CDC Burden of Canine Brucellosis Information Collection

New Information Collection Request

Supporting Statement – Section B

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Section B – Data Collection Procedures

1. Respondent Universe and Sampling Methods

The target audience to respond to this information collection is staff from veterinary diagnostic laboratories in the United States. The laboratories were identified through multiple sources: a review of the Animal and Plant Health Inspection Service-approved *Brucella* diagnostic laboratories, the National Animal Health Laboratory Network laboratories, the American Association of Veterinary Laboratory Diagnosticians (AAVLD), and an internet search (**Attachment F_Veterinary Lab Lists**).

An internet search was used to determine the operational status of each of these labs, which tests they conducted, as well as to identify additional labs not on these lists. Because many of these laboratories were on multiple lists, a total of 141 unique laboratories were identified.

Of these 141 labs, the criteria for inclusion in the data collection included operational status and availability of canine diagnostics at the time this package was compiled. Excluded facilities comprised of 15 labs that were no longer operational and 7 labs that only conducted diagnostics on poultry, marine mammals, or wildlife. This left 119 laboratories.

In total, 119 out of the initial list of 141 laboratories fitting the criteria for inclusion were identified from these sources (89% of all identified laboratories that were operational at the time this package was compiled), **including 44 state departments of agriculture or animal health laboratories, 12 state/federal or federal laboratories, 38 university laboratories, and 15 commercial laboratories.** These laboratories are located in 49 states and 1 territory (**Section A, Attachment C_Veterinary Diagnostic Laboratories**).

Most veterinary diagnostics have been historically conducted at state veterinary diagnostic laboratories[1]. The AAVLD accredits public laboratories[2], and the NAHLN is a collaboration between the Animal and Plant Health Inspection Service (APHIS), the National Institute of Food and Agriculture (NIFA), and the AAVLD[3]. There is no regulatory body governing all commercial labs, and thus identifying them is difficult. **We have expanded our estimated burden to include an additional 10 respondents that may choose to participate but had not been identified through the methods described above.**

The outcomes of this information collection are to assess the burden of disease in the animal host (dogs, in this case), as well as evaluate the knowledge and practices of occupational exposures to the organism. The information collected will be used to guide a longer term strategy for identification of human cases, understanding risk factors and activities associated with zoonotic transmission, and eventually validation of a human diagnostic assay. These strategies will be implemented using other mechanisms.

2. Procedures for the Collection of Information

The information collection instrument will be emailed to the 119 Laboratory Directors or main email addresses who serve the 50 states and Puerto Rico; the District of Columbia, Guam, American Samoa, and Virgin Islands do not have veterinary diagnostic laboratories. The introductory email (**Attachment G_Introductory Email**) will explain the project and the importance of their response, and how the data collected will form the agenda for future CDC human *B. canis* studies. The email will also include a generic link to the web-based information collection instrument. All veterinary diagnostic laboratories that met the inclusion criteria will be sampled (n=119).

In addition, to solicit support for this project, a notice (**Attachment H_Notice** describing the purpose and importance of this information collection will be submitted to the American Association of Veterinary Laboratory Diagnosticians, American Veterinary Medical Association, Animal Health Association, National Animal Health Laboratory Network, and the National Association of State Public Health Veterinarians). These are veterinary associations that are involved with clinical, laboratory, and policy issues and can assist in dissemination of information obtained from this project.

The information will be collected using a web-based Epi Info 7 Web Survey information collection tool. Information collection invitation emails (**Attachment G_Introductory Email**) are distributed to potential respondents via email. Each email contains a generic Uniform Resource Locator (URL), which will be created when the survey is published to the web. Upon clicking the URL, respondents access the Epi Info 7 web-based system and the generic information collection instrument via a secure internet connection through their web browser. The instrument can be saved, which creates a unique URL. The respondent can use this unique URL to complete a portion of the information collection instrument, exit, and return to finish at another time. Once entered and submitted by the respondent, the data are stored in a tightly controlled Epi Info database at CDC. Epi Info Web Survey has received Certification and Accreditation (C&A) and Authority to Operate (ATO) from the CDC's Office of the Chief Information Security Officer (OCISO) for Low EMSSP; everything is low across the board and this system does not contain PII. The collected data will be stored on internal (ITSO) CDC servers that are fully CDC compliant. The data will be received electronically and stored in an Epi-Info database. These data are only shared with BSPB, and only those BSPB staff who work directly on the project will have access to the folder.

A question has been included to assess the completeness of each laboratory's data. Also, for those questions that request data for a given time period, the instrument will modify the time period based on the response to this completeness question. This could affect analysis of trends, but infections can be estimated on an annual basis.

3. Methods to Maximize Response Rates Deal with Nonresponse

A month will be given for completion of the information collection. The email reminder will be sent twice to each non-responder; the first will be distributed one week after the information collection instrument due date and the second will be sent one week after the first reminder (**Attachment I_Reminder Email**).

The response rate for this information collection can be maximized through the support of the National Animal Health Laboratory Network, which communicates with the state veterinary diagnostic labs on a regular basis, and can further emphasize the importance of this project to public health. Verbal telephone reminders following a script will~~may~~ be implemented ~~if~~with participants that have ~~do~~ not yet responded within one week after the second reminder e-mail (**Attachment J_Telephone Script**). Since we do not have experience with this known group, it is difficult to estimate non-responder rate. To estimate burden time for administering this telephone reminder to the known laboratories (n=119), we have over-estimated the non-responders to be 100% to ensure there is sufficient burden time, although we do not believe the non-response will be this high.

The sample for this survey is 100% of known veterinary diagnostic laboratories meeting the inclusion criteria. There is insufficient information about these labs and the samples that they receive to know how nonresponse will affect rate calculations. We do know laboratories may receive both in-state and out-of-state samples. All prevalence estimates will be caveated with the limitation of non-response. We will consult with a statistician to determine if prevalence can be calculated by geographic location. If we are unable to calculate prevalence geographically, we will consider other methods to identify targets for health communication activities.

4. Test of Procedures or Methods to be Undertaken

This information collection instrument was originally developed by the CDC Bacterial Special Pathogens Branch (BSPB) Epidemiology Team. The questions were further refined by review with the BSPB Zoonotic and Select Agent Laboratory (ZSAL). The instrument was then reviewed by two representatives at a federal veterinary diagnostic laboratory, a veterinarian from a state public health department, and one representative at a state veterinary diagnostic laboratory, and further changes were made. Finally, four members of the CDC Bacterial Special Pathogens Branch were asked to complete the information collection instrument using a sample dataset. In the pilot test, the average time to complete the information collection including time for reviewing instructions, gathering needed information and completing the information collection instrument, was approximately 37.5 minutes. Based on these results, the estimated time range for actual respondents to complete the instrument is 30-60 minutes, factoring in time for some Laboratory Directors to consult with other employees and querying their database before completing the information collection instrument. For the purposes of estimating burden hours, the upper limit of this range (i.e., 60 minutes) is used

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Data collected in this information collection requires descriptive statistical analysis, which will be performed in Epi Info 7 and SAS 9.3. The person who will be charged with validating and analyzing the data will be Ms. Rita Traxler, Epidemiologist, NCEZID/BSPB, gna9@cdc.gov, 404-639-0265, with the assistance of an unpaid student. The information collection instrument was designed in Epi Info by a student. The principal investigator for the project is the Brucellosis Veterinary Epidemiologist in Bacterial Special Pathogens Branch: Marta Guerra, DVM MPH PhD, Veterinary Officer, NCEZID/BSPB, hzg4@cdc.gov, 404-639-3951.

LIST OF ATTACHMENTS – Section B

F– Veterinary Laboratory Lists

G– Introductory Email

H– Notice

I– Reminder Email

J- Telephone Script

References

1. Gosser HS, Morehouse L. District, state or regional veterinary diagnostic laboratories. Rev Sci Tech. 1998 Aug; 17(2):444-53.
2. American Association of Veterinary Laboratory Diagnosticians, Inc. Requirements for an Accredited Veterinary Medical Diagnostic Laboratory. Version 6.2. 2014 Oct 9; Accessed 4 December 2014 at http://www.aavld.org/assets/Accreditation/Accreditation_Documents/Requirements/aavld%20requirements%20ac-201%20v%206%202%2010-09-14%20final.pdf.
3. APHIS. About NAHLN. 2014 October 10; Accessed 4 December 2014 at http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_focus%2Fsa_animal_health%2Fsa_lab_information_services%2Fsa_nahln%2Fct_about_nahln.