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More Information about the Animal and Premises Sample Size Tables

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The sample size values in both tables are calculated using the equation:

number of premises to sample (n) = $[1 - (1 - \alpha)1/(p*N)][N - 0.5(\delta * p*N - 1)]/\delta$

from Cannon (2001) where,

 α = confidence level

p = prevalence threshold of disease

N = total number of items in the inference group

 δ = probability of detection for the items being selected

1. Confidence Level

Prior to collecting data, this value is the probability of detection. Once data is collected, it describes the degree of certainty or confidence in detection. Collecting data from all items in an inference group (conducting a census) can be impractical, but errors can result when observing only a subset of items. The confidence level is 100% minus the detection error. In most situations, the recommendation is to use a 95% confidence level. When repeated sampling occurs frequently, a higher value might be advisable. For example, if selecting items from within shipments that occur 100 times each month, a 95% confidence level would ensure the failure to detect happens 5 times or less

each month. In this case, a 99% confidence level might be advisable so that detection failures occur 1 time or less each month.

2. Prevalence threshold for disease

This sets the prevalence threshold for disease among the animals in the epidemiological unit or among premises in the zone or area. Use knowledge about disease transmission to determine the threshold required to detect infection in time to prevent serious consequences. Consider the context of the surveillance, such as mitigations that may prevent the spread or actions that could increase the spread.

3. Total number of items in the inference group

The statements below are true for any collection of items in an inference group (e.g., animals in an epidemiological unit or premises in a zone or area) where only a subset of items will be observed. The following paragraph explains the concepts using animals as the items selected and the total number of animals in the epidemiological unit as the inference group.

The larger the proportion of animals selected relative to the total number of animals in the epidemiological unit, the greater the likelihood of detecting disease if it is present. If the detection threshold is defined as a number of animals rather than a prevalence, the sample size remains a fairly consistent proportion of the population. For example, detecting 10 infected animals using an 86% sensitive testing protocol requires a sample size of 59 animals if there are 200 animals or 30% of the total number of animals; detecting 10 infected animals using an 86% sensitive testing protocol requires a sample size of 300 animals if there are 1,000 animals in an epidemiological unit, which is also 30% of the total number of animals.

Usually, we define the detection threshold as a prevalence. When the threshold is defined as a prevalence and the total number of animals in the epidemiological units is large, the sample size needed is the same regardless of how many animals are in the unit. That's because setting a fixed prevalence threshold for increasingly larger epidemiological units translates to increasingly more infected animals. A 10% prevalence threshold of a 1,000-animal unit means that there are 100 infected animals in the unit, while a 10% prevalence threshold of a 100,000-animal unit means that there are 10,000 infected animals. In both cases, detecting a 10% prevalence using an 86% sensitive

testing protocol requires a sample size of 33 animals. For epidemiological units with a small number of animals, the sample size required to detect a 10% prevalence using an 86% sensitive testing protocol would be something less than 33 animals. Determining what N is large enough to stabilize the sample size depends on the prevalence threshold and the sensitivity of the test.

4. Sensitivity of the diagnostic testing protocol

When selecting animals in an epidemiological unit for diagnostic testing, the sensitivity of the diagnostic testing protocol represents the probability that the entire diagnostic testing process will detect an infected animal when that animal is infected. Diagnostic test sensitivity accounts for error in the test result that could occur during specimen collection, handling and shipping of the specimen, laboratory processes, and interpreting the process output.

When selecting premises to visit for data collection from a zone or area, this input represents the probability that the surveillance scheme used on each premises will detect an infected premises when that premises is infected. It is equivalent to the confidence level achieved on each premises by selecting animals for testing. It is sometimes referred to as the "sensitivity" at a premises level. The sensitivity at the premises level includes both the error in sampling animals on the premises and the error due to a less-than-perfect diagnostic test protocol sensitivity.

5. Specificity of the diagnostic testing protocol

The equation used to determine sample sizes in these tables does not include an input for the specificity of the diagnostic testing protocol. Specificity is assumed to be 100% in this equation. Although most tests do not have 100% specificity, testing protocols that achieve near-perfect specificity should be employed during outbreaks. Such a protocol may include a series of tests at the original lab, confirmation/ruling out of positive results by different laboratories (especially of the National Veterinary Services Laboratory for Foreign Animal Disease), on-premises investigations with additional sampling, or a combination of these steps to minimize the chances of taking actions on false-positives.

Creating a diagnostic testing protocol with near-perfect specificity will result in a diagnostic testing protocol with reduced sensitivity. This is a problem for surveillance designers because the consequences of a false-negative result can impact more than just one producer. This is why it is so important that the

sample size equation accounts for the diagnostic testing protocol sensitivity.

References

Cannon, R.M. (2001). "Sense and sensitivity — designing surveys based on an imperfect test," Prev. Vet. Med., vol. 49, issue 3–4, pp 141-163, ISSN 0167-5877, https://doi.org/10.1016/S0167-5877(01)00184-2.

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