

# **Canine Leptospirosis Surveillance in Puerto Rico**

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## Canine Leptospirosis Surveillance in Puerto Rico

### 1. Respondent Universe and Sampling Methods

The respondent universe will consist of veterinarians and their support staff in participating clinics or shelters (sites) in Puerto Rico, and owners of enrolled dogs seen at a participating site. During the surveillance protocol and data collection instrument development stage, previous collaborators at the Puerto Rico Department of Health (PRDH) were consulted. Every effort was made to select and invite clinics and shelters that would give a good geographic representation of the island, and to include sites from areas where leptospirosis has been previously reported or areas with a high index of suspicion for leptospirosis. Only shelters with an on-site vet or that are serviced by a vet clinic will be invited to participate. Sites that agree to participate will be enrolled. At least 20 and no more than 26 sites will be enrolled in the study.

Dogs meeting the criteria for a suspect case based on the study case definition are eligible for enrollment at participating sites. In clinics, consent from the dog owner is required prior to enrollment. In shelters, consent is not needed as no owner exists. A sample size of at least 385 dogs will be enrolled in the study. There is little known regarding the prevalence of leptospirosis in dogs in Puerto Rico, and therefore this sample size was determined based on a population estimate of 150,000-300,000 dogs by the Humane Society of Puerto Rico (unpublished data), a 95% confidence level with a 5% margin of error, and a prevalence of 50% which is the estimated prevalence of leptospirosis in dogs giving the largest sample size.

Based on anecdotal information from veterinarians in Puerto Rico, we expect an approximate of 2 dogs tested per site per month, one of which may be positive upon confirmatory testing. Assuming those numbers are correct we can expect up to 240 positives (1 positive x 12 months x 20 sites) and 240 negatives. Comparing the proportion of risk factors among leptospirosis positive and negative dogs with those expected numbers will allow us to detect differences as small as 10% with at least 80% power. Any analysis of risk factors will consider the power to detect differences and will be reported in a final report.

Leptospirosis is endemic in Puerto Rico, however, there is very limited data on canine leptospirosis in the island. In 1980, Farrington and Sulzer<sup>1</sup> did a serosurvey of antibodies to *Leptospira* in 116 stray dogs at three shelters in the island. They found seropositivity in 63% of the dogs. Since then, no study has been done on leptospirosis in dogs.

The study associated with the information collection addressed in this request aims to establish the first active surveillance for canine leptospirosis in Puerto Rico to determine the incidence and distribution of leptospirosis in dogs, assess risk factors for infection, characterize circulating *Leptospira* serovars and species, assess applicability of vaccines currently in use based on serovar determination, and assess potential rodent, livestock, and wildlife reservoirs based on infecting serovars found in dogs.

Previous collaboration with PRDH and the current collaboration with the Puerto Rico Veterinary Medical Association (PRVMA) will help ensure that data collection activities are conducted in a

<sup>1</sup> Farrington, N. P. and K. R. Sulzer (1982). "Canine leptospirosis in Puerto Rico." *Int J Zoonoses* 9(1): 45-50.

culturally and linguistically appropriate manner, and enhance participation from the veterinary clinics and animal shelters in Puerto Rico.

<b>Population of dogs in Puerto Rico</b>	<b>Confidence level</b>	<b>Margin of error</b>	<b>Power</b>	<b>Estimated prevalence of canine leptospirosis</b>	<b>Sample Size</b>	<b>Number of sites to enroll</b>
150,000 – 300,000	95%	5%	80%	50%	385	20-26

## **2. Procedures for the Collection of Information**

Three information collection tools – a one-time site questionnaire, a log sheet of enrolled dogs per site, and a case questionnaire for each enrolled dog – will be used in the study. All information collection will be conducted using paper forms and provided in Spanish.

### *Site Information Collection*

Each enrolled site is asked to complete a one-time site enrollment questionnaire. This paper form collects basic information about the site such as site capacity and available resources, an estimate number of dogs seen by the site, an estimate of suspect cases of leptospirosis, the method and communities from which dogs are acquired (shelters only), and dog vaccination practices. Examples of questions include whether the site has a computer and internet access; whether they vaccinate dogs for leptospirosis and if so, what *Leptospira* vaccine is used; how many dogs per week or month are being seen and how many of these have febrile illness of unknown cause; how many dogs are diagnosed or suspected to have leptospirosis; and specifically for shelters, how many dogs are acquired each week, what methods are used to acquire these dogs (i.e. picked up in communities or surrendered by owners), and which communities they come from. The completed site questionnaire is submitted to study coordinators by email or in-person during site training.

### *Case Information Collection*

Participating sites will enroll dogs that meet the criteria for a suspect case based on the study case definition. In clinics, consent from the dog owner is required prior to enrollment. In shelters, consent is not needed as there is no owner. Consent is obtained through the Owner Consent Form. The veterinarian or a veterinary technical staff will explain to the owner the nature of the study and will ask the owner to sign a paper consent form prior to enrolling the dog in the study. After consent is obtained, information collection, specimen collection and testing is pursued.

Information about the enrolled dog is obtained through the Case Questionnaire. This paper form will be completed by the veterinarian or veterinary technical staff by interviewing the dog owner (clinics only), and reviewing administrative and medical records, as necessary. The case questionnaire includes questions about the dog’s signalment, risk factors and exposures,

vaccination history, clinical signs and symptoms, laboratory test results for leptospirosis and routine lab work if available (i.e. hematology, urinalysis, chemistry), treatment given, and outcome. Completed forms may be sent to study coordinators by fax or email, or along with specimen shipments to the Bacterial Special Pathogens Branch (BSPB) at the Centers for Disease and Prevention (CDC).

#### *Enrollment and Specimen Collection Tracking*

Each site is asked to keep a log of all enrolled dogs using the Study Log Sheet. This form is used to keep track of all enrolled dogs and specimens collected in the study, and also serves as an itemized list of contents when shipping specimens to CDC. All information requested in the log sheet can be obtained from the case questionnaire and is limited to basic information needed to track enrolled dogs and collected specimens such as study ID, site ID, owner's last name, dog's name, gender, illness onset date, rapid test results and type of specimens collected. Completed log sheets are sent with the monthly specimen shipments to CDC.

#### *Training of Participating Veterinarians and Veterinary Technical Staff*

Participating veterinarians and their staff will be trained on the study protocol during a 1.5-hour initial training session. The training session will cover the procedures for obtaining consent, collecting data and specimen, and using the leptospirosis rapid test. Materials presented during the training session and additional materials such as a procedure flowchart and copies of data collection forms are compiled in a binder and provided to each site. Refresher training sessions may be given as needed or if requested by the participating site.

#### *Interventions*

Owners of enrolled dogs may be given an informational brochure on leptospirosis, and dogs will be treated with antibiotics based on normal veterinary clinic procedures. Overall findings from the canine leptospirosis surveillance study will be used to develop evidence-based, targeted interventions and recommendations for the prevention of canine leptospirosis which can also lead to reduced leptospirosis transmission in humans, help focus human surveillance efforts based on incidence and distribution data, and guide future investigations into leptospirosis in humans and animals in Puerto Rico.

### **3. Methods to Maximize Response Rates and Deal with Non-response**

CDC and PRVMA will make every effort to provide participating sites with the necessary information, tools and technical support to conduct the information collection. Project coordinators may conduct periodic site visits or phone calls to get feedback from the sites, identify supplies they may need or will be needing soon, identify issues that may become a barrier to information collection, and generally, reach out to the sites for continued participation in the study. Finally, periodic reports may be prepared for the sites to show study progress with the hope that this can also encourage continued participation and response in the study.

All information collection tools are in paper form and provided in Spanish. Veterinarians and their staff find it easier to complete a paper copy of the data collection forms when abstracting

information from administrative and medical records or while interviewing the owner to collect information about their dog's risk factors and symptoms.

#### **4. Test of Procedures or Methods to be Undertaken**

Before implementation of information collection tools, feedback was sought from previous PRDH collaborators who had close ties with the local veterinarians and knew well the conditions vet clinics and shelters work in Puerto Rico. The length of the instrument and the burden this would pose to veterinarians, the method of data collection that would be easiest for the sites, what and how to train the sites on, and the logistics on data collection and submission to study coordinators that would be most convenient to the sites were discussed. All information collection tools were translated to Spanish. Previous collaboration with PRDH and the current collaboration with the Puerto Rico Veterinary Medical Association (PRVMA) will help ensure that data collection activities are conducted in a culturally and linguistically appropriate manner, and enhance participation from the veterinary clinics and animal shelters in Puerto Rico.

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

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All of the data are collected by veterinarians and their staff at participating veterinary clinics and animal shelters in Puerto Rico. Other members of BSPB and PRVMA may be involved in the management and analysis of information collected from surveillance activities and the dissemination of reports to the veterinary community.