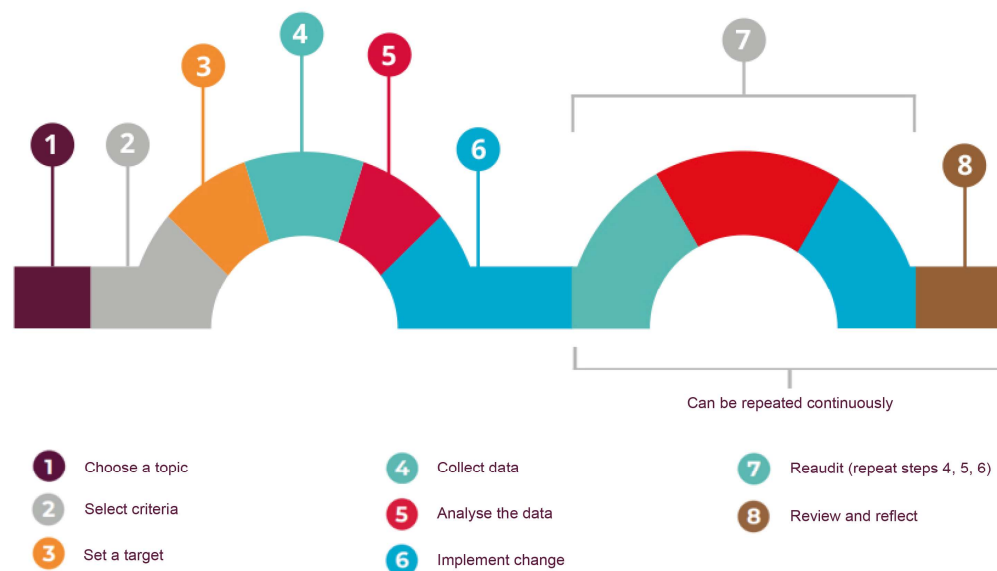


Clinical Audit – addressing ethical concerns

Introduction

Clinical Audit, at its simplest, is the process of collecting and analysing clinical information with the aim of monitoring and improving the quality of care. It is, therefore, important to remember that Clinical Audit carried out as part of Quality Improvement is not just about collecting data, it is also about implementing change to improve the quality of care through the completion of a full Clinical Audit Cycle.

The Veterinary Clinical Audit Cycle



The Veterinary Clinical Audit Cycle by RCVS Knowledge. Available from www.rcvsknowledge.org
Developed by the Royal College of General Practitioners www.rcgp.org.uk/qi-ready

It should also be remembered that Clinical Audit, as part of clinical governance, is a professional responsibility. It is, therefore, something that practices, and their clients, should expect to be carried out in order to improve the quality of care provided.

See [RCVS Code of Professional Conduct: Supporting guidance, section 6. Clinical governance](#) for more information.

Clinical Audits carried out in an individual practice for the purpose of Quality Improvement will not normally raise ethical issues or require formal ethics approval. However, because many aspects of veterinary practice have ethical implications and because the process of data collection in Clinical Audit may look similar to aspects of practice-based Clinical Veterinary Research, it is

important to understand the ethical issues that could arise in order to provide appropriate protection to practice team members, clients and their animals. Examples of different types of Clinical Audit and Clinical Veterinary Research can be found in the scenarios at the end of this document.

The purpose of this document is to highlight the ethical issues that may be encountered when undertaking a Clinical Audit and to indicate how these may be addressed.

Clinical Veterinary Research or Clinical Audit?

Clinical Veterinary Research and Clinical Audit share many similarities – they both start with a question; expect the answer to change or influence clinical practice; require data collection; and depend on using an appropriate method and design to reach sound conclusions (Wade 2005). However, while both Clinical Veterinary Research and Clinical Audit collect data about patients or veterinary services to improve the standards of veterinary practice and patient care, they each have a different intent and focus. Clinical Veterinary Research is about discovering the best or better way to do things, whereas Clinical Audit is designed to find out if you are doing something correctly or whether it can be improved in your practice.

For example:

- A piece of Clinical Veterinary Research may examine outcomes of a particular surgical technique **to establish a body of evidence**; for instance, to provide evidence as to whether it is effective or superior to another technique.
- A Clinical Audit looks at the same technique; however, its purpose is to measure surgical outcomes to identify **whether you can make any improvements to your technique or any local improvements can be made in your practice**.

Although they are different processes, audit and research are closely linked. Without research, we will not know what clinically effective practice is; without audit, we will not know whether it is being practised.

The table below shows some of the key differences between Clinical Veterinary Research and Clinical Audit.

Key differences between Clinical Veterinary Research and Clinical Audit
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Differentiation	Research	Clinical Audit
Definition	Attempts to create new knowledge regarding best practice	Creates knowledge of clinical practice and need for improvement
Aim	To generate or test hypotheses, identify or explore themes	To answer whether a service reaches a predetermined standard
Scope	Usually large scale, over a long time period, one-off/discrete study	Usually small scale, shorter time period, but an ongoing/cyclical process
Measures	Clearly defined research questions, aims and objectives	Current clinical practice against evidence-based clinical guidelines or standards
Interventions	May involve a completely new treatment or placebo	Choice remains that of clinician and patient
Routine care	May involve different treatments, samples or investigations	Does not affect normal treatment
Data collection	Usually involves collection of data additional to routine care	Usually involves analysis of existing data from patient notes
Randomisation	May use random sampling methods	Does not use randomisation
Allocation	May involve allocation of patients to intervention groups	No allocation to intervention
Statistical analyses	Often extensive	Often basic, descriptive
Replication	Results can be replicated	
Generalisability	Results need to be generalisable to a target population	Results are specific and local to one particular patient group
Next step	No mechanism to act on findings	Responsibility to act on findings via an action plan
Influence	Findings can have a wide influence on clinical practice	Findings usually only influence practice within the area evaluated

Ethical approval	Always requires ethical approval	Does not require ethical approval
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Extract from Table 1: Key differences between Clinical Veterinary Research and Clinical Audit: Wylie, C.E. (2015) Prospective, retrospective or clinical audit: A label that sticks, *Equine Veterinary Journal*, 47 (3), pp. 257-259.

Carrying out a Clinical Audit

A Clinical Audit is a step-by-step process in which you measure the level of care provided in your practice, make a change that will work in your practice, and measure the level of care provided to find out if that change has led to an improvement in your practice, either adapting the change, adopting the change or introducing a different change altogether. It is a cyclical process; changes and measurements could be repeated continuously.

When carrying out a Clinical Audit, evidence-based guidelines or standards should always be used when available, but when they are not, the first round of audit data can be used as a basis for improvement in the re-audit.

When undertaking a Clinical Audit, practices should not make a concurrent comparison between two different interventions, as that is likely to fall under Clinical Veterinary Research. It is also important not to make generalisations from Clinical Audit findings for direct application in other practice settings. However, publication of a Clinical Audit can inspire others to consider interventions that might be successful in their own setting. To find out more about Clinical Audit, you may like to complete the RCVS Knowledge's [Clinical Audit course](#).

Ethical considerations in Clinical Audit

Usually, Clinical Audits do not require formal ethics approval. However, in the same way that the purpose of ethics approval for Clinical Veterinary Research is to enable it to be conducted to the best standards and to protect practitioners, the public and the animals that they own, consideration of ethical implications involved in Clinical Audit can ensure that the audit is being conducted in a way that protects all those involved.

Issues you may need to consider:

1. If you collect data and find that there is a major or moderate shortfall in care, including if the results show that the practice is not meeting legal requirements – for example, in the storage of controlled drugs, there is an obligation for the practice to implement changes to lead to improvement.
2. Where there are significant or moderate shortfalls resulting from critical events, the practice should respond to these and implement steps to avoid undesirable outcomes in the future.
3. Any changes made during the Clinical Audit process should be based on the best available evidence and comply with legal requirements and the RCVS Code of Professional Conduct. Interventions that depart from Routine Veterinary Practice will likely require ethics approval before implementation.
4. The results of a Clinical Audit have the potential to lead to significant change in practice and may show differences between individuals. You should consider the impact that this may have on team members and how the issues raised will be handled.
5. If the practice intends to share or publish its audit, the results should be anonymised in such a way that identification of any person is not possible, or informed consent (from those who can be identified) should be in place.
6. If the practice intends to publish the results of an audit in a journal, it is advisable to check the requirements with the journal in advance and ascertain whether formal ethics approval will be required. Further information is available from:
 - [RCVS Advice & Guidance](#)
 - [RCVS Code of Professional Conduct: Supporting guidance, section 25. Routine veterinary practice and clinical veterinary research](#)

Evidence-based Clinical Audit

As the purpose of Clinical Audit is to improve the quality of care, it is key that any criteria and targets, as well as any changes made, are based on the best available evidence, as the implementation of an ineffective procedure may have ethical implications for the quality of care and the welfare of animals. A journal club can provide a useful way of structuring a discussion about published evidence. Where evidence-based guidelines or standards are unavailable, the first round of audit data can be used as a basis for improvement in the re-audit.

RCVS Knowledge has developed a range of resources to help you integrate evidence into your Clinical Audit:

- [Setting up and running a journal club in practice](#)
- [Journal clubs – suggested reading material](#)
- [Tools to assist with creating guidelines and links to published guidelines](#)
- [QI Boxset – Series 4: Guidelines](#)

Any changes made during the Clinical Audit process should be **based on the best available evidence and comply with legal requirements and the RCVS Code of Professional Conduct**.

Data collection and confidentiality

A Clinical Audit carried out in an individual practice for the purpose of Quality Improvement will not usually raise issues regarding confidentiality. However, where multi-centre audits are carried out or there is an intention to make findings public, there are potential ethical considerations that may need to be addressed.

Most Clinical Audits will only collect data relating to patient care, but if you are collecting data from or about the client, it is important to consider client confidentiality and comply with the requirements of the data protection regulations (see [Information Commissioner's Office Guide to Data Protection](#)).

For example, if your Clinical Audit involves a client survey or questionnaire regarding some aspect of your service, will the client be able to complete this anonymously or will there be a way that they could be identified? Note, that even pseudonymisation is not truly anonymous, as it is linked to a person and someone with the linkage can de-anonymise it.

It is important to remember that identification does not just refer to names and addresses, but to any information that would enable an individual to be identified – for example, a job description for a team member; patient details, if it is a rare breed or case that is recognisable; or, a postcode.

If you intend to share or publish the results of your Clinical Audit, it is very important to ensure that individuals (be they team members or clients) cannot be identified unless they have given informed consent for this to happen. If you are contributing to a multi-centre audit, surgical registry, medical registry or benchmarking exercise, issues of confidentiality can usually be

managed by anonymisation of the data before submission. If any personal information of a client is to be shared with a registry, client consent should be sought, and measures should be taken to ensure that the registry has appropriate measures in place to comply with data protection regulations. For further information, see the following sections of the supporting guidance to the RCVS Code to Professional Conduct:

- [Section 11. Communication and consent](#)
- [Section 13. Clinical and client records](#)
- [Section 14. Client confidentiality](#)

Responding to critical events

If during the process of collecting data any shortfalls in care are identified, including a ‘near miss’ or ‘critical event’, there may be ethical implications in continuing to follow procedures that fail to meet expectations for accepted better practice. The practice should consider reporting the incident through [VetSafe](#), and should undertake a **Significant Event Audit** to put steps in place to improve systems and avoid undesirable outcomes in the future.

Implementing change

Once data has been collected, it should be analysed, and consideration should be given as to how to respond to the findings. While there are few ethical problems with trying to improve performance, there may be ethical implications for continuing to follow procedures that fail to meet expectations for a better practice.

While the aim of Clinical Audit is to improve quality of care, it is important to be aware that veterinary surgeons and veterinary nurses have a professional obligation to offer the client a reasonable range of treatment options as part of the process of obtaining informed consent. There may be cases where it is not possible to follow guidelines because of client or patient circumstances, and in the interests of animal welfare, clinical staff may need to exercise professional judgement in providing care to an individual animal. Further information on informed consent is available in the [RCVS Code of Professional Conduct: Supporting guidance: Section 11. Communication and consent](#).

Impact of results on team members

In most cases, people are more willing to adopt changes in working practices if they have been involved in discussions at the planning stage. There is an ethical consideration for practices to inform all team members of any audits that are being conducted that collect data about them.

It is important to emphasise that the purpose of a Clinical Audit or a Significant Event Audit is to improve systems and not to blame individuals; however, in the same way that there are ethical implications for practices, there are ethical implications for individuals who continue to provide care that fails to meet expectations for accepted better practice. Practices should consider what support and training is needed to enable improvements to be made. This should be made available to the whole team rather than targeting individuals.

Novel procedures

If you are considering introducing a new procedure or any intervention on an animal that departs from Recognised, now Routine, Veterinary Practice, you should consider whether this may require formal ethics approval.

The [RCVS provides guidance to clarify the difference between Routine Veterinary Practice \(RVP\) and Clinical Veterinary Research \(CVR\)](#). It notes that this guidance will be useful:

for veterinary surgeons proposing to use new procedures or treatments in individual clinical cases, as these cases will often be at the boundary between what is RVP and what is CVR (25.4)

It further notes that:

what is regarded as routine in relation to a specific veterinary clinician, clinical setting, patient, species or condition at one point in time, may not be regarded as ethically acceptable, nor constitute, routine veterinary practice if carried out by a different veterinary clinician in a different clinical setting, in relation to a different patient, species or condition, and/or at a different point in time. (25.9)

For further information in relation to Routine Veterinary Practice and/or Clinical Veterinary Research, or advice on whether a particular proposed procedure would be covered by this

guidance, please contact the Secretary to the Routine Veterinary Practice Sub-Committee via advice@rcvs.org.uk

Publishing your results

Publication of your Clinical Audit can enable others to benefit from your experience. However, while the publication of Clinical Audits can be informative and demonstrate Quality Improvement, it is important to remember that the results are not generalisable, and there may be many reasons why processes and outcomes differ between practices.

We recommend that any published Clinical Audits are clearly labelled as such and should report a complete Audit Cycle.

If you are hoping to publish your Clinical Audit, we recommend that you contact the journal concerned at an early stage to check their author guidelines and any requirements regarding ethics approval.

Conclusion

The purpose of this document is to highlight the ethical issues that may arise when undertaking Clinical Audit in order to provide appropriate protection to practice staff, clients and their animals. Before you begin, ensure that you have considered the issues raised in this document and that you understand the differences between Clinical Audit and Clinical Veterinary Research. You may find the checklist in the ‘additional resources’ section helpful.

If you are still unsure whether your project is a Clinical Audit or Clinical Veterinary Research, you may wish to refer to the [RCVS Guidance on Clinical Veterinary Research](#), read the report of the [RCVS/BVA Working Party on Ethical Review for Practice-based Research](#) or consult the [RCVS Ethics Review Panel](#).

If you are intending to publish your Clinical Audit, we recommend that you contact appropriate journals for details of their author guidelines and requirements regarding ethics approval. Individuals should not try to avoid the research ethics review process by designating a project as a Clinical Audit rather than as Clinical Veterinary Research.

Additional resources

Scenarios

Scenario 1 – Clinical Audit of blood pressure measurement in cats with chronic kidney disease (CKD)

Following a journal club meeting looking at the evidence on the management of chronic kidney disease (CKD) in cats, the practice team members discuss whether blood pressure is measured in these cases in the practice. They think it may not be happening as part of the initial assessment as recommended in the International Society of Feline Medicine (ISFM) consensus guidelines on the diagnosis and management of feline CKD.

They decide to carry out a retrospective Clinical Audit, looking back through the clinical records of all cats with a new CKD diagnosis made in the past six months to see whether they had a blood pressure measurement taken within this time frame.

Once the team members have these results – which demonstrate a very low frequency of blood pressure measurement in this group, and that there is variation between vets – they are discussed at a team meeting. Barriers to the procedure being carried out are discussed by the whole team and include lack of team training, lack of time, owner reluctance and insufficient blood pressure monitoring equipment. As a result of the meeting all team members receive training, no individuals are singled out.

Following training, a new practice guideline is implemented based on the published guideline that blood pressure should be measured on initial assessment and owners should be educated on the reasons for this. A new blood pressure monitor is purchased and training conducted on its use. The audit is repeated using exactly the same criteria to assess whether the rate of blood pressure measurement in cats diagnosed with CKD has increased.

This is a simple in-house Clinical Audit and requires no ethics approval; however, any differences between individuals should be handled fairly by allowing the whole team to participate in training, without singling out individuals.

References

Sparkes, A.H., et al. (2016) ISFM consensus guidelines on the diagnosis and management of feline chronic kidney disease. *Journal of Feline Medicine and Surgery*, 18 (3), pp. 219-239.
<https://doi.org/10.1177/1098612X16631234>

Scenario 2 – Contributing to a national audit or registry

You have read about the RCVS Knowledge National Audit for Small Animal Neutering and would like to collect and submit data to compare your outcomes with the national benchmark.

You work in a practice that has four other branches and you want to collect data from them all to compare each practice against the national benchmark. The audit spreadsheet has a section for patient ID, the procedure and the post-operative outcome. You collect data from each practice on the same spreadsheet, adding in columns so that you know which practice patients have been seen at and which veterinary surgeon they were seen by. To prevent duplicating data, you use the patient name and the breed as ID.

You make a copy of this spreadsheet, and before submitting the results to the National Benchmark, you delete all identifiable data, including practice and veterinary surgeon names, and patient and breed details.

Collecting, submitting and comparing this data with the national benchmarks does not require ethics approval; however, ethical implications could arise:

- The collection of data should be open; all team members who are affected by the audit should be made aware that data is being collected and stored for auditing purposes, not to identify individual performance.
- If clients can be identified from the data that you are submitting, then client permission should be sought before the data is collected.
- You should password protect the data to secure it further or ensure that it is saved on a safe drive.
- If the data collection reveals a shortfall in care compared to the benchmark, you are obliged to implement changes to improve care. This must be approached carefully to ensure no negative impact on the team. Careful discussions can be had to identify the root cause of this increased complication rate, and evidence-based processes put in place to support the team and patient care.

If you are contributing to a multi-centre audit, surgical registry or benchmarking exercise, issues of confidentiality can usually be managed by anonymisation of the data before submission. If any client information is to be shared with the registry, client consent should be sought and measures should be taken to ensure that the registry has appropriate measures in place to comply with data protection regulations.

References

National Audit for Small Animal Neutering [RCVS Knowledge] [online] Available from: www.rcvsknowledge.org/nasan/ [Accessed 10 February 2023]

Scenario 3 – Comparing medications

At a practice meeting the team discusses the fact that some team members think routine canine neutering surgeries are not as comfortable and pain free as they would expect them to be on recovery. One of the veterinary surgeons suggests that the practice should be using methadone as a pre-medication instead of buprenorphine. The practice principal is not convinced.

You decide that for the next month, half the canine routine surgeries will have buprenorphine and the other half methadone. The pre-medication will be randomly assigned to the two groups. All canine routine neutering patients will be pain scored at intervals throughout recovery. The two groups' results will be compared and then a decision will be made regarding which pre-medication all practices in the group will use going forward.

Although the aim behind this is about implementing change and improving the quality of care, this example counts as Clinical Veterinary Research rather than Clinical Audit as it makes a concurrent comparison between two different interventions. It would require formal ethics approval and informed client consent relating to the allocation of the pre-medication.

If, however, you decide to pain score all canine neutering operations while using your standard buprenorphine pre-medication, then audit the pain scores, hold a practice meeting, discuss the results that were not very good, look at the available evidence and as a result decide to change the pre-medication, this would be the first part of the Clinical Audit Cycle.

This should be followed by a re-audit using the same pain scoring intervals with the new pre-medication and see whether the results have improved by adopting this for the practice where the audit was conducted. This is a Clinical Audit and should not require ethics approval.

Do not forget that results of Clinical Audits are applicable only to the practice where they are carried out. It is important not to make generalisations from Clinical Audit findings for direct application in other practice settings.

Scenario 4 – Introducing a novel procedure

You have read about a procedure used in human medicine that is providing excellent results and you think that it may be useful in treating your veterinary patients. You decide that you will try it in a small number of cases and see how the results compare with your current, conventional treatment. If successful, you hope to be able to publish the results.

Although this is about implementing change and improving the quality of care, this example counts as Clinical Veterinary Research rather than Clinical Audit as it is about developing new knowledge. As the procedure is not yet an established procedure in veterinary practice it will not necessarily count as Routine Veterinary Practice (formerly ‘recognised veterinary practice’). Depending on the evidence base available to support the use of the procedure and the expertise of the veterinary surgeon, the procedure may be able to be carried out as Clinical Veterinary Research or may require a licence under the Animals (Scientific Procedures) Act (ASPA).

It will require ethics approval, an explicit harm/benefit analysis to be carried out and consent from the owner that acknowledges the novel nature of the procedure and the potential risks.

The following provide further information:

- See [RCVS Code of Professional Conduct: Supporting guidance, section 25. Routine veterinary practice and clinical veterinary research](#) for more information to help establish whether a proposed procedure, series of procedures or study is Routine Veterinary Practice, clinical veterinary research or whether, alternatively, it should be regulated under the Animals (Scientific Procedures) Act 1986 (ASPA).
- There is also a series of [frequently asked questions](#) on Routine Veterinary Practice and Clinical Veterinary Research covering the development of novel procedures, use of medicines under the Cascade and informed consent.

The following publications may also be of interest to anyone considering undertaking novel procedures:

- Yeates, J.W. (2016) Ethical principles for novel therapies in veterinary practice. *Journal of Small Animal Practice*, 57 (2), pp. 67-73. <https://doi.org/10.1111/jsap.12402>
- Yeates, J., et al. (2013) Ethical and evidential considerations on the use of novel therapies in veterinary practice. *Journal of Small Animal Practice*, 54 (3), pp. 119-123. <https://doi.org/10.1111/jsap.12031>

- Grimm, H., et al. (2018) Drawing the line in clinical treatment of companion animals: recommendations from an ethics working party. *Veterinary Record*, 182 (23), p. 664.
<https://doi.org/10.1136/vr.104559>

Clinical Audit ethics checklist

Do I need to apply for ethics approval?

Are you sure your project is a Clinical Audit (as opposed to Clinical Veterinary Research)	Yes	Not sure	No
Is all activity within the scope of Routine Veterinary Practice	Yes	Not sure	No
If you are intending to publish your clinical audit, have you contacted journals for details of their author guidelines and requirements regarding ethics approval?	Yes	Not sure	No

If you can answer ‘yes’ to all these questions, you are ready to go ahead with your audit.

If you are ‘not sure’ whether your project is a Clinical Audit or Clinical Veterinary Research you may wish to refer to the [RCVS Guidance on Clinical Veterinary Research](#), read the report of the [RCVS/BVA Working Party on Ethical Review for Practice-based Research](#) or consult the [RCVS Ethics Review Panel](#). Individuals should not try to avoid the research ethics review process by designating a project as a Clinical Audit rather than as Clinical Veterinary Research.

If you have selected ‘no’ as an answer, you should consider the need to apply for ethics approval before carrying out your project.

Other areas to consider:

- ☐ Does the practice have a culture where problems and shortfalls in care can be discussed?
- ☐ Does the practice have a system to ensure that the criteria and targets set for a Clinical Audit are based on best available evidence?
- ☐ Will you be collecting any client data? If so, are systems in place to obtain consent, and/or maintain confidentiality and anonymity?
- ☐ Does the practice have a system in place to improve on major or moderate shortfalls in care?
- ☐ Does the practice have a system of undertaking Significant Event Audits to respond to critical incidents or ‘near misses’?
- ☐ Does the practice have a system to implement changes based on the findings of their Clinical Audit?

- ☐ Does the practice have a process in place to ensure that any changes made during the process of Clinical Audit will be based on the best available evidence and comply with legal requirements and the RCVS Code of Professional Conduct?
- ☐ If you intend to publish your results, have you secured permission from any individuals (staff or clients) to make their information public, or can all identifying information be removed?

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