EBVM Toolkit 4

What type of study is it?

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. Evaluate performance

This handout offers advice on how to identify the design of a study.

**Identifying study design**

**The information needed to** identify the type of study design is normally found in the methodology (i.e. in the methods section of the paper). It is good practice not to rely solely on the abstract when identifying study design as it rarely gives sufficient information for you to be sure that the description is accurate. For example, the abstract may say the study was ‘a randomised controlled trial’ but you would need to read the methodology to see how the randomisation was achieved in order to confirm if this was indeed the case.

The following questions, which are presented both diagrammatically as an algorithm and in a table with accompanying notes, will help you identify the type of study design in the paper you are reading and the relevant critical appraisal checklist.

You should work your way through the questions until you are satisfied with the answer and that you have identified a study design. If you reach the end and are still unsure please contact us at [ebvm@rcvsknowledge.org](mailto:ebvm@rcvsknowledge.org) and we will try and help you
Study Design Algorithm

This diagram is meant to help you identify different types of study design. As always, this does not substitute your judgement, and is merely intended as an aid. Start by answering question 1 and follow through until you are satisfied with the answer.

**QUESTION 1:** Does the researcher have control over which animals are exposed to the intervention from the start?

*intervention:* in this context intervention describes a wide range of activities from drug treatments and other clinical therapies, to lifestyle changes (e.g. diet or exercise) and social activities (e.g. an education program). Interventions can include individual patient care or population health activities.

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QUESTION 2: Is the researcher looking for an association between variables by observing the situation, or the patients, without directly intervening?

1. Is there a comparison or control between interventions*?
   - **NO**: Go to Question 3
   - **YES**: Are exposure and outcome measured at the same time?
     - **NO**: This is an INTERRUPTED TIME SERIES
     - **YES**: Are groups defined by outcome?
       - **NO**: This is a BEFORE-AFTER STUDY or an INTERRUPTED TIME SERIES
       - **YES**: This is a COHORT STUDY
         - Use EBVM Toolkit 9: Cohort study checklist

2. Are groups defined by outcome?
   - **NO**: This is a CROSS SECTIONAL STUDY
     - Use EBVM Toolkit 7: Cross sectional study checklist
   - **YES**: This is a CASE CONTROL STUDY
     - Use EBVM Toolkit 8: Case control checklist
QUESTION 3: Is the aim of the study to validate a test, tool or diagnostic method?

This is a diagnostic validity study.

NO

Go to Question 4

YES
QUESTION 4: Is the aim of the study to review the literature or to give advice?

** a systematic review can include a meta-analysis and a meta-analysis might not be a systematic review. In this context, 'systematic review' will refer to the entire process of collecting, reviewing and presenting all available evidence, while the term 'meta-analysis' will refer to the statistical technique involved in extracting and combining data to produce a summary result.

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<th>Question</th>
<th>Answer</th>
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| 1. Does the researcher have control over which animals are exposed to the intervention from the start? | This question divides studies into experimental and observational.  
**YES:** This is an experimental study where there is an intervention and a researcher responsible for designing the intervention and deciding which animals are exposed/not exposed to the intervention. Go to question 1a  
**NO:** This is an observational study where the researcher examines the outcomes of an intervention within two groups without having any influence over which animals get the intervention. Go to question 2.  
**Tip:** Does the methodology say anything about the researchers determining which groups of animals got the intervention (e.g. drug treatment, clinical therapy, lifestyle change etc) and which did not? Or does it refer to the researchers looking backward (or forward) following a particular group of animals and observing what happens. |
| 1a. Is there a comparison or control between interventions? | **YES:** This means that there was an alternative to the intervention, i.e. there was a control group that received no treatment or other intervention. The researchers made their conclusions by comparing two (or more) different scenarios. Go to question 1b.  
**NO:** If there was no comparison or control group then the study is a Descriptive or non-comparative study. Case studies and case series are examples of non-comparative studies. |
| 1b. Were the interventions randomly allocated? | **YES:** This is a Randomised Controlled Trial where the animals were assigned to different groups by an explicit random process. Use EBVM Toolkit 6: Controlled trial checklist  
**NO:** This is a Non-randomised Controlled Trial where the allocation of interventions was not a randomised process. Use EBVM Toolkit 6: Controlled trial checklist  
**Tip:** The method of randomisation should be described in the methodology (computer randomisation, pot luck, etc.) |
| 2. Is the researcher looking for an association between variables by observing the situation, or the animals, without directly intervening? | This question establishes if the study is observational, or if you are dealing with a diagnostic validity study or a review.  
**YES:** This is an Observational study where the researchers do not manipulate the group or provide an intervention but they do have hypotheses about the relationship between two variables. Go to question 2a  
**NO:** The study does not address an intervention observed by researchers. Go to Question 3. |
| 2a. Is there a comparison or control between interventions? | **YES:** If there was a control group that received no treatment or other intervention then the researchers made their conclusions by comparing different scenarios. Go to question 2b  
**NO:** This is a Controlled Before-and-After (CBA) study or an Interrupted Time Series (ITS). Both can be useful to study changes in a major service delivery. |

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<td>2b. Are exposure and outcome measured at the same time?</td>
<td>This is a <strong>cross sectional study</strong>. This means that the study is like a snapshot in time of a defined situation. In this case, the researchers go to the subjects only once to collect data. For example, if the researchers collected information on the exposure (diet intake) and the outcome (weight) at the same time. Use <strong>EBVM Toolkit 7: Cross sectional study checklist</strong>.</td>
<td>If the researchers collected information more than once, at different points in time, use <strong>question 2c</strong>.</td>
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<td>2c. Are the groups defined by outcome?</td>
<td>This question separates a Cohort study from a Case control study. Consider whether the comparison groups are based on the outcome (e.g. weight) or the exposure (e.g. diet intake).</td>
<td>This is a <strong>Cohort study</strong>. This means that the study starts with groups that have been exposed to the same risk factor (e.g. obesity) and then considers if there is any association between that exposure and the outcome (e.g. diabetes). Cohort studies can be prospective (looking forward) or retrospective (looking backwards). Use <strong>EBVM Toolkit 9: Cohort study checklist</strong>.</td>
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<td>3. Is the aim of the study to validate a test, tool or diagnostic method?</td>
<td>This is a <strong>Diagnostic Validity Study</strong>. This study evaluates the “performance” of a diagnostic test. It might look at how well the test identifies “sick” animals, how reliable the test is or how well it compares with the existing “gold standard”.</td>
<td>Go to <strong>Question 4</strong>.</td>
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<td>4. Is the aim of the study to review the literature or to give advice?</td>
<td>This is likely to be a review paper. A review paper analyses published literature rather than attempting to test a hypothesis. Its aim is to analyse the current state of knowledge. This can be done by seeking the views of experts or by interrogating the available literature (or both). Go to <strong>question 4a</strong>.</td>
<td>Begin again with Question 1 or ask us for help <a href="mailto:ebvm@rcvsknowledge.org">ebvm@rcvsknowledge.org</a>.</td>
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<td>4a. Was there an explicit mention of a literature search?</td>
<td>Some reviews analyse the issue at stake through a narrative that references other work that the authors consider to be important. Other reviews set out to analyse all the published references that are found by using specific keywords to search one or more databases. This question separates the two types of search.</td>
<td>This is an <strong>opinion article</strong>. This means that the authors have not carried out a thorough search of the literature, though they may mention a couple of journal articles to substantiate their claims. Opinion, by definition is subject to bias – therefore an opinion article is the lowest level of evidence.</td>
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### 4b. Is the search comprehensive and explicit?

**YES:** The authors clearly stated which keywords were used and the databases searched. This is provided in a way that means others could perform the same search and obtain the same results. The papers selected for review were based on a set of inclusion/exclusion criteria which are clearly identified. **Go to question 4c**

**NO:** This is a narrative review. The authors mention a generic search and then proceed to draw conclusions based on the papers they find more relevant or interesting.

### 4c. Is the data from different papers combined statistically?

**YES:** This is a Meta-analysis which is a statistical technique for combining the findings from two or more studies. Use **EBVM Toolkit 10: Systematic review checklist**

**NO:** This is a Systematic Review which is a literature review that tries to identify, appraise and synthesise all high quality papers relevant to a research question according to an explicit and reproducible methodology. Use **EBVM Toolkit 10: Systematic review checklist**

**Tip:** A meta-analysis is not necessarily part of a systematic review. It may be part of a smaller review of a few studies that were not chosen systematically as part of a thorough literature search.

If you get to the end of the questions and are still unsure about the type of study design please email [ebvm@rcvsknowledge.org](mailto:ebvm@rcvsknowledge.org) and we will try to help you identify the study design and find a checklist that will allow you to appraise the paper.