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. Evaluating 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 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 library@rcvsknowledge.org and we will try and help you.

Question	Answer
1. Does the paper present the results of a single study, or analyse and present a synthesis of previously published research?	This question divides papers into reports of a single primary research study and synthesised evidence from a number of studies. **Primary:** Where the paper presents the result of a single study this is **primary research**. Go to **question 2.** **Synthesised:** Where the paper analyses and synthesised the results of a number of previously published studies this is **secondary or synthesised evidence**. Go to **question 5.**
2. Does the researcher have control over which animals or participants are exposed to the intervention from the start?	This question divides studies into interventional and observational**.** **YES:** This is an **interventional study** where the researcher is responsible for designing the intervention and deciding which animals or participants are exposed/not exposed to the intervention**.** Go to **question 2a** **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 or participants get the intervention. Go to **question 3**. **Tip:** Does the methodology say anything about the researchers determining which groups 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 or participants and observing what happens.
2a. Is there a comparison or control between interventions?	This question divides studies into comparative and non-comparative (descriptive). **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 2b**. **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.

2b. Were the interventions randomly allocated?	This question divides studies into randomised and non-randomised trials. **YES:** This is a **Randomised Controlled Trial** where the animals or participants were assigned to different groups by an explicit randomisation 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 clearly described in the methodology (computer randomisation, etc). If the study was not randomised think about whether this has led to bias in the results.
3. 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 another type of study. **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 3a** **NO:** The study does not address an intervention observed by researchers. Go to **Question 4**.
3a. 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 3b** **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.

3b. Are exposure and outcome measured at the same time?	**YES**: This is a **cross sectional study**. 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 **EBVM Toolkit 7**: **Cross sectional study checklist** **NO:** If the researchers collected information more than once, at different points in time, Go to **question 3c**
3c. Are the groups defined by outcome?	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). **YES**: **This is a Case control study**. This means that 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 (obesity). Use **EBVM Toolkit 8: Case control checklist** **NO**: **This is a Cohort study**. 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 **EBVM Toolkit 9: Cohort study checklist** **Tip:** The rule of thumb is if the researcher starts with a group of "sick" animals and then examines the risks they have been exposed to, then it is a case control study. If the researcher follows a group of animals that have been exposed to a risk to see if they got "sick" then it is a cohort study.

4.	There are a number of other types of study, including those that deal with diagnostic tests and qualitative research. Is the study evaluating the performance of a diagnostic test (this could include diagnostics that use machine learning)? If **YES:** This is a **Diagnostic Test Study go to question 4a** Is the study seeking to understand the experiences of the human subjects (e.g. members of the veterinary team or clients). If **YES** this is a **Qualitative Study go to question 4b**
4a. Is the aim of the study to validate a test, tool or diagnostic method?	**YES:** This is a **Diagnostic Test Study.** 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 "reference standard". Use **EBVM Toolkit 12: Diagnostic test checklist**
4b. Is the aim of the study to understand the experiences or perspective of human participants?	**Yes:** This is **qualitative study.** Qualitative methods seek to understand the experiences of the human subjects involved. Studies using qualitative methods may be relevant to the delivery of veterinary care or the experience of caring for animals with certain conditions. They may involve veterinary professionals or owners as participants. Use **EBVM Toolkit 11: Qualitative study checklist**
5.Does the paper analyse and report previously published studies?	**YES:** This is likely to be **synthesised evidence.** Go to **question 5a** **NO**: This is likely to be an **opinion article.** The paper may contain a small number of references to substantiate the views of the author but has no explicit methodology. Opinion by definition is subject to bias – therefore an opinion article is the lowest level of evidence.

5a. Was there a comprehensive and explicit search of the literature?	**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 5b** **No:** This is likely to be a narrative review. It may contain references but does not report a clear methodology or explicit criteria for evaluation. Its aim is to present the current state of knowledge. This can be done by seeking the views of experts or by presenting a summary of the available literature (or both). Use **EBVM Toolkit 14: Narrative review checklist.**
5b. Does the paper provide a detailed and systematic appraisal of the literature relating to a whole topic or a focused clinical question?	**YES** **Whole topic:** This is a **Systematic Review** which is a literature review that tries to identify, appraise and synthesise all high-quality papers relevant to a topic according to an explicit and reproducible methodology. Use **EBVM Toolkit 10**: **Systematic review checklist.** **Focused clinical question:** This is a **Knowledge Summary** or **critically appraised topic,** which are concise appraisals of the best available evidence on a defined clinical question. They should follow a explicit methodology to identify and critically appraise the evidence. Use **EBVM Toolkit 13: Evidence summary checklist** **NO: Go to Question 5c**
5c. 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** **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. **NO: Go to question 5d**

5d. Does the paper provide explicit recommendations for the care of animals with a particular condition?	**YES:** This is likely to be a **Clinical Guideline** If the guideline is based on an explicit review and grading of evidence this is an **Evidence-based guideline.** If the guideline is based primarily on expert opinion, without explicit grading of the published evidence, this is a **Consensus guideline.** Some guidelines are a mixture of the two**.** **Use EBVM Toolkit 15: Clinical guidelines checklist.** **No:** Begin again with Question 1 or ask for help from library@rcvsknowledge.org

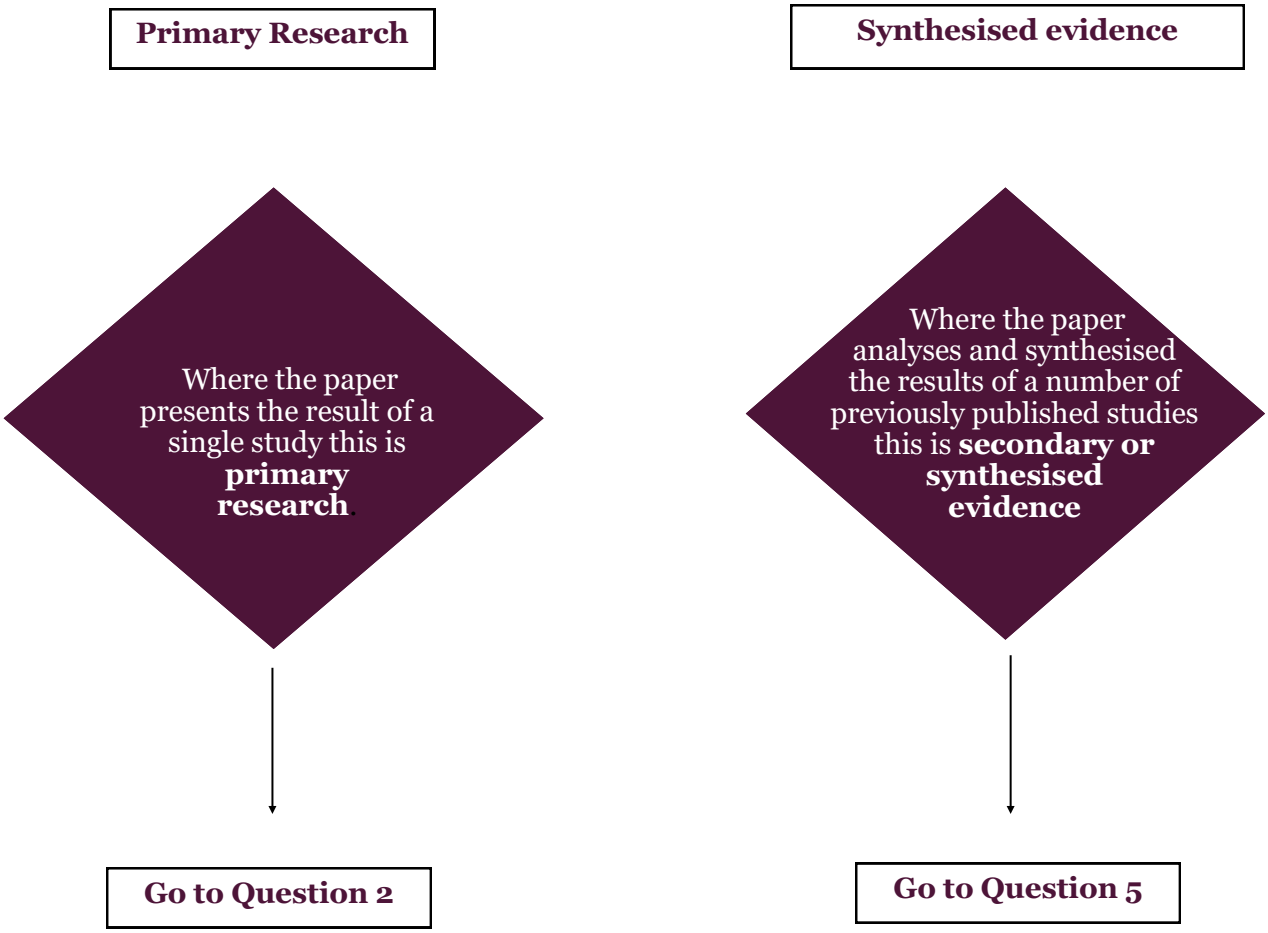
If you get to the end of the questions and are still unsure about the type of study design please email library@rcvsknowledge.org and we will try to help you identify the study design and find a checklist that will allow you to appraise the paper.

Study Design Algorithm

This algorithm will help you identify type of study design in the paper you are reading and the relevant critical appraisal checklist. As always, this does not substitute your judgement, and is merely intended as an aid. You should work your way through the questions until you are satisfied with the answer and that you have identified a study design.

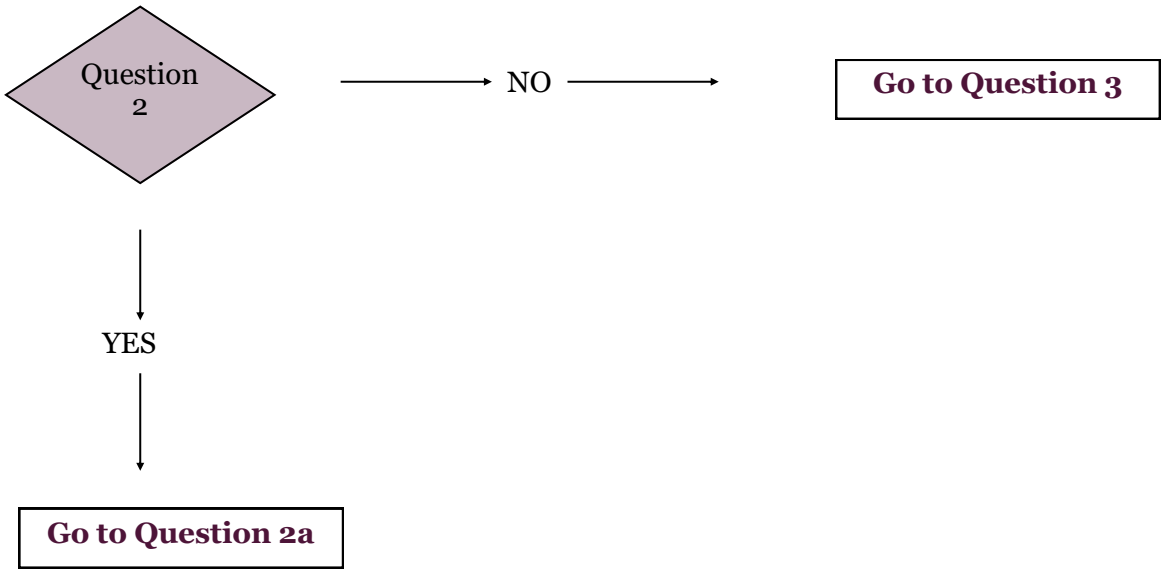
QUESTION 1: Does the paper present the results of a single study, or analyse and present a synthesis of previously published research?

This question divides papers into reports of a single primary research study and synthesised evidence from a number of studies.



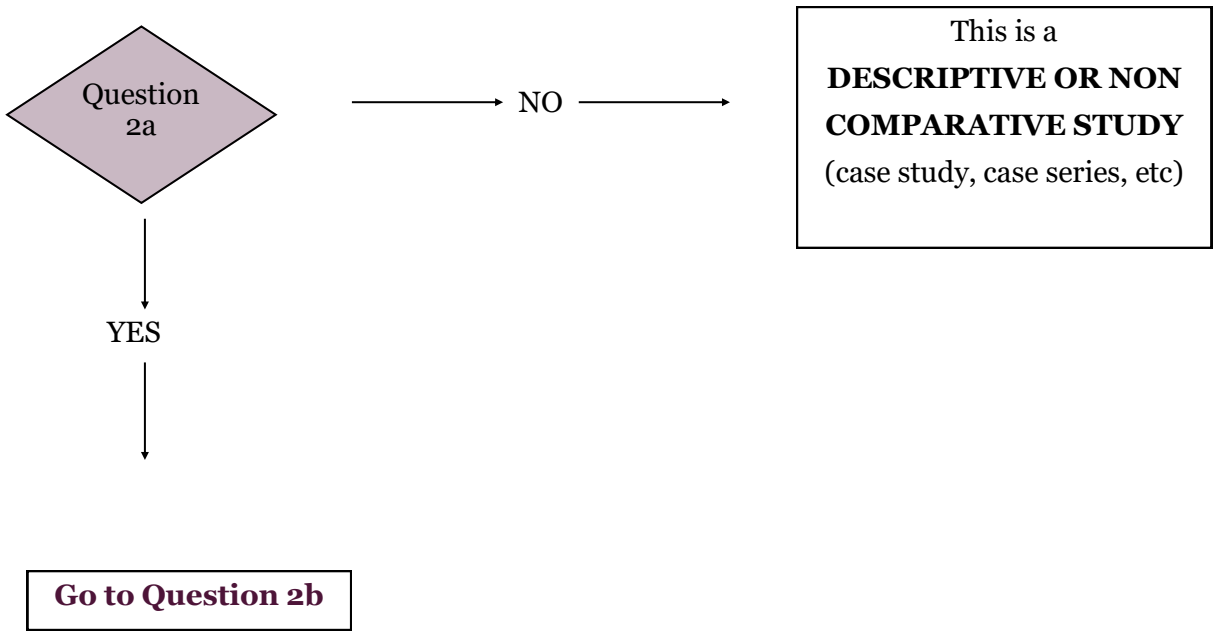
QUESTION 2: . Does the researcher have control over which animals or participants are exposed to the intervention from the start?

This question divides studies into interventional and observational.



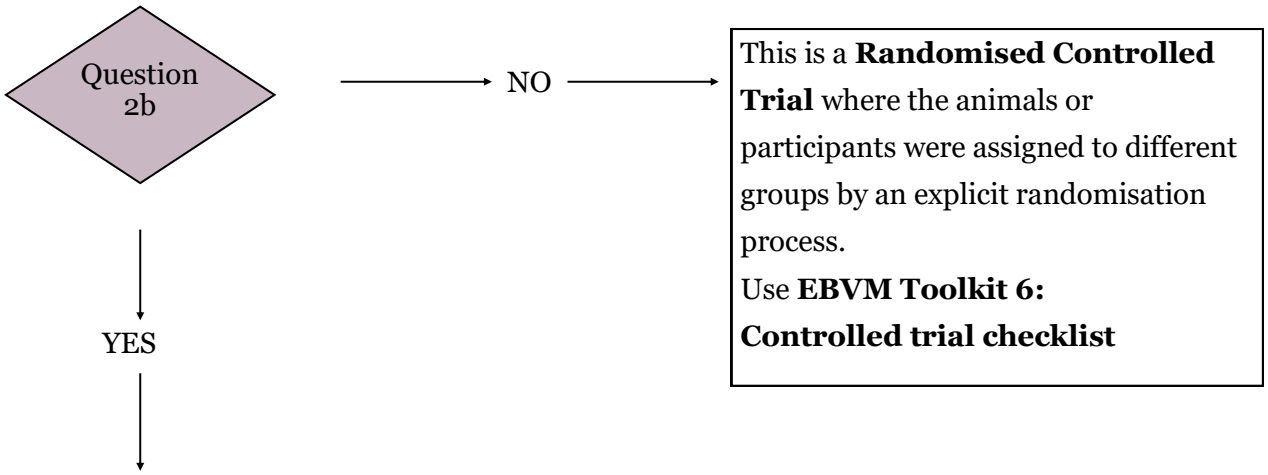
QUESTION 2a: . Is there a comparison or control between interventions?

This question divides studies into comparative and non-comparative (descriptive).



QUESTION 2b: . Were the interventions randomly allocated?

This question divides studies into randomised and non-randomised trials.



Tip:

The method of randomisation should be clearly described in the methodology (computer randomisation, etc).

If the study was not randomised think about whether this has led to bias in the results.

QUESTION 3: . Is the researcher looking for an association between variables by observing the situation, or the animals, without directly intervening?

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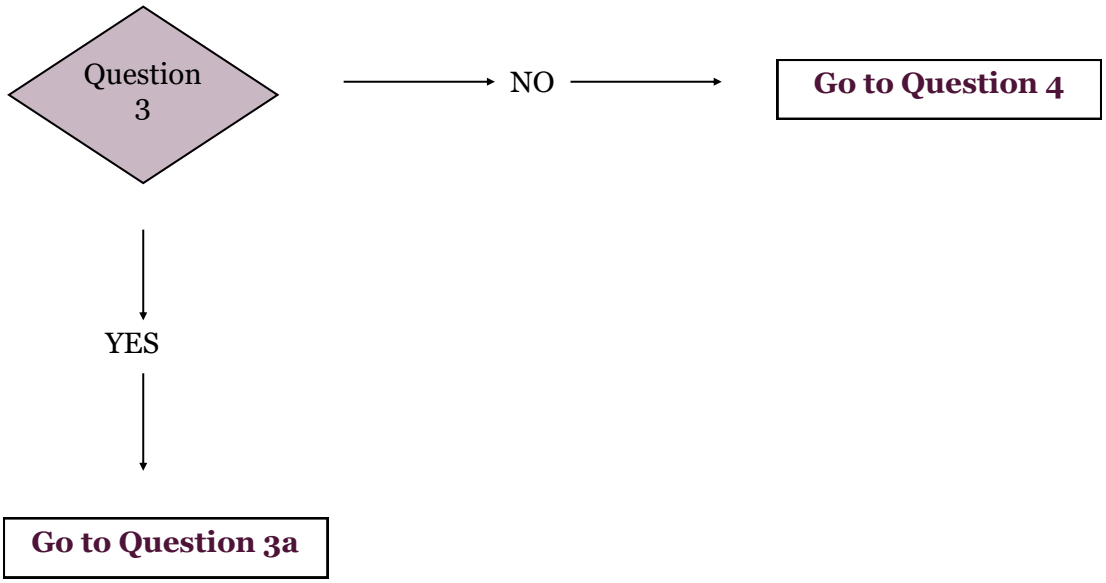
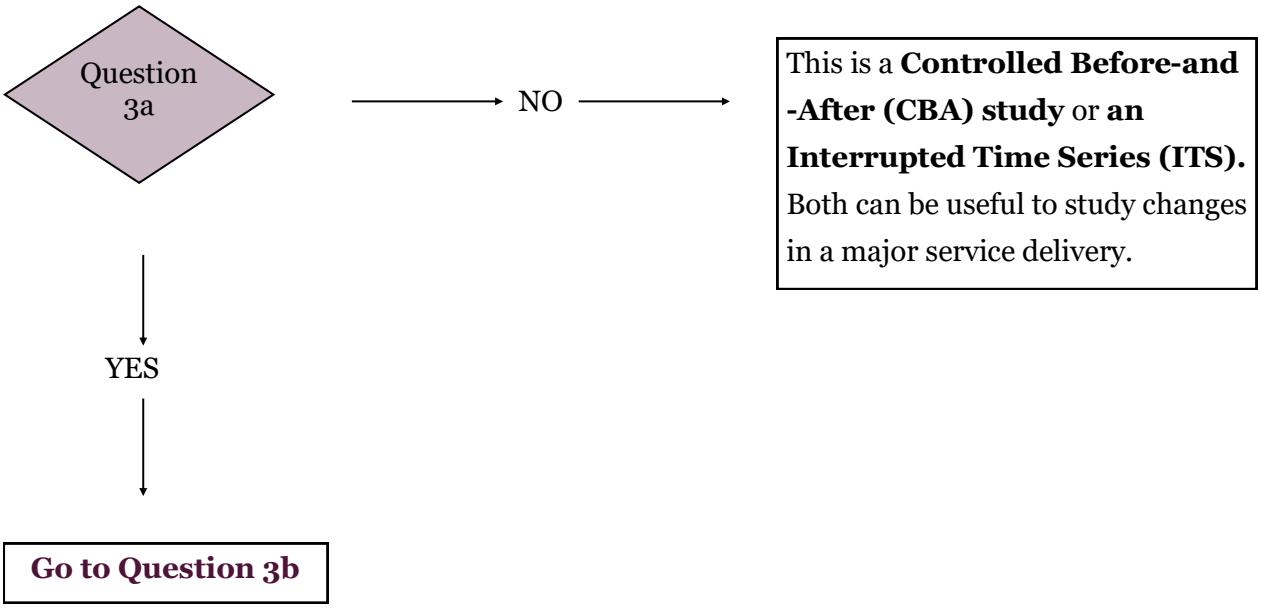
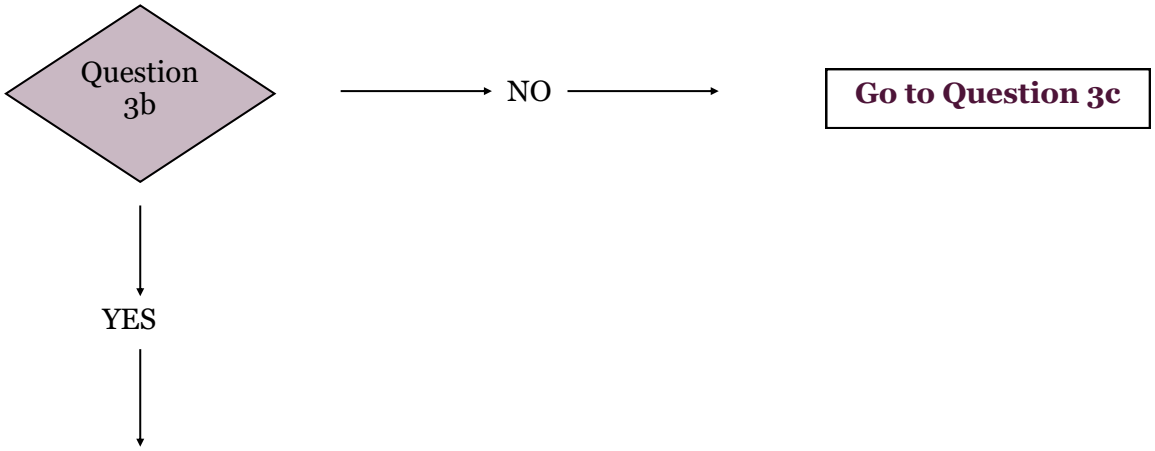


QUESTION 3a: . Is there a comparison or control between interventions?

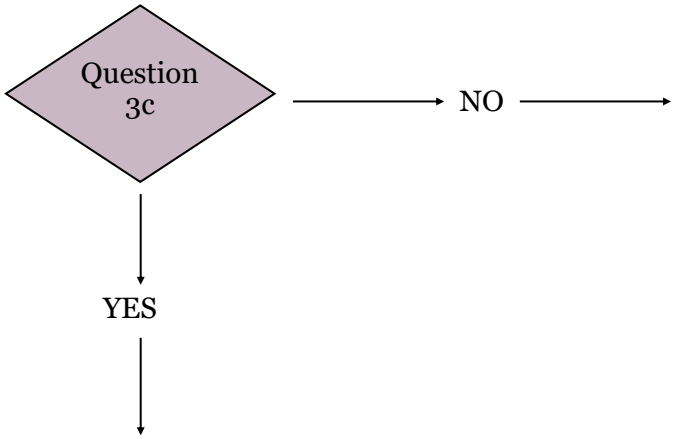


QUESTION 3b: Are exposure and outcome measured at the same time?



This is a **cross sectional study**. 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 **EBVM Toolkit 7: Cross sectional study checklist**

QUESTION 3c: Are the groups defined by outcome?



This is a Cohort study. 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 **EBVM Toolkit 9: Cohort study checklist**

This is a Case control study. This means that 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 (obesity). Use **EBVM Toolkit 8: Case control checklist**

QUESTION 4

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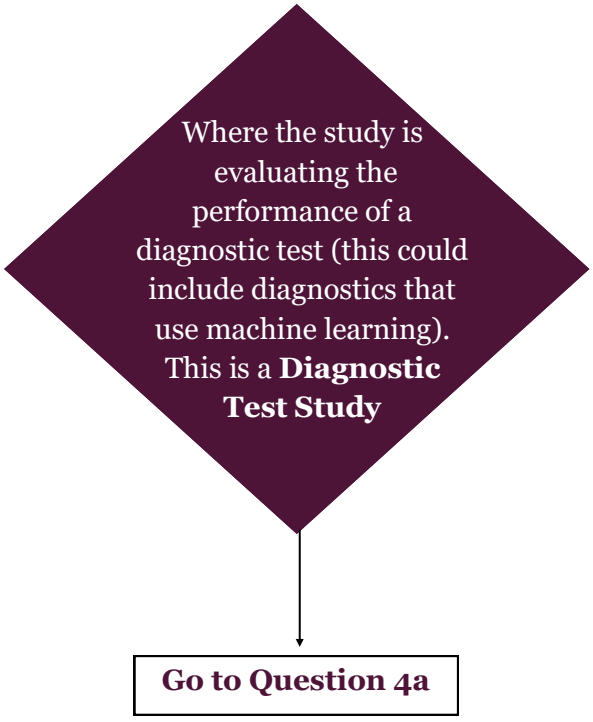
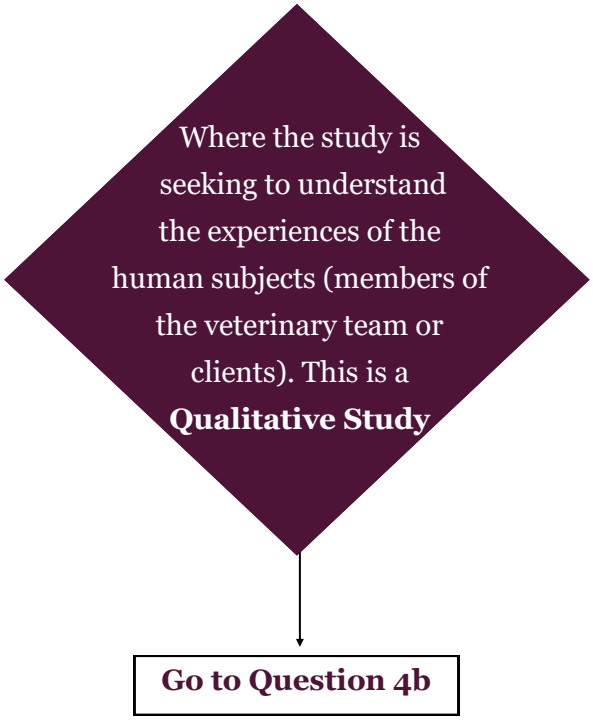
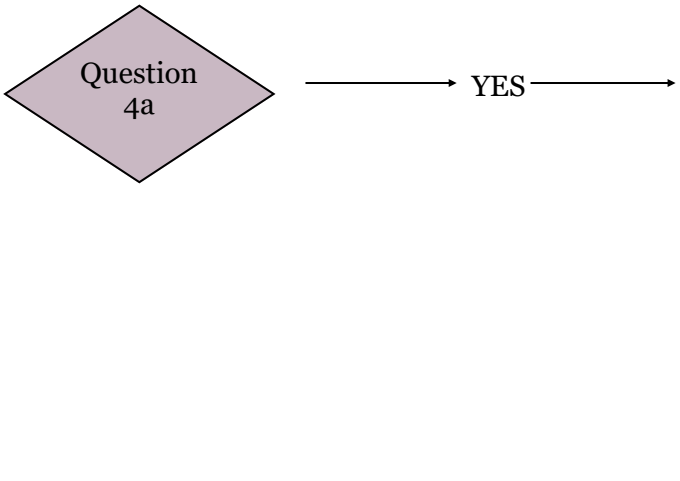
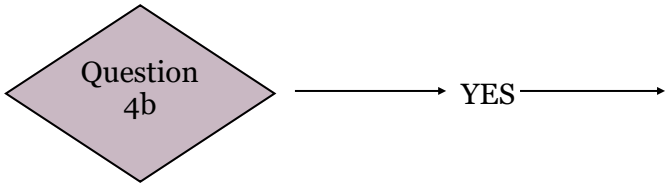




QUESTION 4a: Is the aim of the study to validate a test, tool or diagnostic method?

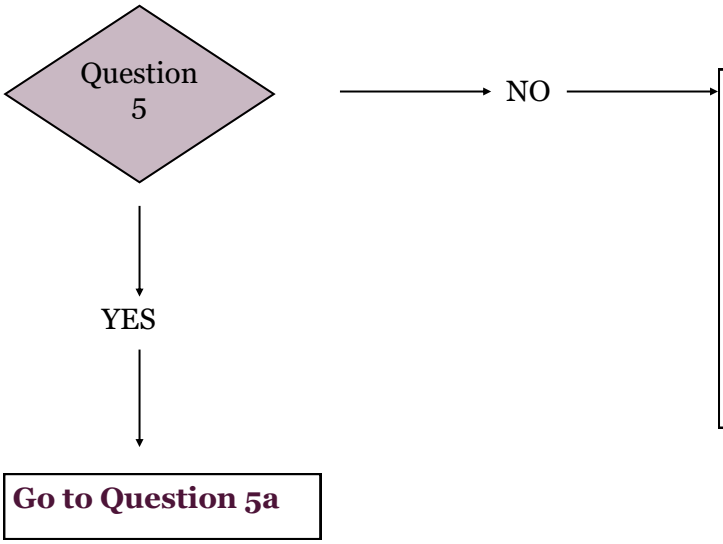


QUESTION 4b: Is the aim of the study to understand the experiences or perspective of human participants?



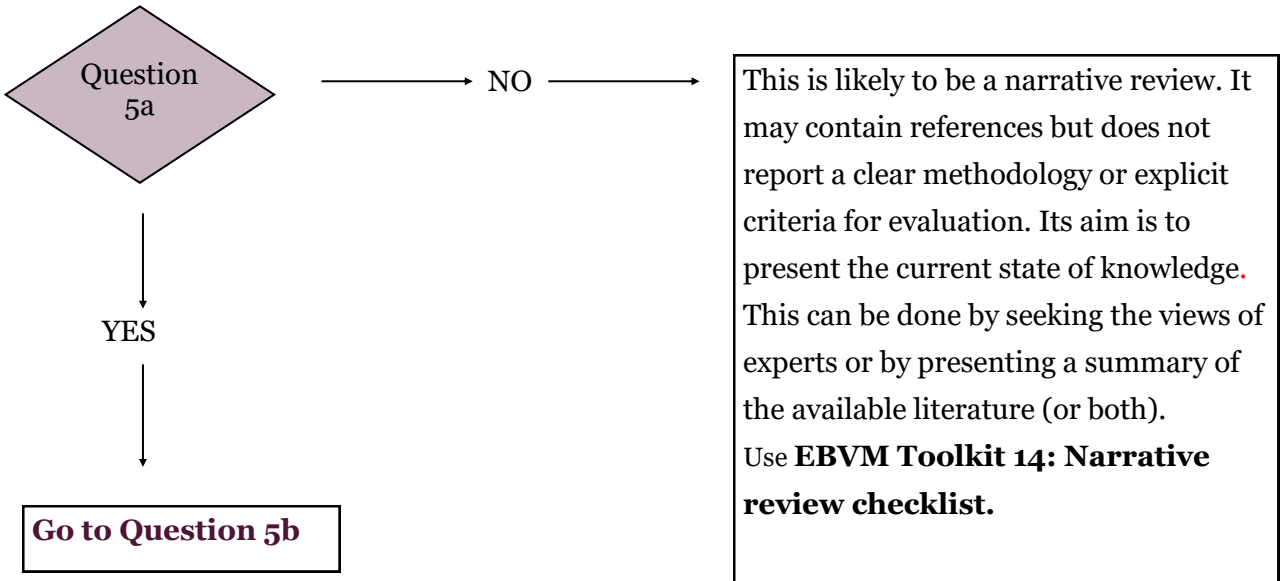
This is **qualitative study .**
Qualitative methods seek to understand the experiences of the human subjects involved. Studies using qualitative methods may be relevant to the delivery of veterinary care or the experience of caring for animals with certain conditions. They may involve veterinary professionals or owners as participants.
Use **EBVM Toolkit 11: Qualitative study checklist**

QUESTION 5: Does the paper analyse and report previously published studies?

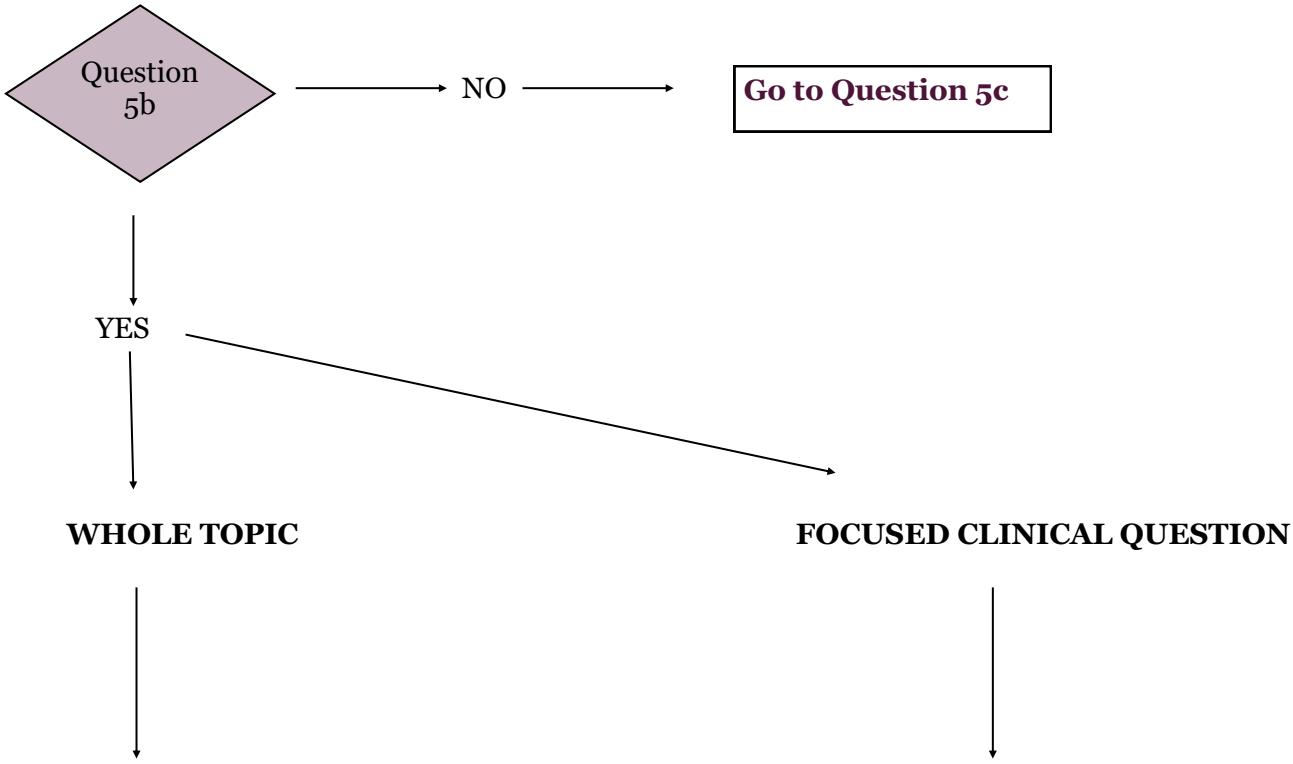


This is likely to be an **opinion article.**
The paper may contain a small number of references to substantiate the views of the author but has no explicit methodology. Opinion by definition is subject to bias – therefore an opinion article is the lowest level of evidence.

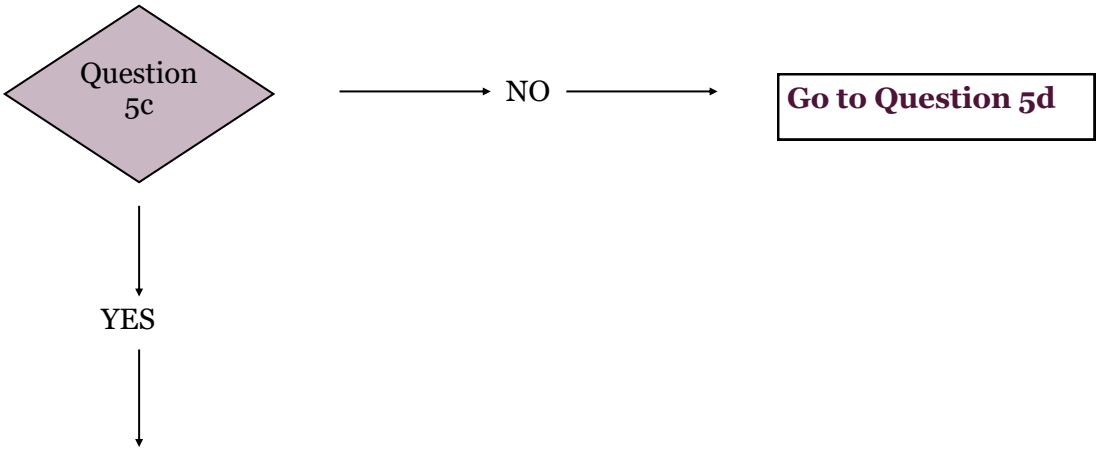
QUESTION 5a: Was there a comprehensive and explicit search of the literature?



QUESTION 5b: Does the paper provide a detailed and systematic appraisal of the literature relating to a whole topic or a focused clinical question?



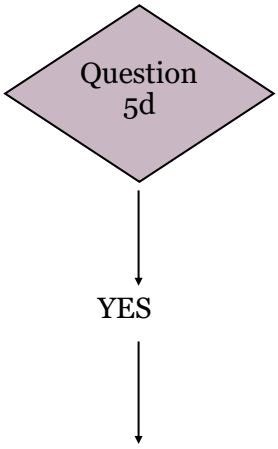
QUESTION 5c: Is the data from different papers combined statistically?



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**

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.

QUESTION 5d: . Does the paper provide explicit recommendations for the care of animals with a particular condition?



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Use EBVM Toolkit 15: Clinical guidelines checklist