

B. Collections of Information Employing Statistical Methods

1. Describe the potential respondent universe and any sampling or other respondent selection methods to be used.

The potential respondent universe will be owners and trainers of horses that are suspected, probable or confirmed cases of equine herpesvirus myeloencephalopathy (EHM) or EHV-1 without neurologic signs, and non-infected horses that will serve as controls. Potential respondents will be contacted by the APHIS-designated data collector after confirmation of an EHM outbreak, i.e., two or more confirmed EHM horses with likelihood of disease transmission having occurred at a common venue. Sampling will occur at multiple venues over a prolonged period (as described below).

2. Describe the procedures for the collection of information including:

Statistical methodology for stratification and sample selection:

☐ Stratification – no stratification strategy

☐ Sampling methodology

Once an outbreak is detected and associated with a venue in a State, the State Animal Health Official (SAHO) where the outbreak originated will be contacted by the USDA-APHIS-VS coordinator to request the State's participation. Participation is voluntary, it is up to the SAHO to choose to participate. If the SAHO elects to participate, they will serve as the APHIS-designated data collector when contacting owners and trainers of affected horses within the state to request their participation. The VS coordinator and data collector will compile a list of potential uninfected horses from the population at risk to serve as controls for risk factor analysis. For statistical precision, APHIS requests data from approximately three controls for each affected horse. Respondents (owners and trainers) will choose whether to complete surveys.

Given the nature of the complex sampling strategy, i.e., its dependence on naturally-occurring outbreaks over multiple States and venues, correlation of animals managed within herds, a longitudinal data collection process, and unbalanced numbers of horses within outbreaks, APHIS anticipate that a larger sample size and multi-year process is required.

a. **Estimation procedures:** Standard statistical analysis methods will be applied with multivariable models appropriately adjusted to account for the correlation expected among animals managed similarly, data arising from naturally-occurring outbreaks over multiple venues and States, and a longitudinal component. Estimates obtained from models will be odds ratios to determine significant exposures to known, novel and potential risk factors with adjustment for covariates.

- b. **Degree of accuracy needed:** Risk estimates for independent or interacting variables derived from multivariable models are considered significant at the $p < 0.05$ level. Because this is a novel approach to analysis of an emerging disease within a specific animal population, there are sparse data available to support calculation of expected measures of variability over multiple risk factors.
- c. **Unusual problems requiring specialized sampling procedures and data collection cycles:** This study is dependent on the continuing natural occurrence of EHM outbreaks over multiple States and venues. This will require a prolonged data collection period to gather an adequate sample for the complex data analysis required.

3. Describe methods to maximize response rates and to deal with issues of non-responses:

NOTE: This is not a typical NAHMS study that will provide national level statistics or be performed on a nationally representative sample. Therefore, APHIS cannot include additional percentages for this question.

There is no official nationally-based reporting of the number of outbreaks, or the number of EHV-1 or EHM cases within outbreaks, and detection and reporting of EHM cases to State Animal Health Officials is not uniform across all States. State Animal Health Officials, Directors of Veterinary Hospital Biosecurity programs and Racing Commission Veterinarians have provided verbal descriptions of outbreaks that have occurred in multiple different venues over the past year. Venues have included veterinary hospitals, racetracks, boarding facilities, and at or after equine events such as shows. Descriptions are often shared on National Equine Industry monthly conference calls. Based on these descriptions, within any given outbreak, the number of EHM cases will likely range from 1 to 10 and the number of EHV-1 cases will likely range from 3 to 20. For epidemiologic investigations, APHIS will attempt to gather survey data on all EHV-1 and EHM cases identified from each outbreak. APHIS will then select healthy control horses from the population at-risk, i.e., the population of horses with likely exposure to EHV-1 as part of the outbreak, and request participation from these horses' owners or trainers. APHIS expects to select 3 controls per each EHM case in each outbreak. NAHMS has not regularly collected data from EHV-1 outbreaks with EHM as a sequel to EHV-1 infection, and has only collected data from one large outbreak in the past year. This was a multi-State EHV-1 outbreak and was not typical in its magnitude or geographic extent of case distribution. It is therefore difficult to predict the response rate APHIS might expect to its requests to animal health officials, horse owners and trainers, and veterinarians to voluntarily provide NAHMS appointed data collectors with data on EHM cases, EHV-1 cases and controls.

Study Design:

- ☐ Many proven questions have been repeated from the previous NAHMS studies.
- ☐ The study minimizes collection of data to that which is absolutely necessary to meet the stated objectives.

- ☐ The equine specialist for NAHMS has made numerous contacts and collaborative efforts to identify the information needs of the industry and the best way to ask for that information via questionnaire. NAHMS staff have published results from earlier studies, demonstrating to the equine health community and industry the contribution of these studies to better understanding of a serious equine health threat.

Contacting Respondents:

- ☐ Owners and trainers will be called by the data collector 3 to 5 times before they are listed as refused or inaccessible.
- ☐ The APHIS designated data collector will set up a convenient time for the producer to complete the questionnaire.
- ☐ Data collectors will arrive at the premises at the mutually agreed upon time.

Data Collection Steps:

- Data will be collected in a single in-person interview.

Data Analysis Steps:

Data will be compiled into an electronic database, with data for new cases and controls entered as they are received by NAHMS staff. Statistical analysis will be performed by the NAMHS VMO/Biostatistician. Analysis will be similar to, and build upon, methods conducted for an earlier case-control study from a large, single-venue outbreak with cases dispersed into multiple States post-event. Those results have been published. The analysis from the current study will require adjustment for cases arising from multiple outbreaks over a larger geography and longer timespan. Data will be analyzed on an interim basis over the data collection period to evaluate adequacy of sample size and measures of effect.

1. Describe any tests of procedures or methods to be undertaken.

The proposed questionnaire has been used previously in an outbreak and revised to accommodate unique situations for future outbreaks. The earlier use of the survey has refined the information collection to reduce respondent burden and improve the usefulness of the information.

2. Provide the name and telephone number of individuals consulted on statistical aspects of the design and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and /or analyze the information for the agency.

The statistical aspects of the design were coordinated by Dr. Kathe Bjork, VMO/Biostatistician, USDA: APHIS, Veterinary Services, CEAH, Fort Collins, CO, (970) 494-7288.

The contact person for data collection is:

- Dr. John Clifford, Deputy Administrator, USDA: APHIS, Veterinary Services, Washington, DC (202) 447-6835.

Analysis of the data will be accomplished by NAHMS veterinarians, epidemiologists, and statisticians under the direction of:

- Dr. Bruce Wagner, National Animal Health Monitoring System, USDA: APHIS, VS, CEAH, 2150 Centre Avenue, Building B MS2E7, Fort Collins, CO 80526-8117 (970) 494-7256.