



Session II-2: Ethics review

Session II-2: Oral presentations

II-2-649

Ethical review of animal experiments: current practice and future challenges

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Over the last 20 years, ethical review of animal use in research, testing and teaching, and its practical implementation, has developed significantly across the world. However, the expectations and outcomes of the process can vary widely. This is not surprising given that:

- there are different concepts of what ethics and ethical review actually means in practice;
- ethical values and judgements inevitably differ between individuals, roles, and establishments, between societies, cultures, and legislative contexts, with differing historical precedent, and over time; and
- ethical review *processes* vary between, and sometimes within, different countries, e.g. in their level of authority, scope of interest, remit and organisation.

Some countries have long experience with ethical review processes and some are just beginning to embrace the principles. It would therefore seem beneficial and timely to start to work

towards harmonised, worldwide “guiding principles”. There are already many good statements of principle from eminent organisations. The difficulty is translating these into workable and worthwhile practical systems. As a first step, it is important to develop a common understanding of what we want to achieve through ethical review. In this context, our presentation will:

- explore the various beneficial outcomes that can come from “doing ethics” in general, and specifically from ethical review of animal use in the life sciences;
- discuss examples of the different ways in which the ethical review process is, or could be, designed to achieve specific outcomes, drawing on available guidance from around the world;
- raise questions for discussion, which might form the basis for further dialogue leading to development of international guidelines.



II-2-553

Ethical review of the use of animals in science – A reflection on the journey and future directions

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In the 1970s, Canada, Sweden and Australia became the first countries to establish committees to review the ethical acceptability of research using animals. Modelled on comparable committees concerned with human subjects, drivers for the establishment of animal ethical review committees (AERC) recognised that such activities presented ethical challenges and that, given the level of controversy in the wider community, scientists needed to demonstrate responsibility and accountability for their actions. Notably, the scientific community was involved in the development of these committees. In Canada and Australia, AERCs were established under an institutional self-regulatory framework whereas in Sweden the committees were under national legislation and external to institutions. Nevertheless, in each country the involvement of “lay” members was seen as important in achieving the expected outcomes.

Since then, AERCs have been established in many countries albeit with differences in their charter and standing, reflecting historical experiences and cultural differences. However, the role of these committees and expected outcomes has become politicised; government policy is most often the driver so that, in many instances, the role of the AERC is mandated in legislation or through contractual agreements with funding agencies. Despite almost forty years’ experience, there have been few reviews into the operation of AERCs, but available evidence raises questions as to the effectiveness of the process and engagement with the wider community. The AERC process would be strengthened by reflection upon and reaffirmation of expected goals, and a better understanding and recognition of the broader social context within which an AERC operates.

II-2-555

The costs and benefits of animal experiments

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Most regulations governing animal experimentation require that the harms expected to be incurred by animal subjects should be balanced against the likely benefits of the project. Too often, however, expected human benefits are based on unrealistic assumptions. To critically assess the human clinical, toxicological and educational utility of animal experimentation, the published literature was comprehensively surveyed to locate relevant systematic reviews. In only two of 20 reviews located did the authors conclude that animal models were either significantly useful in contributing to the development of human clinical interventions or substantially consistent with clinical outcomes. Furthermore, one of these conclusions was contentious. Included were reviews examining the clinical utility of invasive chimpanzee experiments, of highly cited animal experiments published in leading scientific journals, and of experiments ap-

proved by ethics committees at least partly on the basis of specific claims that these animal experiments were likely to lead to concrete advances in human healthcare. Seven additional reviews also failed to demonstrate reliable predictivity of human toxicities such as carcinogenicity and teratogenicity. Results in animal models were frequently equivocal or inconsistent with human outcomes. When considering costs and benefits overall, one cannot reasonably conclude that the human benefits exceed the costs incurred by animals subjected to scientific procedures. On the contrary, the evidence indicates that actual human benefit is rarely – if ever – sufficient to justify such costs. Despite this, deficiencies in the implementation of regulatory and policy requirements to replace, reduce and refine animal use remain marked and widespread. A range of policy initiatives are warranted to address these deficiencies, and are reviewed.



II-2-084

A New Zealand commitment to continuous improvement in AEC decision-making: giving operational effect to key principles

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The role of New Zealand's National Animal Ethics Advisory Committee (NAEAC), as well as provision of advice to the Minister of Agriculture and the Director-General of Agriculture and oversight of the regulatory system governing use of animals in research, testing and teaching, is to support the work of the 33 animal ethics committees in the country. NAEAC clearly has a significant interest in ensuring that AECs have the information they need to make good decisions. To this end the committee:

1. responds to requests for guidance from individual AECs when they require clarification on legislation or ethical principles;

2. holds workshops for AEC members every two years, ensuring inclusion;

3. sends out two to three newsletters a year highlighting issues that have arisen both for AECs and for NAEAC;

4. holds one meeting a year in a regional area where visits to local AECs are made.

This paper looks at the support given by NAEAC to AECs, with a focus on the workshops held over the last 8 years and highlighting topics that participants have found most useful and those where difficulties have arisen.

Session II-2: Poster presentations

II-2-135

The use of activity maps in project authorization

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The use of animals in research raises ethical questions. In order to get a project authorized, persons planning animal experiments must apply to an authorizing body, often providing written information in a standardized form. The information is commonly evaluated on compliance with the 3Rs or accumulated harm to the animal versus benefit of the experiment. Activity maps are commonly used in project planning. Activity planning means to make a detailed plan for necessary activities. Persons and their responsibility and necessary manpower are identified. The activity map gives a chronological overview of activities over time and the dependency between activities is clarified. It is helpful to identify critical activities to make sure that competent and experienced personnel are responsible and available for the project. A project description might consist of a substantial

document and important information is drowned in information overload; an activity map shall describe all activities in a maximum of 1 page (A4, A3). This gives a good overview of all activities. In 2010 a pilot experiment was performed at the Animal Facility at the University of Bergen, Norway. An activity map had to be prepared as an attachment to all project authorization applications. The pilot project identified the following:

- activities, both frequency and total number
- accumulated harm of all activities/procedures on the animal
- different activities' potential for the 3Rs, especially refinement
- specific activities' needs for improvement (refinement)
- quantification of harmful procedures
- severity categorization to be implemented



II-2-164

Advancing ethics review in IACUC oversight of animal research

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Institutional Animal Care and Use Committees (IACUCs) oversee U.S. research institutions' animal programs and have played an important role in reducing some of the worst abuses of animals in laboratories. After 25 years, however, IACUCs struggle with adequate consideration of alternatives, and are criticized for failing to tackle a central issue – the justification and necessity of using animals for research in the first place. Drawing from published studies, we examine how IACUC functioning compares to public expectation, particularly with respect to how IACUCs handle the ethical dimensions of animal research. Critiques include a tendency to focus on technical aspects of refinement and a limited role for the community representative. In

addition, harm-benefit analyses are rarely performed, in contrast with public expectation that broader ethical issues are considered during the research proposal review process. Other ethical committee models demonstrate that such deliberations need not be out of the scope of IACUC responsibility. Recommendations are provided for how US IACUCs could improve consideration of ethical issues and better represent their communities, achieving harmonization with practices in other countries and international standards for ethics review. We also highlight new research pointing to persistent challenges even with optimization of the ethical committee framework.

II-2-335

Incorporating ethics in the alternatives to animal use in scientific research

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Conducting any scientific experiment involves certain methodological aspects, such as the identification of a problem situation, the establishment of an objective, the accuracy in the procedures, the techniques to obtain data, and the management of the information and the final results. These elements of methodology interact with the scientific, professional and social criteria that define and provide evidence on the context in which the research is carried out.

When addressing the so-called “alternative” proposals regarding animal use in research, it can be observed that these are consistent with methodological criteria, research strategies and techniques based on scientific knowledge and procedures implemented in areas such as biology, ethology and veterinary

medicine. Ethical guidelines are not explicitly included in the alternative proposals. Directions and requirements are, however, considered as ethical positions in some academic, normative and committee-related documents.

Considering that ethics, within research and science, places more emphasis on the justification of the experiments rather than on the way they are carried out, some questions arise regarding the interaction and support that ethics may contribute to the reflection and development of the alternative proposals that address animal use in scientific experiments. Thus, some ethical choices regarding these alternative proposals are built from the approaches developed by contemporary philosophical trends that have included animal issues in their reflections.



II-2-348

Using language to find if Australian Animal Ethics Committees use emotion or ethics to assess animal experiments

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In Australia, the ethics of the use of animals for scientific purposes are assessed by Animal Ethics Committees (AECs) that are comprised of the four major parties involved in the animal experimentation debate: veterinarians, scientists using animals, animal welfare representatives and members of the public. AECs are required to assess animal experiments as ethical based on a cost/benefit analysis, suggesting the use of consequentialist ethics. However, people are more likely to use a mixture of frameworks when making ethical decisions. Therefore, we hypothesised that AEC members will make their decisions using argumentation relying on multiple frameworks, including ethical relativism, deontology and emotional ethics; frameworks commonly used in the public debate about animal experimentation. The language used by AEC members, examined using discourse analysis techniques, can indicate which ethical

frameworks they rely upon. Using a role playing method, representatives from each of the four AEC categories discussed the ethical value of eight fictional protocols involving animal experimentation. The discussions were recorded and analysed using Nvivo for instances of emotional and ethical language. Data were analysed using ANOVAs and Tukey tests. Emotional language was more common than ethical language ($p < 0.0001$). Categorical differences found scientists used the least emotional language ($p = 0.012$) but the most utilitarian language ($p = 0.023$). As hypothesised, Australian AEC members did not base their decision exclusively on a cost/benefit analysis. Contrary to the guidelines in use, an ethical decision making process that takes into account emotion should be used to accommodate the AEC members' views.

II-2-485

Chimpanzees in US laboratories

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The use of chimpanzees for biomedical research and testing has sharply declined over the last decade, largely due to ethical concerns, public opinion, economics, as well as scientific failures of the chimpanzee model. The United States is the only developed country in the world to continue invasive research on chimpanzees, with 1000 chimpanzees remaining in six US laboratories. In 2006, The Humane Society of the United States launched its Chimps Deserve Better campaign, which seeks to end invasive research on chimpanzees in the United States and retire chimpanzees in laboratories to appropriate sanctuary. This presentation will provide information on the current trends related to

chimpanzees in laboratories including new laws, demographics of chimpanzees in labs and sanctuaries, costs associated with keeping chimpanzees in labs vs. sanctuary, and scientific evidence regarding failure of their use. An update of the Chimps Deserve Better campaign will also be provided, including an undercover investigation into the largest chimpanzee laboratory in the world, legal and policy actions taken on behalf of chimpanzees in laboratories, efforts to secure permanent retirement for chimpanzees, as well as outreach to corporations, scientists and the public.



II-2-527

Facilitating the role of lay members in ethics and animal care and use committees

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Incorporating independent “lay” members within ethics committees allows a measure of “public” accountability and widens the range of expertise and perspectives on animal care and use. Without doubt, a confident and constructive lay person can help in making significant improvements to animal welfare and the implementation of the 3Rs. They can challenge existing assumptions and practices, which helps to develop and facilitate broader ethical discussions. However, lay members may lack experience in discussing the harms and benefits of animal use and the potential for humane alternatives, so it can be difficult to make a real contribution especially when faced with professional scientific, technical and animal care staff who are experts in the topics under discussion. “External” lay members who are also unfamiliar with local personnel and management practices can find it even more difficult.

If lay membership is to achieve real benefits, it is important to understand and try to alleviate any problems lay members may face. The RSPCA has run an annual Lay Members’ Forum for over 10 years, which has provided “training” for lay members and yielded valuable insight into their information needs. Interestingly, delegates are not only lay members – they come from a range of roles and positions within research establishments, suggesting that some of the issues facing lay members are common to other committee members. Experience from the Forums and elsewhere has enabled the RSPCA to produce a range of resources to help lay members fulfill their roles. These will be described in the poster.

II-2-557

Guidance on the severity classification of procedures involving fish

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Severity classification is an important tool for implementation of the 3Rs and for ethical evaluation of research procedures. The revised EU Directive that comes into force in 2013 requires signatories to ensure that all procedures are classified as “non-recovery”, “mild”, “moderate” or “severe”, using assignment criteria set out by the European Commission. A working group appointed by the Commission produced a report in 2009 that gives examples of procedures within these categories. These examples are, however, most relevant to research using terrestrial laboratory animal species. A working group set up by

the Norwegian Consensus-Platform for the 3Rs (Norecopa) has published a complementary document that gives guidance on severity classification in fish research, including examples of “subthreshold”, “mild”, “moderate”, “severe” and “upper threshold” procedures. This document will make it easier for fish researchers to implement the requirements of the new Directive. Norecopa has established a website (www.norecopa.no/categories) with links to these guidelines and more information on severity classification.