Sub-objective 1:* Monitor the implementation of programs and tools over time and across communities. • *Sub-objective 2:* Collaborate with implementers to evaluate acceptability, suitability, effectiveness, and sustainability of Public Health programs and tools. • *Sub-objective 3:* Broadly disseminate evaluation findings to implementers, the scientific field, and the public.	*DHHS (CDC).*
Objective 2: Adapt and optimize Public Health efforts:	*DHHS (CDC).*

[6] To be developed in G3, SP1, O3.

STRATEGIC PRIORITY 3—MONITOR AND EVALUATE EVIDENCE-BASED PUBLIC HEALTH PROGRAMS AND TOOLS—Continued

Objectives and sub-objectives	Federal entities with accountability
• *Sub-objective 1:* Regularly review and update Public Health products, tools, and guidance based on findings from program evaluations. • *Sub-objective 2:* Disseminate updated Public Health products, tools, and guidance as warranted. • *Sub-objective 3:* Synthesize the state of the field and share lessons learned, promising and best practices, technologies, and opportunities for continuous improvement.	

Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats

STRATEGIC PRIORITY 4—RESPOND TO PUBLIC HEALTH EMERGENCIES RESULTING FROM VBD THREATS

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Provide direct response to public health emergencies: • *Sub-objective 1:* Provide laboratory testing for state, tribal, local, and territorial jurisdictions. • *Sub-objective 2:* Deploy staff to support local response efforts (for example, vector surveillance and vector control) when requested by jurisdictions and Tribes. • *Sub-objective 3:* Disseminate Public Health messaging to support local response efforts. • *Sub-objective 4:* Disseminate data that identifies disproportionately affected populations. • *Sub-objective 5:* Facilitate the process for emergency use of VBD tools during public health emergencies.	*DHHS (CDC, NIH).* *USDA.* *FEMA.*
Objective 2: Support jurisdictions in their response to public health emergencies, including addressing the needs of disproportionately affected populations: • *Sub-objective 1:* Support implementation of local preparedness and emergency response plans. • *Sub-objective 2:* Provide direct technical assistance to jurisdictions in the implementation of their emergency response plans. • *Sub-objective 3:* Make medical countermeasures and VBD prevention and control tools available and ensure equitable access and distribution. • *Sub-objective 4:* Ensure the collection and public access of quality data to inform public health actions.	*DHHS (CDC, NIH).*

Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats

STRATEGIC PRIORITY 5—CLARIFY, FACILITATE, AND IMPROVE PROCESSES TO BRING REGULATED DIAGNOSTIC TESTS, TREATMENT STRATEGIES, VACCINES, AND VECTOR CONTROL PRODUCTS TO MARKET

Objectives and sub-objectives	Federal entities with accountability
Objective 1: Clarify and facilitate the regulatory process for vector control and VBD products, tools, and guidelines: • *Sub-objective 1:* Develop communication strategies that clearly articulate the regulatory process. • *Sub-objective 2:* Provide direction to applicants in their submission and response to regulatory process requirements. • *Sub-objective 3:* Clarify jurisdiction of federal agencies in their regulatory responsibilities for new and innovative products.	*DHHS (FDA).* *EPA.* *USDA.*
Objective 2: Develop innovative strategies to identify and address challenges in bringing vector control and VBD products and tools to market: • *Sub-objective 1:* Conduct regulatory science to ensure that regulatory knowledge gaps are identified for new and emerging technologies. • *Sub-objective 2:* Address the scientific knowledge gaps identified through regulatory science as appropriate.	*DHHS (FDA).* *EPA.*

HHS Tick-Borne Disease Working Group Cross Walk

The purpose of this document is to crosswalk the HHS Tick-borne Diseases Working Group 2018 and 2020 congressional report recommendations with the goals and strategic priorities of the draft *National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in Humans.*

Goal 1: Better understand when, where, and how people are exposed to and become sick or die from vector-borne diseases (VBDs).

• TBDWG 2018 7.2 Allocate increased funding for tick-borne disease in the areas of *research,* treatment, and prevention proportional to the burden of illness and need.

Strategic Priority 1: Better understand vectors, the pathogens they transmit, and the potential effects of a changing climate.

• TBDWG 2018 3.1 Fund studies and activities on tick biology and tick-borne disease ecology, including systematic tick surveillance efforts particularly in regions beyond the Northeast and Upper Midwest.

• TBDWG 2018 6.3 Improve the education and *research* on transmission (including transmission via the blood supply and pregnancy) and treatment of other tick-borne diseases and coinfections.

• TBDWG 2020 9.2 DoD: Recommend that the DoD enhance inter-agency communication and collaboration to

study Lyme disease and other tick-borne diseases.

Strategic Priority 2: Modernize and maintain surveillance systems for vectors, reservoirs, and VBDs.

- TBDWG 2018 3.1 Fund studies and activities on tick biology and tick-borne disease ecology, including *systematic tick surveillance efforts* particularly in regions beyond the Northeast and Upper Midwest.
- TBDWG 2018 3.4 Have public health authorities formally recognize complementary, validated systematic approaches to tick-borne disease surveillance for humans, such as systematic sampling of tick-borne disease reports for investigation that reduce the burden on tick-borne disease reporting but allow for comparability of surveillance findings across states and over time.
- TBDWG 2018 7.7a Testing and Diagnostic Bands: How They Are Used Today and What That Is Doing to Patients: Empower Patients with Data
- TBDWG 2018 8.2 CDC: Dedicate funding within CDC to study—with performance indicators—babesiosis *incidence, prevalence,* treatment resistance, and prevention, including maternal-fetal and transplantation/transfusion transmission risk. Consider using advanced data tools, such as patient registries, to study the potential role of Babesia in tick-borne disease patients with continuing manifestations of disease after initial treatment.
- TBDWG 2018 8.3 DoD: Commence study of tick-borne disease *incidence and prevalence* of active duty Servicemembers and their dependents. Compile data on the impact of tick-borne diseases on military readiness. Create education and preparedness programs that specifically address the unique risks faced by Servicemembers in training and on deployment and by their families.
- TBDWG 2018 8.4 VA: Commence study of tick-borne disease incidence and prevalence of Veterans and eligible family members.
- TBDWG 2020 3.1 Implement multi-agency, ecologically-based One Health efforts on tick-borne diseases promoting *research and enhanced vector surveillance* to identify and validate integrated tick management in keystone wildlife hosts, particularly white-tailed deer, and the sustainable management of their populations.
- TBDWG 2020 3.3 Provide funding to support CDC-directed expanded *tick surveillance* and promoting the development and implementation of best practices for integrated tick management capturing human tick bite events, and streamlining education, training, and coordination amongst relevant Federal, state, and local agencies.
- TBDWG 2020 4.4 Provide HHS with resources to partner with national Integrated Delivery Networks (IDNs) (for example, Geisinger, Kaiser, etc.) to conduct a pilot feasibility study to leverage Electronic Medical Records (EMRs) using Best Practice Alerts at the patient point-of-care for Alpha-gal Syndrome in endemic areas (upholding patient confidentiality).
- TBDWG 2020 4.5 Provide HHS with resources to partner with national Integrated Delivery Networks (IDNs) (for example, Geisinger, Kaiser, etc.) to conduct a pilot feasibility study to leverage Electronic Medical Records (EMRs) using Best Practice Alerts at the patient point-of-care for rickettsial diseases, ehrlichiosis, and anaplasmosis in endemic areas (upholding patient confidentiality).
- TBDWG 2020 8.2 Recommend that CDC work with Council of State and Territorial Epidemiologists (CSTE) to streamline the surveillance process and to reduce the burden on both clinicians and public health departments by permitting direct laboratory reporting of positive cases.
- TBDWG 2020 9.1 VA: Recommend that the VA continue with Recommendation 8.4 from 2018 Working Group report, ''Commence study of tick-borne disease incidence and prevalence of Veterans and eligible family members'' and additionally
  - Establish and update efforts on tracking and investigating the prevalence of Lyme and other tick-borne diseases;
- TBDWG 2020 9.2 DoD: Recommend that the DoD enhance inter-agency communication and collaboration to study Lyme disease and other tick-borne diseases.

Strategic Priority 3: Better understand the risk factors for and effects of VBDs on humans.

- TBDWG 2018 6.1 Prioritize research into the potential pathogenic mechanisms (such as immune response, cross-reactivity, autoimmunity, bacterial persistence, coinfections, and other mechanisms) of persistent symptoms in patients who have received standard treatment regimens for tick-borne diseases, including Lyme disease.
- TBDWG 2018 6.2 Promote research on animal models of Borrelia burgdorferi infection (that is, Lyme disease) and the mechanisms of disease processes in humans with an emphasis on pathologies that are currently lacking, for example, neuroborreliosis.
- TBDWG 2018 6.5 Improve the education and *research on the pathogenesis* of alpha-gal allergy, also known as the tick-caused ''meat allergy.''
- TBDWG 2018 8.2 CDC: Dedicate funding within CDC to study—with performance indicators—babesiosis incidence, prevalence, treatment resistance, and prevention, including *maternal-fetal and transplantation/transfusion transmission risk.* Consider using advanced data tools, such as patient registries, to study the potential role of Babesia in tick-borne disease patients with continuing manifestations of disease after initial treatment.
- TBDWG 2020 4.1 Fund research aimed at characterizing the full clinical spectrum, clinical manifestations, and potential complications of human monocytic ehrlichiosis (HME) and human granulocytic anaplasmosis (HGA), including identification of risk factors for severe illness and the importance of specific comorbidities, patient characteristics (age, gender, and race), immune impairment, and genetic host factors.
- TBDWG 2020 5.1 Provide HHS with resources necessary to fund basic science research and clinical research to investigate the pathology of the human immune response following tick bites (*e.g.,* Alpha-gal Syndrome [AGS]).
- TBDWG 2020 5.2 Support the targeted funding of *research to understand the role of persistence of bacteria and bacterial products in the pathogenesis* and management of Lyme disease (*e.g.,* antibiotic regimens and other therapeutics).
- TBDWG 2020 5.3 Support targeted funding opportunities for research to better inform the diagnosis, *pathogenesis,* and management of Lyme carditis.
- TBDWG 2020 8.1 Fund prospective studies of acute febrile illnesses to assess the burden of tick-borne diseases, including rickettsial, ehrlichial, and anaplasmal pathogens.
- TBDWG 2020 8.3 Further evaluation of non-tick bite transmission of Lyme disease, for example maternal-fetal transmission.
- TBDWG 2020 9.2 DoD: Recommend that the DoD enhance inter-agency communication and collaboration to study Lyme disease and other tick-borne diseases.
- TBDWG 2020 9.4 NIH: Recommend that the NIH create one or more study sections composed of members whose expertise is human clinical diseases and their pathogenesis and immunity not just basic science to evaluate applications focused on practical impact on human health related to tick-borne diseases.

• TBDWG 2020 9.5 NIH: Recommend that NIH receive additional funding which must be dedicated to study Lyme disease including persistent Lyme disease and other tick-borne diseases and conditions; and they encourage researchers to apply for these studies.

Goal 2: Develop, evaluate, and improve tools and guidance for the diagnosis and detection of vector-borne diseases.

Strategic Priority 1: Identify and characterize novel VBD pathogens and their clinical manifestations.

• TBDWG 2018 3.2 Fund systematic studies and activities to identify and characterize novel tick-borne disease agents in the United States.

• TBDWG 2020 4.3 Establish and fund research for sensitive and specific diagnostic tests for the broader range of tick-borne diseases, including tick-borne relapsing fever, Powassan virus, and other *emerging* tick-borne pathogens. Encourage development of these tests as in vitro diagnostics approved by FDA.

Strategic Priority 2: Develop, evaluate, and improve diagnostic tests for VBDs.

• TBDWG 2018 5.1 Evaluate new technology or approaches for the diagnosis of Lyme disease and other tick-borne diseases.

• TBDWG 2018 5.2 Include special populations, especially children, in Lyme disease and other tick-borne diseases diagnostic studies.

• TBDWG 2020 4.2 Establish and fund research for sensitive and specific diagnostic tests for acute rickettsial, ehrlichial, and anaplasmal diseases. Encourage development of these tests as in vitro diagnostics approved by FDA.

• TBDWG 2020 4.3 Establish and fund research for sensitive and specific diagnostic tests for the broader range of tick-borne diseases, including tick-borne relapsing fever, Powassan virus, and other emerging tick-borne pathogens. Encourage development of these tests as in vitro diagnostics approved by FDA.

• TBDWG 2020 5.3 Support targeted funding opportunities for research to better inform the *diagnosis,* pathogenesis, and management of Lyme carditis.

Strategic Priority 3: Develop and evaluate evidence-based recommendations and guidelines on VBD diagnosis in humans.

Strategic Priority 4: Develop, maintain, and distribute non-commercial diagnostic resources to facilitate VBD testing.

Goal 3: Develop, evaluate, and improve tools and guidance for the prevention and control of vector-borne diseases.

• TBDWG 2018 7.2 Allocate increased funding for tick-borne disease in the areas of research, treatment, and *prevention* proportional to the burden of illness and need.

Strategic Priority 1: Develop, evaluate, and improve safe and effective VBD prevention tools such as vaccines, vector control strategies, and health communication tools and products that are tailored for communities that are disproportionately affected.

• TBDWG 2018 4.1 Fund additional studies and activities on the development and evaluation of novel and traditional tick-control methods that have shown promise in other areas of public health entomology.

• TBDWG 2018 4.2 Build trust via a transparent mechanism by which all stakeholders examine and discuss past vaccine activities and potential adverse events to inform future vaccine development in Lyme disease.

• TBDWG 2018 4.3 Support the development of safe and effective human vaccines to prevent Lyme disease with transparent mechanisms by which all stakeholders examine and discuss past vaccine activities and potential adverse events to inform future vaccine development.

• TBDWG 2018 8.3 DoD: Commence study of tick-borne disease incidence and prevalence of active duty Servicemembers and their dependents. Compile data on the impact of tick-borne diseases on military readiness. *Create education and preparedness programs* that specifically address the unique risks faced by Servicemembers in training and on deployment and by their families

• TBDWG 2018 8.5 Develop and disseminate more comprehensive clinician education that highlights diverse symptomology, expanding geography of infecting ticks, and limitations of current testing procedure. In developing the curriculum, include diverse stakeholder groups, including clinicians, research scientists, and patients who represent the spectrum of scientific and medical expertise and perspectives on tick-borne disease.

• TBDWG 2020 6.2 Conduct laboratory, clinical, and field research to address gaps in our capacity to treat and *prevent* the broader range of tick-borne diseases, including particularly babesiosis, tick-borne relapsing fever, Powassan virus infection, and other low-incidence tick-borne diseases.

• TBDWG 2020 7.5 Generate broad awareness of Alpha-gal Syndrome through the following two mechanisms:

○ Label foods/beverages, medications and medical products, cosmetics, etc. containing mammalian-derived components for the safety of consumers with Alpha-gal Syndrome.

Strategic Priority 2: Develop and evaluate data-driven and adaptive predictive models and decision support tools for VBDs.

Strategic Priority 3: Develop and evaluate evidence-based recommendations and guidelines on VBD prevention.

• TBDWG 2020 6.2 Conduct laboratory, clinical, and field research to address gaps in our capacity to treat and *prevent* the broader range of tick-borne diseases, including particularly babesiosis, tick-borne relapsing fever, Powassan virus infection, and other low-incidence tick-borne diseases.

Strategic Priority 4: Develop and evaluate tools and processes for responding to public health emergencies.

• TBDWG 2018 8.1 NIH: Create an NIH tick-borne disease strategic plan, with public input during creation and implementation, to address tick-borne diseases, including all stages of Lyme disease. Include in the strategic plan the coordination of research funding across NIAID, NINDS, NIAMS, and NIMH to increase knowledge of pathogenesis, improve diagnosis, and develop and test new therapeutics for tick-borne diseases. Update every five years.

Goal 4: Develop and assess drugs and treatment strategies for VBDs.

• TBDWG 2018 7.2 Allocate increased funding for tick-borne disease in the areas of research, *treatment,* and prevention proportional to the burden of illness and need.

Strategic Priority 1: Identify, develop, and evaluate safe and effective drugs and treatment strategies (regimens) for VBDs.

• TBDWG 2018 6.3 Improve the education and research on transmission (including transmission via the blood supply and pregnancy) and *treatment* of other tick-borne diseases and coinfections.

• TBDWG 2018 6.4 Conduct additional clinical trials appropriate to the target populations where gaps may exist.

• TBDWG 2020 5.2 Support the targeted funding of research to understand the role of persistence of bacteria and bacterial products in the pathogenesis and *management* of Lyme disease (*e.g.,* antibiotic regimens and other therapeutics).

• TBDWG 2020 5.3 Support targeted funding opportunities for research to better inform the diagnosis, pathogenesis, and *management* of Lyme carditis.

• TBDWG 2020 6.1 Encourage clinical trials on early and persistent Lyme disease.

• TBDWG 2020 6.2 Conduct laboratory, clinical, and field research to address gaps in our capacity to *treat* and prevent the broader range of tick-borne diseases, including particularly babesiosis, tick-borne relapsing fever, Powassan virus infection, and other low-incidence tick-borne diseases.

Strategic Priority 2: Develop evidence-based recommendations and guidelines on the treatment and management of VBDs.

• TBDWG 2020 6.2 Conduct laboratory, clinical, and field research to address gaps in our capacity to *treat* and prevent the broader range of tick-borne diseases, including particularly babesiosis, tick-borne relapsing fever, Powassan virus infection, and other low-incidence tick-borne diseases.

Strategic Priority 3: Evaluate drug and treatment use patterns.

Goal 5: Disseminate and support the implementation of effective public health products, tools, programs, collaborations, and innovations to prevent, detect, diagnose, and respond to VBD threats.

• TBDWG 2018 7.2 Allocate increased funding for tick-borne disease in the areas of research, treatment, and *prevention* proportional to the burden of illness and need.

Strategic Priority 1: Disseminate evidence-based information about VBD prevention and control, guidelines, and recommendations to partners and the public.

• TBDWG 2018 3.5 The Lyme disease surveillance criteria are not to be used alone for diagnostic purposes; public health authorities shall annually and when opportune (such as during Tick-Borne Disease Awareness Month) communicate this and inform doctors, insurers, state and local health departments, the press, and the public through official communication channels, including the CDC's Morbidity and Mortality Weekly Report (MMWR).

• TBDWG 2018 4.4 Prioritize education by informing clinicians and the general public about the regional and specific risks related to tick-borne diseases.

• TBDWG 2018 6.3 Improve the *education* and research on transmission (including transmission via the blood supply and pregnancy) and treatment of other tick-borne diseases and coinfections.

• TBDWG 2018 6.5 Improve the *education* and research on the pathogenesis of alpha-gal allergy, also known as the tick-caused ''meat allergy.''

• TBDWG 2018 7.1 Create a Federal repository for information on Lyme disease and other tick-borne diseases.

• TBDWG 2018 7.7c Testing and Diagnostic Bands: How They Are Used Today and What That Is Doing to Patients: Relay Information as a Neutral Knowledge Broker

• TBDWG 2018 8.5 Develop and disseminate more comprehensive clinician education that highlights diverse symptomology, expanding geography of infecting ticks, and limitations of current testing procedure. In developing the curriculum, include diverse stakeholder groups, including clinicians, research scientists, and patients who represent the spectrum of scientific and medical expertise and perspectives on tick-borne disease.

• TBDWG 2020 3.3 Provide funding to support CDC-directed expanded tick surveillance and promoting the development and implementation of best practices for integrated tick management capturing human tick bite events, and *streamlining education, training, and coordination* amongst relevant Federal, state, and local agencies.

• TBDWG 2020 7.1 Recommend Federal government websites and educational materials and seminars for clinicians, the public, and public health departments, which discuss Lyme disease, provide information that the state of the science relating to persistent symptoms associated with Lyme disease, is limited, emerging, and unsettled; and increase public awareness that there are divergent views on diagnosis and treatment. Consider that shared medical decision-making may be appropriate in some circumstances.

• TBDWG 2020 7.2 Fund and support a directive for CDC (or other appropriate HHS OPDIV or agency) to develop (either directly or through an approved federal contract) a multi-leveled and nationwide curriculum on Lyme disease for clinicians-in-training as well as continuing medical education modules to increase the pool of qualified and practicing clinicians. Provide funding for the U.S. military to participate in this nationwide training and education on Lyme disease and other tick-borne diseases and conditions. This curriculum should be introduced and encouraged at the State level. The final curriculum shall incorporate feedback from patients, clinicians, and research scientists with expertise/experience that represents diverse scientific and clinical experiences on the full spectrum of Lyme disease and other tick-borne diseases/conditions.

• TBDWG 2020 7.3 Fund efforts across the U.S. to expand/require medical education to inform emergency, primary care, and other healthcare providers and to raise clinician and public awareness of rickettsial (including Rocky Mountain spotted fever), ehrlichial, and anaplasmal diseases.

• TBDWG 2020 7.4 Fund efforts across the U.S. to expand/require medical education to inform emergency, primary care, and other healthcare providers and to raise clinician and public awareness of babesiosis, tick-borne relapsing fever, emerging tick-borne viral infections, and other low-incidence tick-borne diseases.

• TBDWG 2020 7.5 Generate broad awareness of Alpha-gal Syndrome through the following two mechanisms:

○ Provide funding/support/resources necessary to create a National Tick-Borne Alpha-gal Syndrome Alert that is focused on awareness, prevention, and education regarding tick associated Alpha-gal Syndrome and that targets key stakeholder groups.

• TBDWG 2020 9.1 VA: Recommend that the VA continue with Recommendation 8.4 from 2018 Working Group report, ''Commence study of tick-borne disease incidence and prevalence of Veterans and eligible family members'' and additionally

○ Make educational modules available to practitioners.

• TBDWG 2020 9.3 CDC: Recommend that if the CDC posts any Lyme treatment guidelines, that they include guidelines on persistent Lyme Disease.

Strategic Priority 2: Ensure current and future capacity to implement and adequately and equitably scale safe, effective, and publicly accepted VBD prevention and control programs.

• TBDWG 2020 3.2 Minimize the public health threat of Lyme disease and other tickborne diseases through special funding for integrated tick management, disruption of tick biological processes contributing to pathogen transmission, and the support of public/private partnerships to develop and promote area-wide tick control strategies.

• TBDWG 2020 3.3 Provide funding to support CDC-directed expanded tick surveillance and promoting the development and *implementation* of best practices for integrated tick management capturing human tick bite events, and streamlining education, training, and coordination amongst relevant Federal, state, and local agencies.

Strategic Priority 3: Monitor and evaluate evidence-based public health programs and tools.

• TBDWG 2018 7.7b Testing and Diagnostic Bands: How They Are Used Today and What That Is Doing to Patients: Engage Diverse Stakeholders—Update the CSTE Surveillance Case Definition with 21st-Century Evidence

• TBDWG 2020 3.1 Implement multi-agency, ecologically-based One Health efforts on tick-borne diseases promoting research and enhanced vector surveillance to identify and *validate integrated tick management* in keystone wildlife hosts, particularly white-tailed deer, and the sustainable management of their populations.

• TBDWG 2020 8.2 Recommend that CDC work with Council of State and Territorial Epidemiologists (CSTE) to *streamline* the surveillance process and to reduce the burden on both clinicians and public health departments by permitting direct laboratory reporting of positive cases.

Strategic Priority 4: Respond to Public Health emergencies resulting from VBD threats.

Strategic Priority 5: Clarify, facilitate, and improve processes to bring regulated diagnostic tests, treatment strategies, vaccines, and vector control products to market.

Although critical to public health and wellness, the following recommendations related to healthcare utilization, access to care, reimbursement or payment for clinical services, and legal protections are outside the scope of this prevention and control strategy:

• TBDWG 2018 3.3 Support economic studies and activities to estimate the total cost of illness associated with tick-borne diseases in the United States, beginning first with Lyme disease and including both financial and societal impacts.

• TBDWG 2018 7.3 Ensure the rights of those dealing with Lyme disease and tick-borne diseases and conditions by reducing the burden of the processes under which patients are currently diagnosed and treated and by which they access care. Basic protections must include, but not necessarily be limited to, those that protect patients from employment discrimination.

• TBDWG 2018 7.4 Ensure the rights of those dealing with Lyme disease and tick-borne diseases and conditions by reducing the burden of the processes under which patients are currently diagnosed and treated and by which they access care. Basic protections must include, but not necessarily be limited to, those that protect students of all ages from discrimination.

• TBDWG 2018 7.5 Ensure the rights of those dealing with Lyme disease and tick-borne diseases and conditions by reducing the burden of the processes under which patients are currently diagnosed and treated and by which they access care. Basic protections must include, but not necessarily be limited to, those that protect patients from health care and disability insurance coverage and reimbursement policies that are unduly burdensome.

• TBDWG 2018 7.6 Ensure the rights of those dealing with Lyme disease and tick-borne diseases and conditions by reducing the burden of the processes under which patients are currently diagnosed and treated and by which they access care. Basic protections must include, but not necessarily be limited to, those that protect the rights of licensed and qualified clinicians to use individual clinical judgment, as well as recognized guidelines, to diagnose and treat patients in accordance with the needs and goals of each individual patient.

• TBDWG 2020 9.6 CMS: Recommend that CMS provides all information and data on Lyme disease and other tick-borne diseases and all applicable agency activities pertaining to these conditions which may include but should not be limited to:

○ Reimbursement costs for the diagnosis and treatment of beneficiaries with Lyme disease and other tick-borne diseases;

○ Demonstration and pilot projects with Lyme disease and other tick-borne diseases as their focus; and

○ Quality measure development and implementation related to Lyme disease and other tick-borne diseases.

[FR Doc. 2022–25241 Filed 11–18–22; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Health; Opportunity To Co-Sponsor OASH-Supported Grantee Workshops

AGENCY: Office of the Assistant Secretary for Health, HHS.

ACTION: Notice.

SUMMARY: The Grants and Acquisitions Management Division (GAM) in the Office of the Assistant Secretary for Health (OASH), in conjunction with the grant making program offices it supports, announces the opportunity for non-federal public and private sector entities to co-sponsor OASH-supported grants workshops (OASH Grants Workshops). Potential co-sponsors must have a demonstrated interest and experience in building capacity among potential grant applicants and grant recipients. Potential co-sponsors must be willing to participate substantively in the co-sponsored activity. Expressions of interest for co-sponsorships of OASH Grants Workshops are received throughout the year at the email address below. OASH intends to co-sponsor a limited number of workshops with other entities each year. Expressions of interest are being received for OASH Grants Workshops that will take place in the next fiscal year (October 2022 through September 2023) or beyond. Expressions of interest for co-sponsorships should be sent by email to *OASH_Grants@HHS.GOV* with ''Co-sponsorship for OASH-supported Grants Workshops'' in the subject field or by mail to Duane Barlow, Grants Branch Chief, OASH, Grants and Acquisitions Management Division, at 1101 Wootton Parkway, Plaza Level, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Duane Barlow, Grants Branch Chief, OASH, Grants and Acquisitions Management Division, 1101 Wootton Parkway, Plaza Level, Rockville, MD 20852; or via phone (240) 453–8822.

SUPPLEMENTARY INFORMATION: The OASH Grants and Acquisitions Management (GAM) Division oversees, administers, and supports grant-making activities of public health offices on behalf of the Secretary of the U.S. Department of Health and Human Services (HHS). The grant-making program offices that GAM supports include: the Office of Infectious Disease and HIV/AIDS Policy (OIDP), Office of Minority Health (OMH), Office of Population Affairs (OPA), Office of Research Integrity (ORI), and Office on Women's Health (OWH). Another OASH component, the Office of Regional Health Operations (ORHO), which includes ten Regional Offices covering all states and territories of the United States and three independent states in the Pacific, through its coordinating function will also be involved in the OASH Grants Workshops.

Consistent with each office's mission and applicable statutory authority, the OASH Grants Workshops aim to build capacity among potential grant applicants and grant recipients in related areas such as applying for and managing grants and cooperative agreements (collectively grants) awarded under the programs listed by Assistance Listing number below:

• 93.007 Public Awareness Campaigns on Embryo Adoption
• 93.085 Research on Research Integrity
• 93.088 Advancing System Improvements for Key Issues in Women's Health