Ethics approval for Clinical Audit

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, as the process of data collection in Clinical Audit may look similar to certain types of practice-based Clinical Veterinary Research, it is important to understand the differences so that ethics approval is obtained where appropriate.

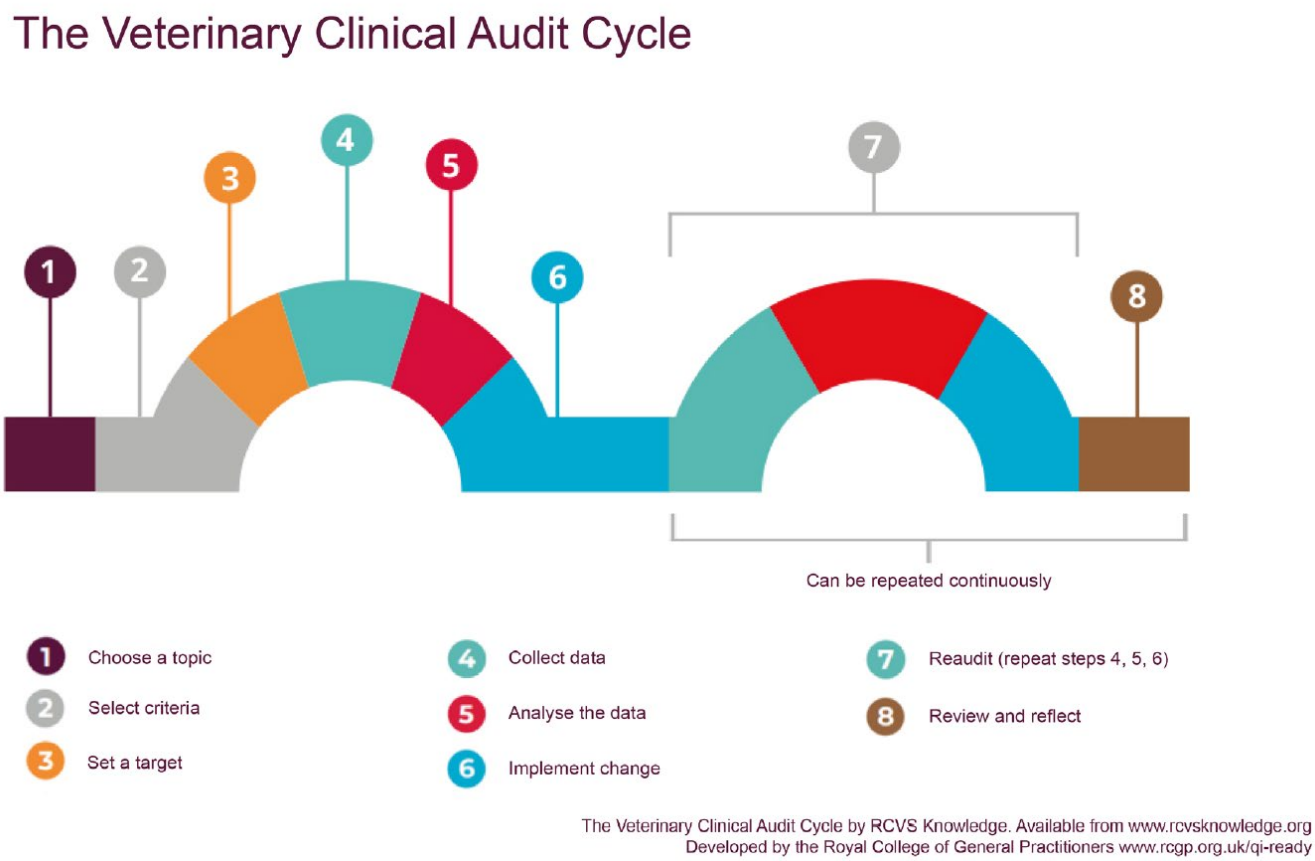
Further details of the distinction between Clinical Audit and Clinical Veterinary Research and discussion of the ethical concerns that can arise in undertaking a Clinical Audit can be found in the document produced by RCVS Knowledge Clinical Audit – addressing ethical concerns - RCVS Knowledge , which includes the following table .

Key differences between Clinical Veterinary Research and Clinical Audit		
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 method	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

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.

Where there is an intention to publish a Clinical Audit, it is recommended that the author contact the journal concerned at an early stage to check their author guidelines and any requirements regarding ethics approval.

It is recommended that any published Clinical Audits are clearly labelled as such and should report a complete Audit Cycle:



Questions to ask when considering ethics approval for a Clinical Audit

Outline of the proposed study

Aim and Objectives: The aims and objectives of a Clinical Audit are to improve the quality of care delivered in practice, and specifically about measuring the improvement in the quality of care following some change in delivery. It is not about generating new knowledge about a treatment or procedure, that is research. The aim should describe the topic that the Clinical Audit will focus on and what it seeks to achieve i.e., why the Clinical Audit is being undertaken; the objectives describe what is going to be measured to show whether the aim has been met.

Background: The background should describe what aspects of practice the applicant is hoping to improve, what criteria and target/standards have been selected against which to judge performance, as well as the target for improvement. This section should provide the rationale for topic selection and include background literature or other evidence to support the criteria and standards that have been selected, and any changes in delivery of care that is being proposed.

Methods: This section should cover what data will be collected and analysed to assess the current standard of care, what changes will be put in place, and how improvements in the quality of care will be assessed against the criteria and targets set. If there are to be any inclusion and exclusion criteria, they should be described here.
The timings for the initial data collection, implementation of change and re-audit should be included. This section should include enough detail to allow anyone performing the same audit to use the same approach and methodology.

Data analysis: This section should describe how the data will be analysed, before and after the changes are implemented. If the initial audit data has already been carried out a brief summary of the findings could be included here.

Results: How will the results be disseminated and acted upon?

Outputs: What outputs are expected from the Clinical Audit and how will they be disseminated?

Human participants and implementation of change

As with clinical research, the impact on human participants should be considered.

- How will team members be informed about the process of Clinical Audit and proposed changes in practice?
- What information will team members be given about the Clinical Audit? Where documentation is being provided to staff, copies should be attached to the application.
- Will individual staff be identifiable from the data collection or analysis, if so, what steps will be taken to protect their anonymity?
- How will the results ne disseminated?
- What training will be given to team members to support the implement of change?
- If any serious shortfalls in care come to light during the Clinical Audit, how will these be dealt with?

Data Protection

Will any personal data (from clients or team members) be collected as part of the Clinical Audit? If so, what measures are in place regarding informed consent and data protection.

If this a multicentre audit, what measures are in place to protect practice and individual confidentiality e.g. anonymisation of data.