



Session 3.5

Ethical review – good practice and outputs

Lecture

Moral issues of animals, alternatives and public policy

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In the New Zealand national animal welfare infrastructure, the National Animal Ethics Advisory Committee (NAEAC), the National Animal Welfare Advisory Committee (NAWAC) and the Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART NZ) all play important and discrete roles in ensuring that the government of the day received independent, broadly-based advice regarding the use of animals in science, in agriculture and for other purposes.

This paper covers the following:

- The genesis of NZ AEC/NAEAC system, including role of scientific community, Government, NGOs etc. with reference also to NAWAC and ACCART/ANZCCART.
- The legal status of committees, evolution of statutory role and importance of independent advice.
- Committee membership balance and succession and importance of consensus decision-making and leadership.
- The importance of formal management of committee activities, including strategic and operational planning and performance review including external feedback.
- The importance of monitoring international developments and building international networks, including reference to CCAC, ICLAS, AALAS and the nascent role of the OIE.
- The importance of policy, legal and ethical development re-use of animals in research, testing and teaching to use of animals in agriculture, and other areas, and *vice versa*.
- The NAEAC role in relation to independent monitoring of AECs and code holders.



Lecture

Documents and guidelines to help scientists provide material suitable for ethical review

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Scientists skilled at presenting results for publication and research proposals for peer group review by grant-awarding bodies often have difficulty with the different approach needed when presenting proposed work for ethical review or public scrutiny. Dialogue with researchers in the UK has provided some principles for documents and guidance that should help scientists in bringing out the points useful for ethical analysis and in developing a style for presenting the work to the lay reader.

Key elements in the documentation are:

1. a clear and logical layout that follows through from the intention of the work, to the plan for carrying it out and the exper-

imental design principles to be followed, to the animal use itself, with a separate section on the costs to the animals and how these would be minimised.

2. prompts that scientists can readily understand for the main issues to be covered in ethical analysis.
3. easily-accessed notes and examples.

With help from journalists a set of guidelines for the style for lay summaries has also been developed.

This talk will give examples of the documents and guidelines and present some of the feedback from those who have used them and those who have been involved in ethical review of the material produced with their assistance.

Poster

Developing lay input into ethical review

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Lay (sometimes known as “citizen”) involvement in the review of animal experiments is now a requirement – or at least recommended practice – in many countries. The involvement of lay participants is important because they widen the perspectives brought to bear on the issues surrounding the use of animals, and in particular on the assessment and weighing of harms and benefits. Although lay representation is most commonly thought of at the level of local and national ethics committees, lay people can make valuable contributions at other stages in ethical review, for example with respect to decisions on research directions, priorities and/or funding, and at the other end of the process when publishing research.

There are, however, many different interpretations of who qualifies as “lay”. It is important to recognise these differences

when interpreting the role, because the individual’s background, expertise and affiliations will clearly influence the nature and extent of their input. Members from different backgrounds also vary in respect of their confidence in contributing to the review process and the resources that they need to help them feel comfortable and be effective in the role.

This presentation draws on the experiences of the wide range of lay members who attend the RSPCA’s Forum for Lay Members of Ethical Review Processes (ERPs), in the UK. It will review their role, describe where they feel they have made the most positive contributions, and explore issues that they find difficult. It will also introduce a number of lay members resources developed by the RSPCA at their request.

**Poster**

Literature survey of 51 approved legal proposals for animal experimentation purposes: No evidence for any human therapy after 10 years is apparent

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In Germany, according to the German Animal Welfare Act, scientists must provide prior to undertaking an animal experiment an ethical and scientific justification in their applications to the licensing authority. In such justifications reference is made to lacking knowledge with regard to development of human diseases or the need of better and even new therapies for humans.

The present study is based on applications of biomedical study groups of three universities in Bavaria (Germany) between 1991 and 1993. These applications have been classified according to their publications as successful in the animal model (Lindl et al., *ALTEX* 18, 171-178, 2001).

We investigated the frequency of citations, the course of citations and the question in which type of research the primary citations have been taken up: in subsequent animal studies, in

in vitro studies, in review articles or in clinical studies. The criterion we applied was whether the scientists succeeded to reach the goal in their applications: to contribute to new therapies or to gain results of direct clinical impact.

The outcome was unambiguous: even though 86 clinically orientated publications in which the above mentioned publications were cited could be tracked (7.1% of all citations), only in 2 publications a direct correlation between the results from animal experiments and observations in humans could be noted (0,16%). But even in these 2 cases the hypotheses that had been verified successfully in the animal experiment failed in any respect.

The implications of our findings may lead to demands concerning improvement of the licensing practice in Germany.

Poster

Animal ethics and the question of killing

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Introduction: About 25 years ago the Australian philosopher Peter Singer replaced the traditional question whether humans are allowed to kill animals by two new questions: the question of killing and the question of suffering. He is convinced that this approach, to consider the issue of killing animals in isolation from the infliction of suffering, is necessary for a clear philosophical understanding of the separate issues involved.

Methods: The ideas of recent philosophers – Peter Singer, Tom Regan, Paul Taylor and others – concerning the question of killing are compared with each other and with ideas of historic philosophers – René Descartes, Thomas Hobbes, Immanuel Kant, Jeremy Bentham and others – touching the question of killing. All arguments are analysed down to their underlying

postulates. Because postulates are finally unprovable their plausibility was compared.

Results: The result is a paradox. The most plausible postulates are found in ancient arguments, although the question of killing was not understood in the modern way. The arguments however published since Singer raised the question of killing are build on postulates of low plausibility.

Discussion: Evidence suggests that the philosophical uncertainty about the question of killing follows from an inadequacy of the human ability to make moral evaluations for the problem in question. The killing of animals without any signs of fear or suffering (shown by the animals involved) seems to be neither moral nor immoral but unexpectedly without a moral status.



Lecture

Processes and policies for ethical evaluation in Nordic Countries and Europe

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Revised Directive (86/609/EEC) shall require detailed and harmonised ethical evaluation of animal studies, and will be based on cost-benefit analysis. In this analysis the likely benefits of the study are weighed against the cost – i.e. harms like pain, suffering and distress – to the animal. It can be foreseen that both commodities to be weighed have to be broken down to smaller elements in order to weigh or attach an ethical value judgement to each and then these elements can be used in the overall assessment of an animal study. What is perhaps even more important is improving all relevant areas of concern, but particularly so that both animal welfare and good science are promoted. Whenever replacement alternatives cannot be used, ethical evaluation can and must focus on the two other alterna-

tives, refinement and reduction and these are also fundamental elements of any harm in a cost/harm-benefit analysis. Processes and policies of ethical evaluation vary considerably in Europe, and need in many cases to be modified. Evaluation of the 6th Framework Programme applications is an example of truly European process: Benefit assessment is carried out first by scientific evaluators, and applications with high scores go to ethical panel. A similar assessment of benefits should be done in all cost-benefit analyses, but the local ethics committees may lack the needed expertise. Nordic Forum for Ethical Evaluation suggested a Cost-Benefit-Means approach for evaluation. In this model, the means are available methods either to improve the benefits or to decrease the costs.

Poster

Improving the effectiveness of research ethics committees

Catherine Schuppli and David Fraser

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Animal Ethics Committees (AECs) play a key role in research governance, but there has been little study of the factors influencing their effectiveness. In-depth interviews with 28 AEC members from four Canadian universities were used to examine how committee effectiveness is influenced by committee composition and dynamics, recruitment of members, workload, participation level and member turnover. We found that a bias toward institutional/research interests versus animal interests may result from a preponderance of institutional and scientist members, an intimidating atmosphere for community and other minority members, and recruitment of community members who are affiliated with the institution and of members who joined for reasons other than to fulfil the committee mandate. Thoroughness of protocol review may be influenced by heavy workloads, type of review process, and lack of full committee

participation. The introduction of new ideas may be limited by low member turnover. We suggest potential solutions to the problems identified so that AECs can improve their effectiveness. Institutional/research bias may be reduced by increasing numbers of community members, training chairpersons to provide a respectful committee atmosphere that encourages participation, and recruiting community members through advertisements followed by interviews. However, policies about the role of community members are often unclear, thus solutions may require further discussion. Ensuring thorough protocol review may be solved by ascertaining that all new members agree to fulfil the mandate of the committee and agree to the workload. Solutions are also discussed in relation to evidence for similar problems in Research Ethics Committees for human subjects.



Lecture

Criteria for expert review by animal experiments committees

Jan van der Valk and Sandra Swart

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The Dutch Act on Animal Experimentation (1996) regulates the protection of laboratory animals. The Act imposes that animal experiments committees (AEC's) should review animal experiments and balance the interest of the experiments against the suffering of the experimental animals. AEC's advice the license holder of the organisation where the experiments are to be performed about the acceptability of each animal experiment. According to the Dutch regulations the AEC's have to be composed of at least seven members which equally represent expertises on experimental animals, on alternatives to laboratory animals, on ethics and lastly on animal welfare and protection. Criteria that persons have to meet in order to be regarded as expert in one or more of these areas have not been described. The expertise of the AEC members can, therefore, not be guaranteed.

This study proposes criteria for each of the four expertises in the AEC. Representatives of the four expertises were consulted in order to draft criteria in a way that both adequate knowledge and expertise can be expected and that a sufficient number of people would qualify to complete the composition of the AEC's.

Furthermore, it is proposed that in order to maintain the knowledge of each expert, compulsory continuing education of AEC members is required. The education should cover general items like statistics, alternatives, ethics, legislation, discussion techniques, importance of consensus, etc. In addition, it is proposed that compulsory courses should be established for each expertise to be regularly updated on developments in their respective areas.

Lecture

Assessing and reporting the impact of animal procedures – a fresh look at severity scales

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In 1997, a severity scale to assess and record the level of welfare compromise to animals used in research, testing and teaching was introduced in New Zealand. Under this scale, the severity of procedures was expressed in terms of different categories of suffering based on numerous examples at the five levels outlined in a paper by Mellor and Reid (Mellor and Reid, 1994). The present paper reports on a review into the operation and effectiveness of that scale and the extent to which it fulfils the purposes for which it was devised. Key features of the scale

are described along with its strengths and limitations, and comparisons with other scales operating internationally are made. Modification of the scale based on the review is outlined and key steps in its implementation are described.

Mellor and Reid (1994). Concepts of animal well-being and predicting the impact of procedures on experimental animals. Improving the Well-being of Animals in the Research Environment, Sydney, ANZCCART.



Lecture

A wider interpretation of the 3Rs model

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The 3Rs model, proposed by Russell and Burch, fifty years ago, and specifically addressed to the scientific world, is nowadays inadequate to cope with more taxing questions posed by a more aware society, increasingly searching for a better equilibrium between the human species and the environment. In an effort to analyse those aspects and to implement a more advanced version of the 3Rs model, the project Anim.Al.See, has explored in details, both from the philosophical and the scientific point of view, alternatives to animal experimentation. For this purpose, concepts and languages involved in specific case-studies, related to each R, have been analysed, both by scientists and philosophers: for replacement, the case of cosmetic testing; for reduction, the single-dose approach in vaccines production, and the use of telemetry; for refinement, the housing of non human primates and the welfare evaluation. On this basis, new

definitions of alternatives, animal experiments, and animal welfare have been worked out, together with more precise definitions of replacement, reduction, and refinement. Recommendations are provided which would be of help to institutions, regulators, ethical bodies. The study performed, by widening the framework of reference, should improve the dialogue between science and society by promoting the awareness of the complexity of the problem, the research for alternative procedures, and the responsibilities of the different subjects involved.

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