



Methods and processes of developing the strengthening the reporting of observational studies in epidemiology – veterinary (STROBE-Vet) statement[☆]



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ABSTRACT

Background: The reporting of observational studies in veterinary research presents many challenges that often are not adequately addressed in published reporting guidelines.

Objective: To develop an extension of the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement that addresses unique reporting requirements for observational studies in veterinary medicine related to health, production, welfare, and food safety.

Design: 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.

Setting: Consensus meeting May 11–13, 2014 in Mississauga, Ontario, Canada.

Participants: 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.

Methods: 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 if 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.

[☆] Note: In order to encourage dissemination of the STROBE-Vet Statement, this article is published in the following journals: Journal of Food Protection, Journal of Swine Health and Production, Journal of Veterinary Internal Medicine, Preventive Veterinary Medicine, Zoonoses and Public Health. The Explanation and Elaboration STROBE-Vet document for each checklist item is available in companion publications in Journal of Veterinary Internal Medicine and Zoonoses and Public Health. The original STROBE statement is published in the Journal of Clinical Epidemiology Web site (<http://www.jclinepi.com>), Annals of Internal Medicine, BMJ, Bulletin of the World Health Organization, Epidemiology, The Lancet, PLoS Medicine, and Preventive Medicine. The authors jointly own the copyright of this article.

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Results: The consensus was that six items needed no modifications or additions. Modifications or additions were made to the STROBE items numbered: 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).

Limitation: Published literature was not always available to support modification to, or inclusion of, an item.

Conclusion: 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.

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1. 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 healthcare, 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, 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, 2016b) 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.

2. 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.

2.1. 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.

2.2. 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

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