

## EBVM Toolkit 3

### Introduction to “Levels of evidence” and study design

There are five key steps to follow in Evidence-based Veterinary Medicine (EBVM).

1. Asking an answerable clinical question
2. Finding the best available evidence to answer the question
- 3. Critically appraising the evidence for validity**
4. Applying the results to clinical practice
5. Evaluating performance

This handout explains how different types of study design can affect the “levels of evidence” a study provides.

#### Introduction

Critical appraisal is a process which is used to help you identify the strengths and weakness of a research paper and how likely the results of the paper are to be biased, how appropriate the study design is for the answer we seek, how well the methods were carried out and how good the reporting in the paper is.

#### Levels of evidence

Research studies in veterinary science can be designed in a variety of ways, depending on the type of question they are trying to answer. These different study designs are often arranged into a hierarchy known as the ‘levels of evidence’ with practitioners encouraged to find the highest level of evidence possible to answer their clinical question.

Whilst the idea of ‘levels of evidence’ suggests that there is a hierarchy of quality between the different types of studies it should be noted that each type of study has its own strengths and limitations. For example, a case-control study is a perfectly appropriate way to study the aetiology of a disease and a qualitative study would appropriately address questions regarding the quality of life of a patient after an intervention. Randomised controlled trials are often celebrated as high quality evidence because their methodological design inherently reduces bias, but you should remember that their strength lies in their ability to address the efficacy of a given intervention.

The table on page 2 shows a broad categorisation of studies arranged according to the level of evidence. As you move up the table the study design corresponds to increasing quality and reliability of the evidence. The higher the level the more confident you can be in the accuracy of the results with less chance of statistical error or bias.

“Stronger” evidence▲

Systematic review
Meta analysis
Randomised Controlled Trial
Cohort study
Case control study
Case series
Case report
Opinion

This evidence hierarchy is designed to help you to concentrate your efforts on sources that are most likely to provide a reliable answer. It is important to remember though that the hierarchy is based on study design and you should always critically appraise the individual studies. A poorly designed Randomised Controlled Trial (RCT) may provide lower level evidence than a good cohort study.

## Types of study design

### Experimental

Experimental studies are those where there is an intervention (e.g. treatment, drug therapy, surgical method, exposure to a chemical etc) and a researcher responsible for designing the intervention and deciding which animals are exposed to the intervention.

Experimental studies include:

- **Randomised controlled trials** (RCTs) can either be experimental laboratory studies or clinical trials. RCTs have two important features:
  - there are at least two groups - a treatment group and a control group
  - patients are randomly assigned into the two groups.Randomised control trials are considered the ‘gold standard’ when assessing the efficacy of a treatment because they minimise the chance of bias.
- **Non-randomised controlled trials.** Not every intervention can, or should, be randomised. Non-randomised controlled trials can detect associations between an intervention and an outcome but they cannot rule out the possibility that the association was caused by a third factor linked to both intervention and outcome.
- **Cross over trials** comprise the administration of two or more interventions one after the other in a specified or random order to the same group of patients.

### Observational

Observational studies are those where the researcher examines the outcomes of an intervention within two groups without having any influence on which animals get the intervention. They “only” observe. e.g.: a researcher could consider the rate of complication following different types of surgery by looking back at all the surgical cases and analysing those that resulted in complications.

Observational studies include:

- **Case-control studies** are where animals which have a disease condition are identified and any causal or risk factors are compared to a control group. Information regarding the exposure is

historical. The study starts with groups that already have the outcome (e.g. diabetes) and it looks back to examine what might have been the exposure factors (e.g. obesity).

- **Cohort studies** identify a group of animals and follows them over a period of time to see how their exposures affect their outcomes compared to another group (either the general population or another cohort of animals) that were not exposed to that factor. A cohort study can be prospective (looking forward) or retrospective (looking backwards)
- **Cross-sectional studies** are studies that describe the characteristics of sample groups of animals. Data is collected at one point in time and two groups are identified – usually animals with a specified disease and those without. The relationships within the groups to given parameters are then considered. The relationships are usually expressed as an odds ratio. As the data is taken at one point in time causal links cannot be established.
- **Controlled Before-and-After/Interrupted Time Series** are studies that measure the characteristics of a group of animals before and after an event or intervention. The two sets of data are then compared to judge the effect of the event or intervention.

### Descriptive studies

Descriptive or non-comparative studies are designed to record what is seen – they give a picture of what is happening in a population but do not attempt any comparison to a control group: These studies have value if the aim of the paper is to highlight a dramatic finding, or report a rare occurrence. Descriptive studies will not be able to prove causation, so when using this type of study care should be taken to avoid over-interpreting the findings by making conclusions regarding causal links.

Descriptive studies include:

- **Case reports** which are reports on a single patient. They describe the presentation and/or course of a disease.
- **Case series** which are collections of case reports and can provide descriptive quantitative data.

### Reviews

These are studies which review the literature or accepted practice and include:

- **Systematic reviews** are comprehensive surveys of a topic in which all the primary studies of the highest level evidence have been systematically identified, selected, appraised and summarised according to explicit, and reproducible, methodologies.
- **Meta analyses** are surveys in which the designs of all the included studies are similar enough statistically that the results can be combined and analysed as if they were a single study. Analyses of this type are normally accompanied by some sort of graphical representation e.g. a forest plot.
- **Narrative reviews** lack specific search protocols or explicit criteria for which papers are included or excluded. They may mention a generic search but they rely on experts to draw conclusions based on the papers *they* find more relevant or interesting.

- **Opinion pieces** are not based on a literature search. Instead the authors give their opinions without any explicit appraisal of existing literature though they may mention a couple of journal articles to substantiate their claims.