**PREVENTIVE VETERINARY MEDICINE**

An International Journal reporting on Methodological and Applied Research in Veterinary Epidemiology, Animal Disease Prevention & Control and Animal Health Economics, and on the contributions of Veterinary Epidemiology to One Health, including Environmental Health

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**Appendix**

Authors: These minimum items of information are needed by our referees and Editors to evaluate your manuscript. Additional information may be appropriate, depending on your study design and objectives.

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http://www.consort-statement.org (for clinical trials; there are elaborations for abstracts, cluster designs, reporting of harms, herbal interventions, non-inferiority and equivalence studies, trials of non-pharmacologic interventions, and pragmatic trials)

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1. For **ALL descriptive and comparative studies**:
   a. **Source** of subjects
   b. **Eligibility** criteria
   c. **Sample-size justification** appropriate for the study design and primary hypothesis. This should include details of adjustment for clustering (including the levels of *clustering*, the assumed cluster size, and either the *design effect* or the *intracluster correlation*) if clustering was present.
   d. Methods by which the data were acquired
   e. Diagnostic **sensitivity and specificity** of any tests used. (Analytic sensitivity and reproducibility might be appropriate alternatives for some studies.) Correction to the *true prevalence* is expected for e.g., seroprevalence studies.
   f. Descriptions of the observed data (including measures of subject-level variation), stratified on the outcome implied by the primary hypothesis. These descriptions should include time, place, "demographics," and relevant management and health information.
   g. Declaration of the **experimental unit**
   h. Descriptions of the **formal random mechanism** (e.g., lottery or table of random numbers) and the list frame (enumerating every eligible subject and/or cluster) used at any step claimed to be "random"
   i. Descriptions of the **pilot, repeatability, and validation testing of any questionnaire** used to acquire data for the study. Also needed are: the language of the survey instrument, the time it took to complete, how it was administered, the types of questions (e.g., closed, semi-closed, open), and the training of any persons administering the survey. Making a copy available to the review process is desirable (in English as well as the language of administration).

2. For **comparative studies** (including both observational and intervention studies):
   a. Numerical descriptions of **all tested risk factors** or pre-intervention characteristics of the subjects, stratified on the primary hypothesis/outcome of the study
   b. Descriptions of how **blindness** was accomplished for all subjective evaluations

3. For **randomized controlled trials and other intervention studies**:
   a. **Approval** by your institution's animal-welfare committee and description of measures taken for rescue analgesia or rescue euthanasia.
   b. Methods by which the owners of the animals gave **informed consent** for their animals to be in the trial
   c. Methods used for **allocation concealment** after the animals were determined to be eligible for random assignment to the various experimental or control groups
   d. **Description and justification of the "control" group's "treatment"** (e.g., standard therapy, placebo to mimic the delivery system in the absence of a standard therapy, or "do nothing" to mimic both the treatment and its delivery)
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4. For **simulation studies and risk assessments**:
   a. Distinction between deterministic and stochastic processes
   b. Descriptions of (and justifications for) all choices of **distributions and their parameter Values**
   c. Description of numbers, training, experience, and representativeness of any "experts" used to provide opinions
   d. Declaration of the **stakeholders** for any risk assessment
   e. Distinction between assumptions, input data, calculations from intermediate steps in the modeling process, and model predictions
f. Descriptions of the assumed chance variation and assumed knowledge uncertainty in the inputs, and methods used to deal with those sources of total uncertainty

g. **Sensitivity analyses** of key assumptions and of the input variables that had the greatest uncertainty

h. Descriptions of the **variability in the "outputs"** from stochastic models

5. For **statistical-hypothesis tests:**

a. Declarations of the unit of statistical analysis and of the dependent ("outcome") variable

b. **Alpha and tails**, and any methods used to adjust for multiple comparisons (to protect experiment-wise alpha from the problem of **multiplicity**)

c. **Methods used to adjust for clustering within the data**

d. Methods used to determine that the **statistical assumptions were met** (e.g., that the data were Gaussian or that the odds ratio or hazards ratio was constant across the observed range of the risk factor)

e. Methods used to look for **collinearities** or other interrelationships among the risk factors being tested

f. Methods used to select or to retain risk factors within multivariable models (including the **test criterion**)

g. Clear declaration of any variables "forced into" the model (not allowed to drop out; this implies a need to account for that factor) or offered to the model on a priori grounds despite any screening results (this implies that the factor was part of a major hypothesis)

h. Description of the **goodness-of-fit** of any models

i. How **missing data** were handled

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