

Clinical Veterinary Research

Its importance and

Some practical implications

David B. Morton

Valuable contributions can be made from practice-based research?

What is their added value?

Industry/VMD - Drug development ATCs

GPs have enormous experience of:

- breadth and depth of clinical cases and environments often not available in research settings
- awareness of practical knowledge gaps
- animal owner involvement and farm environments

LEGAL BITS

EU Dir 2010/63/EU Exemptions

Non-Experimental Clinical Veterinary Practices (CVR)

(NB 'Experimental' usually applies to research on normal animals and not those that are usually clinically ill - pets, farmed, owned)

Procedures and techniques performed on animals by veterinary surgeons (or RVNs under direction) in the course of their professional daily duties, **which ensure the health and welfare of animals committed to their care.**

IN UK All projects must be reviewed by RCVS and undergo Ethics Review

APPLIES to projects involving (possibly) SENTIENT ANIMALS

(i.e. vertebrates and invertebrates) (unlike ASPA)

OTHER ASPA (EU Dir) Exemptions (Animals (Scientific Procedures) Act) (Not clear who approves these!)

Non-Experimental Agricultural Practices

Animal Identification

Practices involving recognised animal husbandry

Other ASPA (EU Dir) Exemptions

Veterinary clinical trials required for veterinary medicinal products making that claim (ATCS)

Practices not likely to cause pain, suffering, distress or lasting harm

WHAT IS RVP?

- Doing something that is in the ordinary course of clinical diagnosis or treatment?
- Must be an intention to benefit the individual animals used.
- CVR examples:
 - Comparing two existing procedures
 - Developing a new treatment or diagnostic procedure

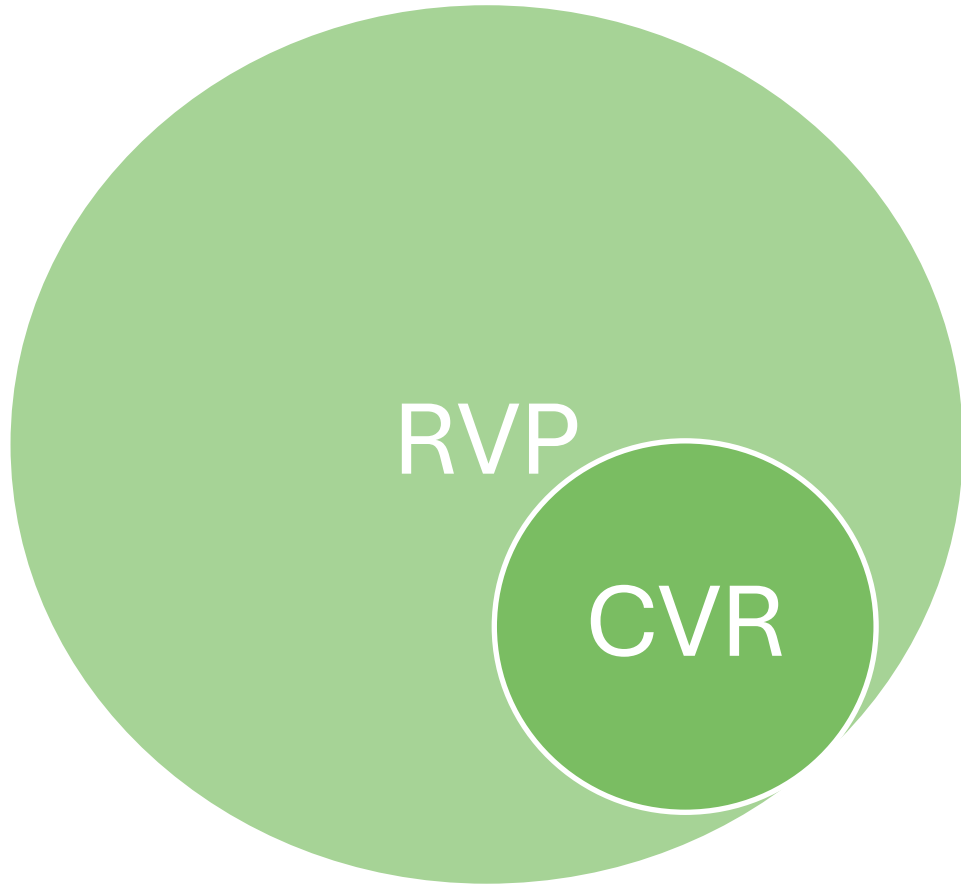
When is it Routine Vet Pract, or Clinical Vet Res, or EXP-RES?

RVP: Established treatment (etc) for an entirely therapeutic or diagnostic reason = RVP but not CVR

CVR: Where the procedure is being carried out for the primary purpose of developing new knowledge, and is still necessary for diagnosis or treatment of that animal BUT possible also to improve diagnosis or treatment of other animals

EXP_RES: Where treatment is not necessary and may cause harm

Clinical veterinary research 'CVR'



HARM:BENEFIT ASSESSMENT has to be carried out by EC

- Is it likely to be of direct benefit to other animals?

If well-defined then is RVP.

- Examples:
 - To make a diagnosis
 - To monitor efficacy of a treatment
 - To assist management e.g. farm, disease status), breeding, genomics
- Include use of excess tissues (surplus + clinical waste), biobanks

Assessment of potential benefits when treatment not been used before?

- Must reasonably be expected to result in a similar or better outcome than that following conventional treatment (equipoise)
- Must be sufficient background knowledge, or judgement with **a sound evidential** basis.
- NOT acceptable to use an animal in development of new/improved procedure without any evidence of benefit.

CATEGORISATION OF HARMS

Adverse effects in subject animals and sometimes those in contact, may be physical (pain), psychological (behaviour, mental health) or physiological (homeostasis)

- Avoidable harm when carrying out procedures
- Necessary harm – acceptable **purpose** with least harm
- Least harm - no avoidable or unnecessary harm caused

- **Minimal harm – the lowest level of harm that must not be exceeded taking given a necessary, LEGAL, and justifiable purpose.**

PRACTICAL BITS

ETHICS REVIEW KEY CRITERIA

Science: project design and integrity (EBVM)

Animals: avoidance and minimising harms (benefits

Human: owner/keeper consent, confidentiality, privacy, H&S

Legal: compliance data protection (GDPR), AWA, Animal Sentience, H&S

Humans as participants (MRCVSs, RVNs, on-line surveys, (and clinical audits with an intent to publish)

VMD-ATC: restricted to 'claims of medicinal product, blinding and randomisation (CONTROLS: placebos, nocebos (in animals?)).

Legal compliance covered **but not ethics**

Publication requirements

AIM TO PROVIDE SOUND EVIDENCE BASED VETERINARY CLINICAL MEDICINE

GOOD SCIENCE: requires more than RVP to ensure that
DATA are ROBUST, RELIABLE, REPRODUCIBLE, and
PUBLISHABLE

Important to MAXIMISE ANIMAL WELFARE LONG TERM as
FUTURE ANIMAL WELFARE MAY BE JEOPARDISED IF DATA
UNSOUND

RETROSPECTIVE REVIEWS e.g., CLINICAL RECORDS

Competence & setting

- If you have not undertaken this before:
 - Do you have the skills/qualifications/competence?
 - Are the clinical facilities adequate? E.g., availability of diagnostic and surgical equipment, **aftercare**
 - Is there support available in case of an emergency, or proper support for the recovery period in practice?

TENSION BETWEEN ROUTINE PRACTICE AND ROBUST SCIENCE

- Evidence needed to show it is not by chance
- Monitoring and measuring rate of reaction, healing after orthopaedic surgery (repeated imaging) repeat sampling (bloods, biopsies)
- **CONTROLS** always need justification eg Placebo treatments (VMD), current therapy
- INDIVIDUAL WELFARE VS GROUP (sentinel animals)

NB OVERARCHING PRINCIPLE IS TO CAUSE LEAST HARM FOR A GIVEN ACCEPTABLE OBJECTIVE

Taking samples: official purposes

- If for public health you need explicit government involvement or direction
- Forensic samples of live animals for investigation of disease or neglect are permissible.

How to apply for ethics review

Complete Application Form (accompanying guidance notes on form and separately)

Need to be an MRCVS/RVN

Identify PI and deputies (single and **multicentre** projects, UK and abroad)

Lay language

Abstract and Summary

Animals/subjects, selection, signalment, etc

Methodology

Harms and Benefits

Consent : Farmer, owner, keeper

DPA/GDPR compliance, publication, videos, photos, records

Import/Export personal data (and samples)

Further info

- Chapter 25 & FAQs
- RCVS RVP subcommittee: advice@rcvs.org.uk
- RCVS Ethics Review Panel: ethics@rcvs.org.uk
- Home Office: ASPA.London@homeoffice.gov.uk
- VMD: postmaster@vmd.gov.uk

THANK YOU AND ANY QUESTIONS

- Happy to advise on some of the ethical issues in applications
- dbmgm2@gmail.com

Non-Experimental Clinical Veterinary Practices – (CVR) advancing clinical knowledge (for benefit) for ‘sick’ animals

RCVS Ethics Review Panel set up for GPs in 2016 (i.e. those with no access to an institutional EC); Deals with around 150app/year, mainly SA + horses+farm and all other vertebrates and invertebrates (AWAct 2006)

NB: Penalty for Non-compliance is potential removal from Register
(cf ASPA Licence withdrawal, fine, jail)

AVEC

AVEC set up to try to harmonise decisions, raise standards, provide education/training

Quarterly meetings with speakers

TRAINING EC members (courses, materials, other resources)

GUIDANCE (use in education, consent, multicentre projects, data protection, funding)

MEETINGS (speakers, debate, clinical cases: (e.g. JPS/JH and VMD; overlap ASPA, “black holes”)

DISCUSSION (Chat forum)

- **WEBSITE** in progress

ESTABLISHING AVEC

WHERE ARE WE NOW?

- **MEMBERSHIP**

- Representatives from all established UK vet schools which form the current executive group (~15 persons)
- Applications being sought for individual membership

- **PROJECTS**

- Training courses and options for delivery
- Adapt/Adopt current Guidance document (mainly RCVS)

- **WEBSITE**

Just starting with help of BSAVA

- **RCVS (may involve AVEC?)**

- Considering how to implement their responsibilities e.g. Approve ECs?
- Adopt harmonised criteria and standards for consistency