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Issues of reporting in observational studies in veterinary medicine

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ABSTRACT

Observational studies are common in veterinary medicine; the results may be used to inform decision-making, future research, or as inputs to systematic reviews or risk assessment. To be of use, the results must be published, all of the outcomes that were assessed must be included in the publication, and the research (methods and results) must be reported in sufficient detail that the reader can evaluate the internal and external validity. In human healthcare, concerns about the completeness of reporting – and evidence that poor reporting is associated with study results – have led to the creation of reporting guidelines; these include the STROBE statement for observational studies.

There is evidence from a limited body of research that there also are reporting inadequacies in veterinary observational studies. There are differences between human and veterinary observational studies that might be relevant to recommendations for reporting. Such differences include: the use of observational studies in animal populations for simultaneously estimating disease frequency and risk-factor identification; the distinction between the animal owners who consent to participate and the animals that are the study subjects; and the complexity of organizational levels inherent in animal research (in particular, for studies in livestock species). In veterinary medicine, it is common to have clustering within outcomes (due to animal grouping) and clustering of predictor variables. We argue that there is a compelling need for the scientific community involved in veterinary observational studies to use the STROBE statement, use an amended version of STROBE, or to develop and use reporting guidelines that are specific to veterinary medicine to improve reporting of these studies.

1. Introduction

Observational studies are widely used in veterinary medicine to address a variety of types of research questions. Observational approaches may be used: to address descriptive questions (e.g. to estimate the prevalence or incidence of a condition); to evaluate diagnostic-test accuracy or effectiveness of interventions; or to identify and evaluate risk factors or exposures. For the latter, the intent might be to identify potential causes of a disease, verify the magnitude of an association, confirm or refute observations from previous studies, or to improve upon the methodological approach of previous studies (Vandenbroucke et al., 2007). Observational studies can be hypothesis – generating; alternatively, they can test specific hypotheses using either primary or secondary data (von Elm et al., 2007). The range of observational designs that are available allow flexibility to address research questions with, for example, rare exposures (cohort) or rare outcomes (case–control).

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Regardless of the research question being addressed or the specific observational design being used, it is important that observational studies be conducted rigorously to reduce the potential for bias. Equally important is that the results be presented in a manner that allows the reader to assess internal validity (potential for bias) and external validity (generalizability). In human healthcare, empirical evidence of inadequacy of reporting and evidence that poor reporting is associated with bias in the estimation of outcomes (in studies using a variety of study designs) has led to the development of guidelines for reporting study results (Simera et al., 2010). Recent initiatives have begun to address issues with reporting of research studies in veterinary medicine (overviewed in Erb, 2010). Our objectives are: to describe the relevance of clear reporting – including the ethical aspects; to review reporting guidelines developed for human healthcare and veterinary medicine; and to discuss the need for guidelines for observational studies in animal populations. This paper is based on a presentation made at the 2012 Calvin W. Schwabe Symposium honouring the lifetime achievement in veterinary epidemiology and preventive medicine of Dr. Ian Dohoo. Dr. Dohoo has provided leadership in veterinary epidemiology throughout his career, including the design of observational studies, as incorporated in his seminal textbook Veterinary Epidemiologic Research (Dohoo et al., 2009).

2. The research publication

For research in general (including observational research), a research publication is thought of by some researchers as the "end product" of the research process. However, the research publication also is the "raw material" for another process or purpose (Altman, 2012). For instance, the research publication may be used to inform further research, to guide clinical decision-making or the creation of guidelines or policies, or it may be used in synthesis research. In the human-healthcare literature, synthesis research commonly uses systematic review and meta-analysis to summarize the body of literature on a topic. In the veterinary literature, systematic reviews and meta-analysis are increasingly being published and quantitative risk assessment also is a common methodology that makes use of primary research-study results.

For a publication to be usable as raw material for any of these purposes, it must be available (i.e. published in a public forum). Failure to publish results from some studies on a topic can lead to distorted estimates of intervention efficacy when data from published studies are pooled ("publication bias"), with the estimated treatment effect tending to be overestimated (Thornton and Lee, 2000). Failure to report the results of all outcomes within studies (outcome-reporting bias) also can affect the ability for research to be useful for further purposes. There is empirical evidence that, within clinical trials, outcomes that are statistically significant have higher odds of being reported in a publication (Dwan et al., 2008). Thus, both publication bias and outcome-reporting bias have the potential to cause serious bias in meta-analyses of randomized controlled trials. The same is true for other types of research (including observational research). Finally, in addition to complete results being made available in a public forum, both the methods and results of the research also must be clearly reported in publications. Research studies should be reported such that the reader can understand what was planned, what was done, what was found, and what was included (von Elm et al., 2007). An evaluation of the proportion of results from observational studies of diet, nutrition, and physical-activity associations with prostate or bladder cancer found that only 61% of 3284 results published in 767 studies reported sufficient information to be used in meta-analyses estimating dose–response associations; significant associations were more likely to be usable (reported in sufficient detail) than results that were not statistically significant (Bekkering et al., 2008).

In the human-healthcare literature, the authors of many publications have argued that it is a moral obligation of the researcher to publish the results of studies, to include results for all of the outcomes evaluated, and to provide clear and accurate reporting of the study (Savitz, 2000; Moher, 2007; Altman and Simera, 2010). An underpinning of the ethical review process is that the benefits of research involving human subjects or animals outweigh any potential harm to the participants. In clinical trials, there is the potential for harm in the treatment group (for example, if there are adverse side effects associated with the treatment) and in the control group (if the treatment is effective and study subjects are therefore not benefiting from receiving the treatment). In observational research, the investigator does not allocate study subjects to treatment group. However, there still is the potential for harm: psychological discomfort, physical discomfort associated with outcome assessment, or a logistical burden associated with participation in the research. In clinical trials, the subjects themselves have the potential to benefit from a treatment that they might otherwise not receive. In observational research, however, the study subjects are already receiving (or not receiving) an intervention or exposure. Therefore, there is no direct benefit for the study subjects participating. Thus, it could be argued that all of the benefits of observational research are to society through the advancement of knowledge – rather than to the study subjects participating in the research (Savitz, 2000). The realization of these benefits is the responsibility of the investigator, through complete publication of the results and clear reporting of the study methods and results.

3. Reporting guidelines for research in human populations

Studies in human healthcare have reported inadequacies in reporting in studies using a variety of study designs, including observational studies (for examples, see Pocock et al., 2004; Tooth et al., 2005; Groenwold et al., 2008; Papathanasiou and Zintzaras, 2010). Concerns with the quality of reporting (and the potential for poor reporting to be associated with the estimates of the outcomes) has lead to the development of reporting guidelines for many study designs. The Equator Network