ORIGINAL ARTICLE

Methods and Processes of Developing the Strengthening the Reporting of Observational Studies in Epidemiology – Veterinary (STROBE-Vet) Statement

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Impacts

- Guidelines for reporting of observational studies in veterinary medicine should improve the comprehensiveness of reporting.
- Improved reporting should increase readers ability to assess the internal and external validity of the study results.
- Improved reporting should increase the potential for study results to be useful for decision-making or for secondary data use.

Keywords:
Reporting guidelines; veterinary; observational study; animal

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Summary

The reporting of observational studies in veterinary research presents many challenges that often are not adequately addressed in published reporting guidelines. A consensus meeting of experts was organized to develop an extension of the STROBE statement to address observational studies in veterinary medicine with respect to animal health, animal production, animal welfare and food safety outcomes. The consensus meeting was held 11–13 May 2014 in Mississauga, Ontario, Canada. Seventeen experts from North America, Europe and Australia attended the meeting. The experts were epidemiologists and biostatisticians, many of whom hold or have held editorial positions with relevant journals. Prior to the meeting, 19 experts completed a survey about whether they felt any of the 22 items of the STROBE statement should be modified and whether items should be added to address unique issues related to observational studies in animal species with health, production, welfare or food safety outcomes. At the meeting, the participants were provided with the survey responses and relevant literature concerning the reporting of veterinary observational studies. During the meeting, each STROBE item was discussed to determine whether or not re-wording was recommended, and whether additions were warranted. Anonymous voting was used to determine whether there was consensus for each item change or addition. The consensus was that six items needed no modifications or additions.

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Modifications or additions were made to the STROBE items numbered as follows: 1 (title and abstract), 3 (objectives), 5 (setting), 6 (participants), 7 (variables), 8 (data sources/measurement), 9 (bias), 10 (study size), 12 (statistical methods), 13 (participants), 14 (descriptive data), 15 (outcome data), 16 (main results), 17 (other analyses), 19 (limitations) and 22 (funding). Published literature was not always available to support modification to, or inclusion of, an item. The methods and processes used in the development of this statement were similar to those used for other extensions of the STROBE statement. The use of this extension to the STROBE statement should improve the reporting of observational studies in veterinary research related to animal health, production, welfare or food safety outcomes by recognizing the unique features of observational studies involving food-producing and companion animals, products of animal origin, aquaculture and wildlife.

Introduction

Observational studies are a common methodological approach in veterinary research and have been used to estimate the frequency of a disease or condition, test hypotheses, generate new hypotheses or generate data suitable as input for systematic reviews and meta-analyses, risk assessments and other data-dependent models, such as mathematical and simulated disease models. Thus, observational studies may be used to estimate the prevalence or incidence of a condition, to investigate the distribution of conditions in time and space, to explore risk factors and compare management options, to create explanatory models or to evaluate diagnostic test accuracy. Comprehensive and transparent reporting of an observational study's design, execution and results is essential for the interpretation of the research in terms of evaluating its applicability for the reader and its potential for bias and for the data to be used as input for other studies, such as meta-analyses and risk assessments. The peer-review process also benefits from guidelines describing appropriate reporting. In human health care, inadequacies in reporting of key information in observational studies have been documented (Tooth et al., 2005; Groenwold et al., 2008; Papathanasiou and Zintzaras, 2010). Although there is less documented empirical evidence of deficiencies in reporting observational studies in veterinary medicine, the absence of evidence is not evidence of absence. Indeed, some evidence of inadequate reporting exists in the literature on pre-harvest food safety (Sargeant et al., 2011).

The STROBE statement (www.strobe-statement.org) was developed to provide guidance for the reporting of observational studies related to human health. It consists of a 22-item checklist that is accompanied by a document describing the development of the STROBE statement (von Elm et al., 2007) and an elaboration document that provides explanations of each item, as well as examples of complete reporting of each item (Vandenbroucke et al., 2007). The STROBE guidelines focus on cohort, case–control and cross-sectional studies of aspects of human medicine and public health, although many of the principles also apply to other observational study designs, such as hybrid designs or ecological studies. The STROBE statement has been modified for use in specific content areas within epidemiology, including genetic-association studies (STREGA) (Little et al., 2009), molecular epidemiology (STROBE-ME) (Gallo et al., 2012) and molecular epidemiology for infectious diseases (STROME-ID) (Field et al., 2014).

There are some nuances of conducting and reporting studies in animal populations that are unique from other areas of epidemiology (Sargeant and O'Connor, 2014). Thus, the CONsolidated Standards Of Reporting Trials (CONSORT) statement for reporting randomized controlled trials in human medicine (Moher et al., 2001) was previously modified for use in veterinary medicine. The result was the creation and publication of the reporting guidelines for randomized controlled trials for livestock and food safety (REFLECT) statement (O'Connor et al., 2010; Sargeant et al., 2010). Similarly, while the STROBE statement and the accompanying elaboration document provide an excellent resource for conducting, reporting and reading observational studies, modifications to address specific issues in veterinary medicine will increase its applicability in this field (Sargeant and O'Connor, 2014).

Here, we describe the methods and processes used to develop an extension of the STROBE statement that forms the basis for the standardized reporting guidelines for observational studies in veterinary medicine (STROBE-Vet). As a separate companion paper, the STROBE-Vet explanation and elaboration document (O'Connor et al., 2016a,b) provides the methodological background for the items contained in the STROBE-Vet statement, as well as illustrative examples of appropriate reporting. We strongly recommend that the STROBE-Vet checklist be used in conjunction with the explanation and elaboration document for all observational studies related to animal health, production, welfare or food safety outcomes.

Methods

The process for extending reporting-guideline statements (e.g. STROBE and CONSORT) to meet the specific needs of individual disciplines has been documented (Boutron et al., 2008; Moher et al., 2010). We used these reports to design the approach used for developing the statement reported herein.

Steering committee

A steering committee was responsible for the development of the revised veterinary extension of the STROBE statement. This group, comprised of four members (co-authors JMS, AMOC, HNE and IRD), first met to discuss the idea in December 2012. The committee agreed to explore the need for modifying the original STROBE statement and to use the approach reported previously as a guideline for the modification (Moher et al., 2010). The committee secured funding for the project, identified potential participants, invited the potential participants to attend a consensus meeting, organized the meeting and was responsible for subsequent steps involved in preparation and publication of the papers as detailed below.

Funding

Funding was required to cover the costs of the consensus meeting (e.g. travel, accommodations and meeting rooms). The decision was made by the steering committee not to seek funding from pharmaceutical or biological companies commonly associated with veterinary research. Efforts to obtain funding were limited to not-for-profit non-government organizations, academic institutions and a publishing company. Funding was received from the Canadian Association for Veterinary Epidemiology and Preventive Medicine (CAVEPM), the Centre for Veterinary Epidemiology (CVER) at the University of Prince Edward Island, the Centre for Public Health and Zoonoses (CPHAZ) at the University of Guelph, Iowa State University, Cornell University and the publishing company VER Inc, Prince Edward Island, Canada. Sufficient funds were obtained to pay for all local expenses for the participants at the consensus meeting. Funds to cover travel costs for participants were not obtained; therefore, in general, participants fully funded their own travel and the sources of these funds were not identified.

Identification of participants

The committee's aim was to bring together a group of experts familiar with the design, conduct and statistical analysis of observational studies concerning animal health, production, welfare and food safety. Another aim was to include researchers with experience in a wide variety of areas, including food-animal production, companion animal medicine, veterinary public health and food safety. Representation from multiple countries was sought, with an effort to include several participants with relevant editorial experience.

The steering committee decided to limit the size of the meeting to approximately 20 participants, including the four committee members. The size limitation was based on funding and the need for a group size that facilitated interaction and active discussion. The steering committee identified experts for invitation based on areas of expertise (many with multiple areas) and geographic locations. Invitations to attend the meeting were sent via email by JMS to the first 20 individuals on the list. The email invitation requested that individuals wishing to participate commit to (i) completing a pre-meeting survey to determine whether modifications to the checklist items of the STROBE statement seemed necessary for veterinary medicine, and if so, to suggest appropriate modifications; (ii) attending a consensus meeting in Mississauga, Canada; and (iii) self-funding their travel to that meeting. If an initial invitation was declined, an alternative individual with similar expertise and from the same geographic region was contacted using the same email invitation.

The steering committee also contacted the authors of the original STROBE statement papers to inform them of our interest in modifying the STROBE statement and to solicit support for, and participation in, the initiative.

Identification of specific issues

Using the approach described previously (Moher et al., 2010), a survey was sent to the invitees soliciting input on each checklist item in the STROBE statement to improve relevance to observational studies related to animal health, production, welfare and food safety. The intent of this survey was to guide discussion at the consensus meeting; thus, human ethics approval was not required. The survey was sent by email as a spreadsheet attachment to the invitees, as well as to individuals who were invited, but were unable to attend the meeting and had indicated that they still wished to provide input by completing the survey. The survey included the 22 items of the STROBE statement and asked the respondents to indicate whether each item should be modified (yes/no), and if yes, to describe the modifications that the respondent felt would be appropriate. At the end of each section (Abstract, Introduction, Methods, Results, Discussion and Conclusion), space was provided for the respondents to propose additional items of relevance for reporting on studies related to animal health, production, welfare or food safety.

After the surveys were returned, the responses for each checklist item were anonymously compiled.

The consensus meeting

A 2 1/2-day consensus meeting was held on 11–13 May 2014 in Mississauga, Ontario, Canada, with a total of 17 participants from Australia, Canada, Denmark, the United Kingdom and the United States of America, as well as two assistants for logistical support and documentation. Prior to the meeting, participants were provided with an electronic copy of the STROBE statement (von Elm et al., 2007) and its elaboration document (Vandenbroucke et al., 2007), as well as the results of the survey. At the meeting, participants were provided with the same materials in printed form.

The meeting began with an evening session consisting of introductions, an overview presentation on reporting guidelines in general and their relevance to veterinary medicine and a discussion of the format for the meeting, the scope of the initiative and the expectations of the participants in the guideline-development process. This included a discussion and vote on the approach that would be used to reach consensus. To facilitate confidential voting and recording of the voting results throughout the meeting, electronic remote voting devices were used. Three voting criteria were discussed as indicators of consensus: unanimous agreement among the 17 experts minus 2 (88%), minus 3 (82%) or minus 5 (70%). The participants agreed that a unanimous vote minus three persons would be required for consensus. In some instances, experts would leave the room for brief periods. In this case, at least 16 experts had to participate in each vote, with unanimous vote minus three still defining consensus.

At the start of the first full day of discussion, two of the authors (Myriam Cevallos and Matthias Egger) of the STROBE statement papers attended by teleconference. They provided an overview of the process for developing the STROBE statement, common uses and misuses, and a discussion of STROBE statement extensions.

For the remainder of the meeting, the following approach was used for the STROBE statement checklist items 1 through 22. Initially, the moderator described the item, the key elements of that item as presented in the STROBE elaboration document and the suggestions from the pre-meeting survey for modifying that item. The discussion sessions were moderated alternately by one of two members of the steering committee (JMS and AMOC). The moderator facilitated a group discussion of the key elements, including a discussion as to whether the proposed modifications should result in modification of the wording of the STROBE item. Following the discussion, participants (including both moderators) voted to accept or reject the modifications to the wording of the statement item. If there were no modifications proposed, the vote was to accept the item as originally written. If an item received sufficient votes to indicate consensus, it was accepted. If the item did not receive a consensus vote, it was tabled for further discussion at the end of the meeting. After the completion of voting on each item, a discussion of the key elements that should be considered within the elaboration document occurred. Participants were also asked to provide written suggestions for discussion points to include in the elaboration document. Two non-voting assistants served as record keepers to record the results of the voting, take notes of the discussion and collect additional written suggestions on each item from the participants.

Preparation of reporting guidelines

After the meeting, the steering committee compiled a draft report of the meeting that included the proposed modifications to the STROBE statement, a summary of the suggestions for the elaboration document and a request for feedback from the participants. The steering committee collated the comments and suggested revisions, and developed the modified STROBE statement for observational studies in veterinary medicine related to animal health, production, welfare or food safety outcomes. A draft of the STROBE-Vet statement was previewed by graduate students (see details in the Results section). A draft of the elaboration document was then prepared by the steering committee and circulated among the participants for input.

Results

In total, 23 experts were invited to participate in the consensus meeting and 14 accepted, although one invitee was subsequently unable to attend. The nine individuals who declined had other commitments, including teaching obligations during the time of the consensus meeting. All four of the steering committee members attended for a total of 17 participants. The methodological expertise of the participants included epidemiology, statistics, systematic review and meta-analysis, and risk assessment, with content expertise in food safety, health, production and welfare in food-producing, companion/recreation animals (e.g. dogs, cats and horses), aquaculture and wildlife. The group was comprised of seven individuals working in Canada, five from the United States, four from Europe and one from Australia. There were 13 academicians, three emeritus academicians and one government employee. Members of the STROBE group were consulted throughout the process, and two members (Myriam Cevallos and Matthias Egger) participated in the first morning of the consensus meeting.

Nineteen pre-meeting surveys were completed by 12 of the 13 invitees, all four steering committee members and three additional individuals who were invited to the consensus meeting, but were unable to attend. The individual who accepted the invitation but was subsequently unable to attend the meeting did not complete the pre-meeting survey.

The participants agreed that the scope would include observational studies using samples/information of animal origin with outcomes related to animal health, production, welfare or food safety. This wording was meant to encompass a broad range of veterinary research involving animals (including animal populations such as herds, farms or flocks), products of animal origin (such as meat or milk) or samples from animals (such as blood or faeces). Studies involving human health outcomes related to animal exposure were considered outside the scope of this initiative. For these studies, the original STROBE statement would be the appropriate guideline to use.

The participants agreed that the scope would include both observational studies of hypotheses (hypothesis-driven or hypothesis generating) and population-based descriptive studies, such as those estimating the frequency and distribution of disease. At least in the pre-harvest food safety literature, it is common for disease frequency estimates to be a key component of observational studies (Sargeant et al., 2011).

The majority of items (whether modified or not) received a consensus vote the first time that a vote was undertaken. Consensus was not achieved on the first vote for two items: item 4 and item 9. For item 4, the discussion revolved around whether the 'key elements' of study designs should be explicitly included in the item itself. For item 9, the discussion pertained to whether euthanasia represented a distinct source of bias (see further discussion, below).

To meet the needs for a STROBE statement for observational studies in veterinary research, the consensus was that the following 16 items on the STROBE checklist needed modification to make them more appropriate for veterinary medicine: 1 (title and abstract), 3 (objectives), 5 (setting), 6 (participants), 7 (variables), 8 (data sources/measurement), 9 (bias), 10 (study size), 12 (statistical methods), 13 (participants), 14 (descriptive data), 15 (outcome data), 16 (main results), 17 (other analyses), 19 (limitations) and 22 (funding) (Table 1). The participants identified the modification of these items as essential to the STROBE-Vet statement checklist, rather than solely having these issues discussed in the elaboration document.

Some of the modifications proposed to the STROBE statement were minor wording changes intended to provide more details for the veterinary community. For example, item 1b (abstract) was modified to include what the participants identified as key components of an 'informative and balanced summary' (the wording used in the original STROBE statement).

Other modifications were more substantial. For instance, throughout the STROBE statement, reference is made to three common observational study designs (cohort, case–control and cross-sectional), with the wording of some reporting recommendations different for the three designs. However, in veterinary medicine, many observational studies do not adhere strictly to one of these three classical designs, and large population cohort studies are rare. Therefore, the STROBE-Vet statement does not make reference to the three common observational study designs, but rather focuses on reporting the key features related to the observational research. This modification impacted items 1a, 6, 12, 14 and 15 (Table 1). An example of an addition is item 7 (variables), which now calls for the specification of the putative causal structure (with a causal diagram being highly encouraged) for all hypothesis-driven studies. Another example is item 8 (data sources), which now calls for information on questionnaire development (if relevant). Also, throughout the STROBE statement, the word 'participant' is used. In veterinary medicine, there generally are two components to the concept of 'participant': the owner/manager of the animals included in the study population and the animals themselves. Rather than modifying the wording for participant throughout the checklist, a footnote was added to note this point and to recommend that relevant information concerning both types of 'participants' should be reported.

An issue that had relevance to several of the items was that of non-independence of observations (items 3, 5, 6, 7, 10, 12a, 13a, 13b, 13c, 14a, 14b and 15). It is common in veterinary medicine, particularly in livestock and shelter medicine (where companion animals are kennelled), for animals to be housed or managed in groups. Individuals within groups will tend to be more similar to each other with respect to outcome status compared to individuals in other groups, that is non-independence of observational units. It is necessary to account for any non-independence of the observational units in the design, sampling strategy and statistical analysis to avoid violating the assumption of independence underlying many statistical procedures. The non-independence of observational units may be hierarchical, for instance animals within pens, pens within barns, barns within same-owner facilities. However, this is not always the case. For example, some organizational structures may not be purely hierarchical (e.g. cross-classified data structures) and non-independence can also result from repeated samples taken over time from the same animal or facility (Dohoo et al., 2009). To be consistent with the REFLECT statement (O'Connor et al., 2010; Sargeant et al., 2010) www.reflect-statement.org, 'organizational

Table 1. Modifications to the original Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement checklist for the STROBE-Vet statement

	Item	STROBE recommendation	STROBE-Vet recommendation
Title and Abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	(a) Indicate that the study was an observational study and, if applicable, use a common study design term [a] (b) Indicate why the study was conducted, the design, the results, the limitations and the relevance of the findings
Introduction			
Background/ Rationale	2	Explain the scientific background and rationale for the investigation being reported	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any pre-specified hypotheses	(a) State specific objectives, including any primary or secondary pre-specified hypotheses or their absence (b) Ensure that the level of organization[b] is clear for each objective and hypothesis
Methods			
Study design	4	Present key elements of study design early in the paper	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations and relevant dates, including periods of recruitment, exposure, follow-up and data collection	(a) Describe the setting, locations and relevant dates, including periods of recruitment, exposure, follow-up and data collection (b) If applicable, include information at each level of organization
Participants [c]	6	(a) *Cohort study* – Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case–control study* – Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study* – Give the eligibility criteria, and the sources and methods of selection of participants (b) *Cohort study* – For matched studies, give matching criteria and number of exposed and unexposed *Case–control study* – For matched studies, give matching criteria and the number of controls per case	(a) Describe the eligibility criteria for the owners/ managers and for the animals, at each relevant level of organization (b) Describe the sources and methods of selection for the owners/managers and for the animals, at each relevant level of organization (c)Describe the method of follow-up (d) For matched studies, describe matching criteria and the number of matched individuals per subject (e.g. number of controls per case)
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders and effect modifiers. Give diagnostic criteria, if applicable	(a) Clearly define all outcomes, exposures, predictors, potential confounders and effect modifiers. If applicable, give diagnostic criteria (b) Describe the level of organization at which each variable was measured (c) For hypothesis-driven studies, the putative causal structure among variables should be described (a diagram is strongly encouraged)
Data sources/ measurement	8[d]	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	(a) For each variable of interest, give sources of data and details of methods of assessment (measurement). If applicable, describe comparability of assessment methods among groups and over time (b) If a questionnaire was used to collect data, describe its development, validation and administration (c) Describe whether or not individuals involved in data collection were blinded, when applicable (d) Describe any efforts to assess the accuracy of the data (including methods used for 'data cleaning' in primary research or methods used for validating secondary data)

Table 1. (Continued)

	Item	STROBE recommendation	STROBE-Vet recommendation
Bias	9	Describe any efforts to address potential sources of bias	Describe any efforts to address potential sources of bias due to confounding, selection or information bias
Study size	10	Describe how the study size was arrived at	(a) Describe how the study size was arrived at for each relevant level of organization (b) Describe how non-independence of measurements was incorporated into sample-size considerations, if applicable (c) If a formal sample-size calculation was used, describe the parameters, assumptions and methods that were used, including a justification for the effect size selected
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	(a) Describe all statistical methods for each objective, at a level of detail sufficient for a knowledgeable reader to replicate the methods. Include a description of the approaches to variable selection, control of confounding and methods used to control for non-independence of observations
		(b) Describe any methods used to examine subgroups and interactions	(b) Describe the rationale for examining subgroups and interactions and the methods used
		(c) Explain how missing data were addressed	(c) Explain how missing data were addressed
		(*d*) *Cohort study* – If applicable, explain how loss to follow-up was addressed *Case–control study*– If applicable, explain how matching of cases and controls was addressed *Cross-sectional study* – If applicable, describe analytical methods taking account of sampling strategy	(d) If applicable, describe the analytical approach to loss to follow-up, matching, complex sampling and multiplicity of analyses
		(e) Describe any sensitivity analyses	(e) Describe any methods used to assess the robustness of the analyses (e.g. sensitivity analyses or quantitative bias assessment)
Results			
Participants	13[d]	(a) Report the numbers of individuals at each stage of study – for example numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up and analysed	(a) Report the numbers of owners/managers and animals at each stage of study and at each relevant level of organization, for example, numbers eligible, included in the study, completing follow-up and analysed
		(b) Give reasons for non-participation at each stage	(b) Give reasons for non-participation at each stage and at each relevant level of organization
		(c) Consider use of a flow diagram	(c) Consider use of a flow diagram and/or a diagram of the organizational structure
Descriptive data on exposures and potential confounders	14[d]	(a) Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders	(a) Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders by group and level of organization, if applicable
		(b) Indicate number of participants with missing data for each variable of interest	(b) Indicate number of participants with missing data for each variable of interest and at all relevant levels of organization
		(c) *Cohort study* – Summarize follow-up time (e.g. average and total amount)	(c) Summarize follow-up time (e.g. average and total amount), if appropriate to the study design
Outcome data	15[d]	*Cohort study* – Report numbers of outcome events or summary measures over time	(a) Report outcomes as appropriate for the study design and summarize at all relevant levels of organization
		Case–control study – Report numbers in each exposure category, or summary measures of exposure	(b) For proportions and rates, report the numerator and denominator

Table 1. (Continued)

	Item	STROBE recommendation	STROBE-Vet recommendation
		Cross-sectional study – Report numbers of outcome events or summary measures	(c) For continuous outcomes, report the number of observations and a measure of variability
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g. 95% confidence interval). Make clear which confounders were adjusted for and why they were included	(a) Give unadjusted estimates and, if applicable, adjusted estimates and their precision (e.g. 95% confidence interval). Make clear which confounders and interactions were adjusted. Report all relevant parameters that were part of the model
		(b) Report category boundaries when continuous variables were categorized	(b) Report category boundaries when continuous variables were categorized
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—for example analyses of subgroups and interactions, and sensitivity analyses	Report other analyses done, such as sensitivity/robustness analysis and analysis of subgroups
Discussion			
Key results	18	Summarize key results with reference to study objectives	Summarize key results with reference to study objectives
Strengths and Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Discuss strengths and limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies and other relevant evidence	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies and other relevant evidence
Generalizability	21	Discuss the generalizability (external validity) of the study results	Discuss the generalizability (external validity) of the study results
Other information			
Transparency	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	(a) *Funding* – Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based (b) *Conflicts of interest* – Describe any conflicts of interest, or lack thereof, for each author (c) *Describe the authors' roles*- Provision of an authors' declaration of transparency is recommended (d) *Ethical approval* – Include information on ethical approval for use of animal and human subjects (e) *Quality standards* – Describe any quality standards used in the conduct of the research

[a]Underlined text represents modifications or additions to the original STROBE wording.
[b]Level of organization recognizes that observational studies in veterinary research often deal with repeated measures (within an animal or herd) or animals that are maintained in groups (such as pens and herds); thus, the observations are not statistically independent. This non-independence has profound implications for the design, analysis and results of these studies.
[c]The word 'participant' is used in the STROBE statement. However, for the veterinary version, it is understood that 'participant' should be addressed for both the animal owner/manager and for the animals themselves.
[d]Give such information separately for cases and controls in case–control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

structure' was used rather than 'hierarchy' throughout the STROBE-Vet statement. In addition to modifying the wording of relevant checklist items, the elaboration document includes discussion of this issue.

The final item in the STROBE checklist pertains to funding sources. The STROBE-Vet statement substantially expands this item to encompass the broader concept of 'transparency'. Using numbered subitems, the transparency item addresses sources of funding, conflicts of interest, authors' roles, ethical approval (animal, human or data use, as applicable) and the use of any quality standards.

There was considerable discussion during the meeting on the significance of euthanasia in veterinary medicine. It is possible, and common under some disease or production

circumstances, for animals to be euthanized or electively culled during studies. There is no equivalent to this in human medicine; therefore, much discussion was devoted to this topic. Although the participants agreed that the occurrence and frequency of euthanasia or culling should be reported in studies where it occurred, there were differing opinions as to whether euthanasia is a distinct issue related to the potential for information or selection bias, or whether it is just a component of a death/survival outcome that needs to be reported. At the end of the meeting, a vote was held and the consensus was to include a discussion of euthanasia in the elaboration document, but not to modify the wording within the STROBE-Vet expansion.

The draft statement was previewed by 17 graduate students from two graduate student journal clubs (Epidemiology Journal Club and Ruminant Group Journal Club) in the Department of Population Medicine at the University of Guelph. The students identified phrases for which they would like clarification or further explanation. Their comments were incorporated into the elaboration document.

Discussion

Here, the development of an extension to the STROBE statement for reporting observational studies in veterinary research is described. The intention of these guidelines, in concordance with the STROBE statement, is to provide guidance for authors when describing the design and results of observational studies. The guidelines are also useful for editors, peer reviewers and readers of observational study reports. It is intended that these guidelines will be applicable to the broad range of research questions addressed in veterinary medicine using observational studies, including studies in which the objective was to describe disease occurrence, exploratory studies used to generate hypotheses and hypothesis-driven studies. The guidelines are applicable to research conducted in both developed and developing nations. It is not the intention for these guidelines to be prescriptive regarding format or order of reporting based on the item numbering. The items in the STROBE-Vet expansion were ordered to correspond to the items in the STROBE statement, which follows the typical order of sections within a scientific manuscript. It is important that all of the relevant checklist items are addressed in sufficient detail within a manuscript.

The STROBE-Vet guidelines are also not intended to be prescriptive about the conduct of observational studies, but rather they focus on the clarity of reporting similar to that of the STROBE statement (Vandenbroucke, 2007). Likewise, the STROBE-Vet statement is also not intended to be used as a tool to assess the quality of the research design or execution (von Elm et al., 2007). Both the issue of prescriptive design and use for quality assessment have been identified in the literature as misuses of the STROBE statement (da Costa et al., 2011). There are several systematic reviews published on quality assessment tools for observational research (Sanderson et al., 2007; Shamliyan et al., 2010; Jarde et al., 2012).

The guidelines presented herein represent the consensus of a group of individuals deemed to be experts in observational studies in veterinary research, and thus, the results represent expert opinion. A systematic review of published literature was not conducted for any of the items, and published evidence was not always available to support modification to or inclusion of an item. The steering committee attempted to balance content expertise and, to some extent, geographical location of the selected participants. However, the existing networks of the steering committee members influenced participant selection, the necessity for the experts to self-fund their travel resulted in a predominance of North American experts, and the steering committee members knew each other professionally prior to this initiative. Therefore, there is the potential for selection bias to have impacted our results. We expect that these guidelines will evolve over time and we welcome comments or suggestions. When used in conjunction with the Explanation and Elaboration document, we expect that these guidelines will lead to improved reporting of observational research in veterinary medicine.

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Potential Conflicts of Interest

None of the authors have conflicts of interest to declare.

References

Boutron, I., D. Moher, D. G. Altman, K. F. Schulz, P. Ravaud, and C. Group, 2008: Methods and processes of the CONSORT Group: example of an extension for trials assessing nonpharmacologic treatments. *Ann. Intern. Med.*, 148, W60–W66.

da Costa, B. R., M. Cevallos, D. G. Altman, A. W. Rutjes, and M. Egger, 2011: Uses and misuses of the STROBE statement: bibliographic study. *BMJ Open* 1, e000048.

Dohoo, I. R., S. W. Martin, and H. Stryhn, 2009: Veterinary Epidemiologic Research. VER Incorporated, Charlottetown, Canada.

von Elm, E., D. G. Altman, M. Egger, S. J. Pocock, P. C. Gotzsche, J. P. Vandenbroucke, and S. Initiative, 2007: Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 335, 806–808.

Field, N., T. Cohen, M. J. Struelens, D. Palm, B. Cookson, J. R. Glynn, V. Gallo, M. Ramsay, P. Sonnenberg, D. Maccannell, A. Charlett, M. Egger, J. Green, P. Vineis, and I. Abubakar, 2014: Strengthening the Reporting of Molecular Epidemiology for Infectious Diseases (STROME-ID): an extension of the STROBE statement. *Lancet Infect. Dis.* 14, 341–352.

Gallo, V., M. Egger, V. McCormack, P. B. Farmer, J. P. Ioannidis, M. Kirsch-Volders, G. Matullo, D. H. Phillips, B. Schoket, U. Stromberg, R. Vermeulen, C. Wild, M. Porta, and P. Vineis, 2012: STrengthening the Reporting of OBservational studies in Epidemiology - Molecular Epidemiology (STROBE-ME): an extension of the STROBE statement. *Eur. J. Clin. Invest.* 42, 1–16.

Groenwold, R. H., A. M. Van Deursen, A. W. Hoes, and E. Hak, 2008: Poor quality of reporting confounding bias in observational intervention studies: a systematic review. *Ann. Epidemiol.* 18, 746–751.

Jarde, A., J.-M. Losilla, and J. Vives, 2012: Methodological quality assessment tools of non-experimental studies: a systematic review. *Anales de Psicología/Annals of Psychology* 28, 12.

Little, J., J. P. Higgins, J. P. Ioannidis, D. Moher, F. Gagnon, E. von Elm, M. J. Khoury, B. Cohen, G. Davey-Smith, J. Grimshaw, P. Scheet, M. Gwinn, R. E. Williamson, G. Y. Zou, K. Hutchings, C. Y. Johnson, V. Tait, M. Wiens, J. Golding, C. van Duijn, J. McLaughlin, A. Paterson, G. Wells, I. Fortier, M. Freedman, M. Zecevic, R. King, C. Infante-Rivard, A. Stewart, and N. Birkett, 2009: Strengthening the reporting of genetic association studies (STREGA): an extension of the STROBE statement. *Eur. J. Epidemiol.* 24, 37–55.

Moher, D., K. F. Schulz, and D. G. Altman, 2001: The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 357, 1191–1194.

Moher, D., K. F. Schulz, I. Simera, and D. G. Altman, 2010: Guidance for developers of health research reporting guidelines. *PLoS Med.* 7, e1000217.

O'Connor, A. M., J. M. Sargeant, I. A. Gardner, J. S. Dickson, M. E. Torrence, C. E. Dewey, I. R. Dohoo, R. B. Evans, J. T. Gray, M. Greiner, G. Keefe, S. L. Lefebvre, P. S. Morley, A. Ramirez, W. Sischo, D. R. Smith, K. Snedeker, J. Sofos, M. P. Ward, and R. Wills, 2010: The REFLECT statement: methods

and processes of creating reporting guidelines for randomized controlled trials for livestock and food safety. *J. Vet. Intern. Med.* 24, 57–64.

O'Connor, A. M., J. M. Sargeant, I. R. Dohoo, H. N. Erb, M. Cevallos, M. Egger, A. K. Ersboll, S. W. Martin, L. R. Nielsen, D. L. Pearl, D. U. Pfeiffer, J. Sanchez, M. E. Torrence, H. Vigre, C. Waldner, and M. P. Ward, 2016a: Explanation and elaboration document for the STROBE-Vet statement: Strengthening the Reporting of Observational Studies in Epidemiology – Veterinary extension. *J. Vet. Intern. Med.*, doi:10.1111/vim.14592.

O'Connor, A. M., J. M. Sargeant, I. R. Dohoo, H. N. Erb, M. Cevallos, M. Egger, A. K. Ersboll, S. W. Martin, L. R. Nielsen, D. L. Pearl, D. U. Pfeiffer, J. Sanchez, M. E. Torrence, H. Vigre, C. Waldner, and M. P. Ward, 2016b: Explanation and elaboration document for the STROBE-Vet statement: strengthening the Reporting of Observational Studies in Epidemiology – Veterinary extension. *Zoonoses Public Health* 63, 662–698.

Papathanasiou, A. A., and E. Zintzaras, 2010: Assessing the quality of reporting of observational studies in cancer. *Ann. Epidemiol.* 20, 67–73.

Sanderson, S., I. D. Tatt, and J. P. Higgins, 2007: Tools for assessing quality and susceptibility to bias in observational studies in epidemiology: a systematic review and annotated bibliography. *Int. J. Epidemiol.* 36, 666–676.

Sargeant, J. M., and A. M. O'Connor, 2014: Issues of reporting in observational studies in veterinary medicine. *Prev. Vet. Med.* 113, 323–330.

Sargeant, J. M., M. O'Connor A, I. A. Gardner, J. S. Dickson, M. E. Torrence, I. R. Dohoo, S. L. Lefebvre, P. S. Morley, A. Ramirez, and K. Snedeker, 2010: The REFLECT statement: reporting guidelines for randomized controlled trials in livestock and food safety: explanation and elaboration. *Zoonoses Public Health*, 57, 105–136.

Sargeant, J. M., A. M. O'Connor, D. G. Renter, D. F. Kelton, K. Snedeker, L. V. Wisener, E. K. Leonard, A. D. Guthrie, and M. Faires, 2011: Reporting of methodological features in observational studies of pre-harvest food safety. *Prev. Vet. Med.* 98, 88–98.

Shamliyan, T., R. L. Kane, and S. Dickinson, 2010: A systematic review of tools used to assess the quality of observational studies that examine incidence or prevalence and risk factors for diseases. *J. Clin. Epidemiol.* 63, 1061–1070.

Tooth, L., R. Ware, C. Bain, D. M. Purdie, and A. Dobson, 2005: Quality of reporting of observational longitudinal research. *Am. J. Epidemiol.* 161, 280–288.

Vandenbroucke, J. P., 2007: The making of STROBE. *Epidemiology* 18, 797–799.

Vandenbroucke, J. P., E. von Elm, D. G. Altman, P. C. Gotzsche, C. D. Mulrow, S. J. Pocock, C. Poole, J. J. Schlesselman, M. Egger, and S. Initiative, 2007: Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): explanation and elaboration. *Epidemiology* 18, 805–835.

