BALANCE: Evaluating fairly (blinding/masking)

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We have covered the importance of appropriate comparison groups, adequate sample size, and fair allocation to ensure that veterinary practitioners can trust a truth claim to provide clinically important information that will stand the test of time. The next topic that we want to introduce to help veterinary practitioners assess truth claims is the importance of having fair and balanced assessment of the outcomes. Whether an outcome being investigated is objective (such as body weight or serum hormone concentration) or subjective (such as being sick versus healthy or lame versus sound), making sure that the person measuring or evaluating the outcome is not aware which treatment an animal received or which risk factor an animal possesses, is critical to ensure that pre-existing beliefs do not influence findings. Ensuring that outcome evaluators do not know to which experimental group animals have been assigned is called ‘blinding’ or ‘masking’.

Even seemingly objective outcomes (such as mortality – an animal surviving or dying) can have a subjective component when the investigator is allowed to determine how long to capture death loss data or when the study may have exit-criteria allowing the investigator to remove animals from the study prior to death. In the case of objective measurements such as concentrations of metabolites in blood, if animals with certain risk factors (for example, breed, co-morbidity, or genetic status) are tested more frequently or using different methodology than animals lacking the risk factor, any difference in outcome may be due to the frequency or method of assessment and not the risk factor itself.

Although clinical observations are one of the most relevant measures of treatment performance, subjective outcomes based on observation are very susceptible to bias based on pre-existing notions regarding treatment efficacy. This does not mean researchers are intentionally modifying results, but every researcher has an underlying hypothesis that can subconsciously influence the likelihood of deciding which category to subjectively assign an animal.

Blinding (also called masking) are the methods used to ensure that study outcome evaluators do not know to which experimental group animals have been assigned. In fact, when at all possible, all personnel involved in caring for study animals as well as those making observations should be unaware of the treatment allocation of animals.

Blinding allows imperfect, subjective measures of clinical illness to serve as valid study outcomes. Even in cases where the observer may be very poor at observing clinical signs, the comparison between the treatments can still be meaningful if the observer is completely unaware of the treatment each animal received - because a blinded observer should have had approximately equal error-risk among the treatment groups.

Blinding isn't effective if anything about the treatment or management of the animals provides a clue that an animal is in a different treatment group from another animal. For example, the study must not use different color collars or tags for animals receiving different treatment, products being compared that are administered by any route must not have different constancy or visual characteristics, the compared products must not produce detectable differences in treated animal such as a visual effect on the animals' haircoat, or a noticeable difference in the smell of animals, and animals in different treatment groups must not be observed or measured at different frequencies or by different methods.

Reports in both the veterinary and human medical literature document the increased risk of biased outcomes when blinding is not explicitly described. For example, a study reported in the Journal of the American Medical Association found that studies that did not clearly indicate the method of blinding or that did not adequately use blinding, exaggerated the effectiveness of interventions by an average of 30% to 40% (Schultz et al, 1995). Another study investigating the importance of blinding found that un-blinded orthopedic studies reported 70% greater intervention effectiveness than blinded studies (Poolman et al., 2007). These studies point out that if blinding is implemented rigorously, the risk of biased outcome assessments is greatly reduced.

In order to address anxiety about trusting a truth claim, the person making the claim must provide sufficient information for veterinarians to be assured that study outcomes were measured or collected in a way that ensures equal and fair assessment of all the animals in all the treatment groups. Every outcome for every animal must be evaluated in exactly the same way by a person who is completely unaware of which animals received a different treatment or had a different risk factor from any other animal in the study.

Schulz KF Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias: dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *JAMA* 1995;273:408-412.

Poolman RW, Struijs PA, Krips R, Sierevelt IN, Marti RK, Farrokhyar F, Bhandari M. Reporting outcomes in orthopaedic randomized trials: does blinding of outcome assessors matter? *J Bone Joint Surg Am* 2007;89:550-558.

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