Animal welfare and animal ethics committees: where are the goalposts now?

Proceedings of the Conference held at the Gold Coast International Hotel, Queensland October 17 – 19, 2002

Australian and New Zealand Council for the Care of Animals in Research and Teaching 2003

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Edited by

Rory Hope

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ANZCCART 2003

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Contents

Thorny issues and ethical conundrums

Ensuring team decision-making in Animal Ethics Committees

ANZCCART Student Award presentation

Posters

Preface

The choice of Queensland for the location of this ANZCCART conference was fitting for several reasons. First, the new *Animal Care and Protection Act 2001* had recently come into force. The implementation of the Act required a major effort in training officers and establishing Animal Ethics Committees, and much of the responsibility for implementing the changes was taken up by the Queensland Department of Primary Industries (DPI) – one of the major sponsors of the Conference. Second, the University of Queensland agreed to proceed with the establishment of a Chair in Animal Welfare, funded by government and industry. The University of Queensland was the major financial sponsor of the conference. Finally, ANZCCART had not previously held a Conference in Queensland.

The conference brought together a group of people interested in and involved with animal welfare and animal ethics, with the aim of addressing the question "Animal welfare and animal ethics committees: where are the goalposts now?" The Planning Committee designed the conference (and chose the speakers) so that it strongly focuses on this general theme. The committee produced a program that gave strong emphasis to "audience participation". Unfortunately, much of the discussion and debate that occurred cannot be captured in this formal publication. In addition, several of the speakers did not supply a copy of their paper to the editor.

Members of the Conference Planning Committee were: Mary Bate, Jane Conole, Graham Jenkin, Deb Kelly, Linda Murphy, Glenys Oogjes, Mike Rickard, Margaret Rose, John Schofield, Lyn Scott, and Rory Hope. The Committee received considerable assistance from Noel Standfast and Bronwyn Williams (DPI, Queensland), Peter Johnston (NSW Agriculture) and Ros Judson (ANZCCART, Adelaide). The organisers proved to be an enthusiastic and dedicated team.

ANZCCART acknowledges the conference sponsorship provided by the University of Queensland and the Queensland Department of Primary Industries (major sponsors). Other sponsors were: the Bureau of Animal Welfare (Department of Natural Resources and Environment, Victoria), the NHMRC Animal Welfare Committee, Griffith University, the CRC for Innovative Dairy Products, the University of Newcastle, and the Animal Welfare Unit (NSW Agriculture).

Rory Hope
Director, ANZCCART

Introduction

This Conference was held from Thursday 17 – Saturday 19 October at the Gold Coast in Queensland. The theme was chosen to attract a much wider range of participants than usual, especially those that act as Category C (with welfare experience) and Category D (lay persons) members on Animal Ethics Committees as defined in the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes. A total of 153 attended the conference with 20 visitors from NZ and close to half of the total being C and D Members of AECs. This was the largest attendance thus far at an ANZCCART Conference.

The conference was divided into 8 Themes or Sessions and embraced topics such as effective operation of AECs, education and communication, the public/user interface, dealing with external applications to do research work, achieving good animal welfare outcomes, dealing with thorny issues and ethical conundrums and the special issues raised in dealing with research on genetically modified organisms. The meeting got off to a good start with the QDPI Group play-acting as an AEC, which displayed many of the difficult behaviours, which are faced by AEC members. This set the tone for an extremely good humoured but frank interchange of ideas and personal views throughout the remainder of the conference.

A number of issues were identified which ANZCCART and others can take forward and address in the future. The issue of effective monitoring of experimental animal use was a recurrent theme. On behalf of the Board I wish to thank all of those who contributed to the organization and sponsorship of what seemed to be generally agreed was a spectacularly successful conference as well as those who attended for their good-spirited participation.

Mike Rickard
CHAIRMAN

At the conference dinner - Graham Jenkin, Mike Rickard and Linda Murphy
(Photo by Louise Gilbert)

Note from the Editor

In keeping with the spirit of the Conference the editors have allowed a range of presentation styles in the submitted papers. Much of the conference was devoted to informal discussion and debate and records of these sessions were not kept. Several speakers did not supply full papers. In these cases the abstract submitted prior to the conference has been reproduced.

Session Title:

Genetically modified organisms: issues for Animal Ethics Committees

Cloning - an overview of techniques and potential benefits

Nancy T. Ruddock and Andrew J. French
Monash Institute of Reproduction and Development, Monash University, Clayton, Victoria, and
CRC for Innovative Dairy Products, Melbourne, Victoria.

Abstract

Ever since the production of Dolly (1996), the first mammalian clone produced from a fully differentiated cell, there has been a flurry of interest in the techniques used for cloning and the potential benefits of the technology [1]. Cloning is achieved by nuclear transfer, a process by which a nucleus, or small somatic cell, is introduced into an enucleated oocyte. Potential benefits of the technology are in the faster dissemination of important genetic information, the potential to help in the preservation of endangered species and in the ability to increase our understanding of biological events and to do more precise transgenesis. The ability to do transgenesis opens the field for neutraceutical and pharmaceutical production in farm animals. Unfortunately, the nuclear transfer procedure(s) are quite inefficient, with less that 5-10% of embryos transferred resulting in the live birth of an animal [2]. Our laboratory is currently involved in cloning research for agricultural purposes, with aims to decrease the numbers of pregnancies lost and increase the number of healthy animals born with this technology.

1. Introduction

Cloning by nuclear transfer is not a new technique, as clones have been produced in a variety of animals, including mammalian species, by fusing embryonic blastomeres to enucleated oocytes [3, 4]. This technique was first performed in the frog fifty years ago [5]. By using this technique, it was discovered that developmental competence, or the ability to form a new animal decreased as the cell became further differentiated from an embryonic state. This led scientists to believe that cloning using adult cells was not possible, that these cells had differentiated too far from their embryonic precursors. With the birth of Dolly the sheep, from an adult cell, these preconceived beliefs in mammals were proved false, opening the door to a variety of uses for the cloning technology. Since 1996 and the announcement of Dolly, more than 500 cloned and transgenic cloned animals have been born, with the largest numbers being in cattle and goats. A number of offspring have also been derived from cloned animals and all are currently being thoroughly tested. Recently, the U.S.A and Japan have performed extensive testing of cloned animals and cloned meat and milk products. The U.S.A. found that there were no differences in cloned and natural mated products, and Japan went a step further and approved the consumption of embryonic cloned meat and milk products. Japan is also currently considering approval of somatic cell cloned products.

2. Somatic cell nuclear transfer (cattle)

Somatic cell nuclear transfer is performed with an enucleated oocyte and the cell from an adult animal. The stage of the cell cycle for both must be carefully considered. Different laboratories have used metaphase II arrested oocytes or activated oocytes as donors, and cells that were in G0, G1, or M phase. In our laboratory, metaphase II arrested oocytes are enucleated, followed by the fusion of a G0 or G1 cell. This fused couplet is then activated four hours post-fusion and allowed to develop to the blastocyst stage *in vitro* before being transferred into a recipient animal.

3. Potential benefits of cloning

The significant implications of somatic cell nuclear transfer technology were apparent to many scientists worldwide, enabling opportunities for the multiplication of elite or rare/endangered animals and the engineering of cell lines for the production of transgenic cloned animals, for various biomedical and agricultural purposes. The technology also offered a powerful new way to investigate and improve our understanding of basic cell biology. In the dairy and beef cattle industries, cloning can be used to increase genetic gain by disseminating genetics of elite bulls faster, or rescue those animals injured and no longer able to provide semen samples. For endangered species, the technology provides a way to bring back genetics lost in dwindling populations or animals with low fertility due to disease or old age. Finally, cloning provides scientists the opportunity to do site-directed transgenesis, unlike transgenesis by pronuclear injection in which transgenes are randomly inserted into the genome. This technology allows you to insert the gene in the exact location you want, or

delete a gene prior to using the cell to create a transgenic animal. The technology also prevents the production of mosaic animals in which not all cells have the desired transgene or gene knock-out. Fourteen therapeutic products derived from cloned transgenic animals are currently being investigated, with some, like antithrombin III and α1-antitrypsin, in Phase III and II of human trials, respectively [6]. Neutraceuticals are naturally occurring compounds that can be added to increase the nutritional value of milk produced, i.e. the addition of Omega 3 fatty acids to bread. The production of therapeutic pharmaceuticals or neutraceuticals in the milk of cattle is desirable, because bacteria are not always able to make functional human proteins and it may be easier to produce and purify the proteins from the milk of cows.

4. Limitations

While the potential benefits of the cloning technology are immense, the techniques involved are far from optimized. The success rates with most cloning programs are at best 10-15% of embryos transferred resulting in a live birth, while *in vitro* fertilized embryos result in a live birth approximately 60-70% of the time [2]. This pregnancy loss is attributed to a failure to 'reprogram' the adult cell DNA to a more embryonic or totipotent state and occurs in all three trimesters of pregnancy. The DNA code itself is not the problem, but how the DNA is packaged, or the epigenetics of the cell [7]. This includes primarily DNA methylation status and methylation and acetylation of the histones which package the DNA. Many scientists, including those in our laboratory, are investigating how the 'reprogramming' of DNA is accomplished so that embryonic and foetal loss following nuclear transfer can be minimized.

The main abnormalities observed in cloned pregnancy are the failure to establish and maintain a healthy placental structure [8] and abnormalities in the foetal growth rate and organogenesis. In cattle, the majority of full-term placentas have a variety of problems including very few and overly large placentomes. There is also an increased incidence of foetal overgrowth resulting in overly large calves, and increased incidences of abnormalities in the respiratory system and in liver, kidney, heart and bone growth.

5. Animal welfare

All embryos created in our laboratory are produced from abattoir-derived, in vitro matured oocytes. As stated above, we are actively involved in research aimed at understanding the reprogramming process, so that we can avoid the mistakes that lead to embryonic and foetal loss. Modifications to the nuclear transfer and oocyte activation techniques are also being investigated. Only the best embryos in terms of cell number and morphology are chosen for transfer, and embryo transfers are non-surgical. Because of the high pregnancy loss, recipient animals are monitored closely following embryo transfer. Recipient animals are checked monthly during pregnancy by both rectal palpation and by ultrasonography. During the last month of pregnancy recipient animals are kept in paddocks close to the main farm buildings and checked several times per day. It is the practice of our laboratory to perform caesarian sections on all recipient animals 1 week prior to anticipated delivery. This is done in order to prevent recipient animals from suffering if offspring are overly large, and to be able to closely monitor calves following delivery. Recipient animals that carry a pregnancy to term are not kept in the recipient herd, as animals are only subjected to one surgical procedure. Calves are given pre-tested colostrum and reared in a calf-rearing facility with shelter and rice hulls for bedding under close observation. Any calves that become sick and appear to be suffering are euthanized immediately, and all cloned products and animals that are put down in this way are incinerated following an independent pathological examination. Cloned calves are also tested for organ function and undergo behavioral testing. When the calves reach puberty, males are tested for semen quality and females are mated to test fertility and then milk characteristics. Transgenic clones are also tested for the production of the inserted transgene.

6. Concluding remarks

Since the birth of Dolly, hundreds of healthy clones have been produced around the world, including within Australia. At present ethical and moral constraints limit the commercial potential of the technology. Although the success rates in cloning are presently low, the potential benefits of the technology in agriculture, biomedical science and the preservation of endangered species continue to drive scientists to pursue research in the field. In the past year there has been a dramatic decrease in foetal loss and the incidence of calf abnormalities. This increased calving rate and decreased abnormalities is thought to be due to changes to the nuclear transfer technique, donor cell line choice and treatment, embryo culture conditions, embryo selection and an increased understanding of 'reprogramming' and basic cell biology. Following these improvements in pregnancy outcome and extensive testing of cloned products, the U.S.A. and Japan have reported that there is no difference

between cloned and non-cloned meat and milk products. These initial tests of cloned animals and their by-products point to a future for this technology in agriculture and for the production of neutraceuticals and pharmaceuticals for human use.

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3. McGrath, J and Solter, D. 1984. Inability of mouse blastomere nuclei transferred to enucleated zygotes to support development in vitro. Science 226: 1317-1319.
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6. Clark, J and Whitelaw, B. 2003. A future for transgenic livestock. Nature Reviews (Genetics) 4: 825-833.
7. Rideout, WM, Eggan K, and Jaenisch, R. 2001. Nuclear cloning and epigenetic reprogramming of the genome. Science 293: 1093-1098.
8. Hill, JR, Burghardt, RC, Jones, K, Long, CR, Looney, CR, Shin, T, Spencer, TE, Thompson, JA, Winger, QA and Westhusin, ME. 2000. Evidence for placental abnormality as the major cause of mortality in first-trimester somatic cell cloned bovine fetuses. Biol Reprod 63: 1787-1794.

Session Title:

Education Showcase

A compendium of education resources

Contributed by Margaret Rose
Chair, Animal Research Review Panel, New South Wales Agriculture

Multimedia

- *Anaesthesia of Rats*. An interactive training and teaching tool on CD-ROM. BSL Publishers, PO Box 246, 3990 GA Houten. E-mail: rats@blspubl.com. http:www.bslpub.com/rats

- *Careful how you hold me* –an insight into caring for laboratory animals. A multimedia program on CD-ROM for researchers, students and animal technicians. Available from Melbourne University Press, http: www.mup.com.au

- *Experimental Design* -a multimedia learning package on CD-ROM to teach better experimental design written by Michael Festing and David Dewhurst Available from Sheffield Bioscience Programs http: www.sheffbp.co.uk

- *Laboratory Animal Medicine & Science Series II*. American College of Laboratory animal Medicine. Developed in conjunction with the University of Washington's Health Sciences Center for Educational Resources (UW-HSCER). This CD-ROM includes the text and images from all the Series II programs. For further information:http: www.aclam.org.

- *Pain Assessment in the Rat*. This CD has been developed by John Roughan and Paul Flecknell and contains movies illustrating a behaviour-based pain scoring scheme in rats. Purchasing information available at www.lal.org.uk/digital.

- *Digital Material for Trainers.* A series of 12 digital video CD's covering handling, procedures, anaesthesia and surgery for common laboratory animals. Three CD's include interactive course notes. Purchasing information available at www.lal.org.uk/digital/Video.htm

- *Euthanasia with Care*. A video designed as a teaching resource for animal technicians and scientific staff; covers the general principles and specific methods of euthanasia for commonly used laboratory species. (Duration 25 min) Available from Institute for Animal Technology (UK) and can be purchased on-line at www.iat.org.uk

- *Necropsy procedures for small laboratory animals.* A 22 minue video available from The Microbilogy Laboratories, 56 Northumberland Road, North Harrow, Middlesex, HA2 7RE, UK. E-mail: needham@microlabs.demon.co.uk.

- *Environmental Enrichment*. A video produced by UFAW (35 min) which is aimed at those responsible for the care of animals in captivity, including animal technicians. The needs of animals are explored and practical suggestions given for improving their living conditions. Purchasing details available from: http: www.ufaw.org.uk

- *The Rat –recommended technical procedures*. A video (24 min) produced by the Canadian Association for Laboratory Animal Science for animal technologists, graduate students and laboratory assistants as an introduction to safe handling techniques and methods for injection and blood sampling in the laboratory rat. Purchasing details: www.calas-acsal.org

- *Handling and sexing of some common laboratory animal species*. A video produced by the Canadian Association for Laboratory Animal Science as a guide to those new to the field of laboratory animal care and includes an introduction to the concept of microbiological containment. Purchasing details: www.calas-acsal.org

Other Learning Aids

- *Koken Rat* – anatomical model with tail vein to practice venepuncture. Available from B & K Universal, e-mail: info@bku.com

- *PVC Rat* –for simulation of catheter implants and microsurgery. Includes an interactive CD-ROM program for patient monitoring. Available from Microsurgical Development foundation, e-mail: info@microdev.nl, or http:www.microdev.nl

- *DASIE (Dog Abdominal Surrogate for Instructional Exercises)* - a laminated fabric and polyurethane model designed and constructed to resist cutting, and to hold sutures in a manner similar to normal tissues. Used for practicing aseptic technique, instrument handling, suturing and ligation. Available from DASIE International, email: dasieinternational@hotmail.com

Data Bases

- *AWIC* (Animal Welfare Information Centre, National Agricultural Library, USA) http: www.nal.usda.gov/awic.htm
- *Altweb* **–**an extensive database for information on alternatives to animal testing hosted by the John Hopkins Centre for Alternatives. http: www.altweb.jhsph.edu/
- *Compmed* – an e-mail discussion group on scientific and welfare issues concerning the use of animals in research and teaching. For further information contact ken@dcm.wustl.edu.
- *Norina*: an inventory of some 3,700 alternatives to the use of animals in teaching at all levels from primary school to university. Developed by the Laboratory Animal Unit of the Norwegian College of Veterinary Medicine, Oslo. http://oslovet.veths.no/NORINA/default.html
- *National Library of Medicine* (USA) publishes a regular annotated bibliography on alternatives to the use of animals in biomedical research. http://www.nlm.nih.gov/altanim.htm
- *Assessment of animal welfare*: http:www.vetinfo.demon.nl/aw/index.html
- *Refinement of housing conditions and environmental enrichment for laboratory animals* :http: www.awionline.org/lab_animals/biblio/refine.htm
- *Animal Models in Biomedical Research*. National Institutes of Health http:www.nih.gov/science/models

Websites for information on *transgenic*s

- www.med.umich.edu/tamc/links.html#Search
- www.mgu.har.mrc/ac/uk/stocklist
- www.jax.org

On-line references/policies

- Report of the American Veterinary Association Panel on euthanasia. AVMA (2000) *Journal of the Veterinary Medical Association*, 218: 669-696. http:www.avma.org/resources/euthanasia.pdf
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- *Essentials for Animal Research – a Primer for Research Personne*l. http:www.nal.usda.gov/awic/pubs/noawicpubs/essentia.htm
- Recommendations for euthanasia of experimental animals, LASA (1996/97) *Laboratory Animals*, 30: 293-316; 31: 1-32. http:www.lal.org.uk
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- *Methods and Welfare Considerations in Behavioral Research with Animals.* National Institutes of Mental Health (2002) Copies available from: http:www.nimh.nih.gov/research/animals.pdf
- *Laboratory Animals* website – www.lal.org.uk - contains selected journal articles which address practical methods to promote the 3R's. Select 'publications' on their home page to be able to review and download material.
- *ILAR* (Institute for Laboratory Animal Resources) http:dels.nas.edu/ilar. Copies of recent issues available on-line.
- *Genetic engineering: animal welfare and ethics* The Boyd Group (UK) *(1999)* Copies available from www.boyd-group.demon.co.uk/genmod.htm

- *The use of genetically modified animals* The Royal Society (UK) *(2001)* Copies available from www.royalsoc.ac.uk/policy/index.html
- *Report on biotechnology* Animal Procedures Committee (UK) *(2001)* Copies available from www.apc.gov.uk

Organisations

- *AWIC* (Animal Welfare Information Centre, US Department of Agriculture): http:www.nal.usda.gov/awic/
- *CCAC (*Canadian Council on Animal C*are*) http:www.ccac.ca/english/welcome.htm
- *UFAW* (Universities Federation for Animal Welfare, UK) http: www.ufaw.org.uk
- *Laboratory Animals Ltd.*. http:www.lal.org.uk
- *ILAR* (Institute for Laboratory Animal Resources) http:dels.nas.edu/ilar
- *FRAME* (Fund for the Replacement of Animals in Medical Experiments) http:www.frame.org.uk
- *LAWTE* (Laboratory Animal Welfare Training Exchange) http: www.lawte.org

Should scientists be required to complete a course in animal care and ethics?

Panel Members: Mrs Elizabeth Grant A.M. (Chair)
Michael Perry
Lyn Scott
Margaret Rose
Tammie Roy

ABSTRACT

The Australian Code Of Practice for the Care and Use of Animals for Scientific Purposes (the Code) establishes a framework for self-regulation, which governs the use of animals for such purposes. For the processes set out in the Code to achieve the expected outcomes, it is necessary that all those involved understand these processes and their role and responsibilities. To achieve the goals of the Code it is important for those involved to have access to relevant information and that all persons involved in the use and care of animals have the necessary skills and knowledge.

The Code highlights the responsibilities of individual researchers, who must have an appreciation of the ethical and technical issues involved with their use of animals. Researchers must use the best available scientific techniques and be competent in the procedures they perform (clause 1.15); the Animal Ethics Committee must be satisfied that those involved in each project have the qualifications and experience appropriate to the species being used and the procedures to be performed (clause 2.2.11.iii). The Code also requires that persons supervising students must ensure that, prior to using animals, students receive appropriate instruction in their ethical and legal responsibilities as well as the appropriate methods of animal care and use [clause 7.2.3].

Recognising that the skills and knowledge of those involved are essential to achieve high standards of animal welfare and scientific outcomes, courses for people using animals in research and teaching have been developed by organisations such as the Canadian Council for Animal Care, the National Research Council in the United States and the European Communities Biologists Association. In the United Kingdom and the Netherlands, there are compulsory detailed courses for animal researchers.

The Panel discussed whether Australia should follow trends on other countries and require scientists to complete a formal course before using animals for scientific purposes. If so, should there be an agreed content and scope for such courses and how should skills and knowledge be assessed?

ATHOS Ethic, Animals and Administration System

Debra Ramsey
Baker Heart Research Institute, Melbourne, Victoria

ABSTRACT

ATHOS is the Precinct Animal Centre's Ethics, Animals and administration system, developed to streamline the various processes involved with animal usage in medical and scientific research – incorporating ethics, animal inventory and end usage. With its user-friendly question/answer field format, ATHOS simplifies otherwise tedious paper tasks into a series of quick comprehensive on-line tasks.

Benefits of ATHOS

- User-friendly AEC and PAC Services menus allow users to swiftly become proficient with the ATHOS software.
- Ensure studies are compliant with approved AEC conditions and enable animal numbers, costs of studies to be tracked against users, projects and budget.
- Online service requests enable user to deliver requests under appropriate AEC conditions to the animal facility without leaving their desk.
- AEC Help interface enables online access to regulatory web sites, approved standard operating procedures and policy documents.
- System requirements amount to little more than a browser and Adobe Acrobat Reader, minimising the costs and fuss involved in implementing and setting up the system at the users end (i.e.: for scientists and researchers).
- Internal operation (i.e.: the controlling or "Secretary" system) is conducted in a highly secure environment, designed to reside only on those work-stations needing access to that part of the system.
- Password protection in the login facility limits system access to authorised persons, ensuring system efficiency.
- A multi-user platform allows simultaneous access to the software by authorised users.
- Self-learning opportunities are available to users, guiding them through every step of the software process with a comprehensive set of help files.
- The system allows internal and external client interface.

System structure

The ATHOS system consists of distinct modules designed to track relevant categories of information.

The modules include: -

- AEC secretary system: - that maintains a register of organisations, personnel details, user access rights, controls AEC application status, and approval, is the system interface for all AEC approved conditions and transactions.
- Web interface; for users to complete and lodge AEC applications for committee consideration, provides access to help documents and web sites, approved AEC Standard Operating Procedures and enables completion and lodging of animal facility service requests against approved AEC conditions.
- Animal Facility system for receiving service requests, processing and reporting on animal use against approved projects and non-AEC activities.

The structure of this module system is such that the reports generated are meaningful, providing the animal ordering system and AEC process and user accountability with greatly improved efficiency.

The ATHOS system was made possible with the support of the Baker Heart Research Institute (BHRI) and the Baker / Alfred Animal Ethics Committee and the hard work and commitment to the project by Chris Spreckley and ADB Computer Group.

Session Title:

The public / animal user interface: transparency and accountability

Community views of animal research

Phillip Petersen
Wordnet, Rochedale South, Queensland

Abstract

This talk looks at what the broader community thinks of animal research and how they form their views, from the viewpoint of an ex-scientist and current science and medical writer and editor.

What does the community think about animal research?

Let's first look at the medical and scientific communities. As you might expect, various polls have shown an overwhelming consensus that animal research is necessary - 99% of American doctors, 96% of UK doctors, 94% of Nobel Prize winners, and very few dissenters in universities, medical research charities or veterinary institutions. However, 92% of UK doctors think more funds should be employed in seeking alternatives and this view has strong support throughout the medical and scientific communities.

If we look now at the wider community, polls suggest things are very different. A 1990 Harris poll for *The Observer* in the UK found only 46% in favour of animal tests for medical drugs and 48% against. This is despite the fact that, by law, all prescription drugs must be tested in animals for safety and efficacy before human use - a fact it seems that few people are aware of.

A 1995 Gallup poll in the UK produced a similar result - 40% in favour, 50% against. However, an ICR poll for Associated Press in the US in the same year found that 62% of Americans thought using animals to test medical treatments was right under some circumstances, while 8% said it was always right.

Some authors have attributed the difference between these two polls to the fact that, in the early 1990s, animal rights campaigning in the US was met with forthright defence by the major scientific societies, funding agencies, medical organisations and government.

I would suggest it was due more to the fact that the UK poll asked for an all or none response, while the US poll allowed for discretion.

This, I think, can be seen in the international comparison over 15 countries that the Pifers did in 1994 (Pifer *et al*., 1994).

They asked respondents to grade their degree of agreement with the statement, 'Scientists should be allowed to do research that causes pain and injury to animals like dogs and chimpanzees if it produces new information about human health problems.'

The results (Table 1, Pifer *et al*.,1994) indicated that the US was one of only three countries that had a majority in favour, but it was a much smaller majority than in the Gallup poll. In 5 countries, there was a two to one or greater proportion of those against, while the remainder showed a fairly even split.

They looked at the effect of gender on responses (Table 2, Pifer *et al*.,1994). Female opposition was greater in all countries.

They then looked at the effect of science knowledge (Table 3, Pifer *et al*.,1994). Patterns were inconsistent. There were five countries, which showed an increase in support with greater knowledge, including three where there was an actual switch from majority opposed to majority in favour, but there were also three, which showed an increase in opposition. For the others, there was no consistent trend.

Finally, they looked at the effect of environmental interest (Table 4, Pifer *et al*.,1994). Seven of the fifteen countries showed a trend to increasing opposition with increasing interest in the environment but the other eight, a slight majority, did not.

What can we conclude from this? Firstly, that countries are different. Secondly, that females are the ones who most need to be convinced. Thirdly, that science education may not be the answer. Finally, that it ain't all due to the greenies.

The following year, Linda Pifer followed up this survey with one of US youth (Pifer, 1995). While only 32% disagreed with the statement, 'continued research with animals will be necessary if we are to ever conquer diseases such as cancer, heart disease

and AIDS,' 61% disagreed with the statement that, 'scientists should be allowed to do research that causes pain and injury to animals like dogs and chimpanzees if it produces new information about human health problems'. Disturbingly, 55% thought that 'most of the scientific research done with animals is unnecessary and cruel.'

She also looked at some factors influencing opinions. The group which most violently disagreed with the proposition that scientists should be able to do research causing pain and injury to animals was those with anti-science attitudes, with 82% versus 58% for those pro-science. However, gender caused an even bigger difference, with 73% of females and 48% of males disagreeing. Pro-feminist attitudes were also important, with 70% for high versus 50% for low. The difference between those scientifically literate, at 62%, and those who were not, at 51%, was not as great, but still substantial.

While these surveys are suggestive, two later surveys throw more light on the subject. The first, by Peter Aldhous and colleagues in the UK (Aldhous, 1999) asked the question, 'On balance, do you agree or disagree that scientists should be allowed to conduct any experiments on live animals?'

Before they did so, they split the subjects into two groups. The first group was simply asked the question without preamble. 60% of respondents disagreed and 24% agreed, leaving a large 16% undecided. Some groups who might have been expected to be against were very much so: people who had signed petitions on animal welfare 86%, vegetarians 85%, members of animal welfare organisations 83%, people who had bought 'cruelty-free' cosmetics 77%. But even people who had taken a drug for a serious illness and knew the drug had been tested on animals were, by a slender margin, opposed. Incidentally, 35% of the total had taken a drug for a serious illness but only 18% of these knew the drug had been tested in animals. Women, at 71%, were much more anti than men, at 57%. The only group, which showed a majority in favour, was those who had worn a fur coat or taken part in a blood sport in the past two years, at 62% in favour.

The second half of the sample was first told: 'Some scientists are developing and testing new drugs to reduce pain, or developing new treatments for life-threatening diseases such as leukaemia and AIDS. By conducting experiments on live animals, scientists believe they can make more rapid progress than would otherwise have been possible'. Here the situation was dramatically different. Now the percentages changed to 45% for and 41% against, a swing of 22%. The swing varied between different groups, from 14% for members of animal welfare organisations to 30% for people who had bought 'cruelty-free' cosmetics. You'll note that this still leaves a large 14% of subjects undecided. But when it gets down to specifics, things change.Their data showed that people carefully weigh up the costs and benefits of individual experiments before deciding whether they approve. There is a clear dependence on purpose, ranging from very strong support for leukaemia in kids to a good majority of disapproval for cosmetic testing - even if mice are not subjected to pain, illness or surgery. The factors of pain, illness or surgery strongly influence people's views. The swings tend to increase from an initial acceptability from 36% for leukaemia, through 40% for AIDS and on to >50% for the others. The decline in support for basic research is particularly dramatic - a 68% swing. Scientists conducting basic research using animals have reason for concern.

Perhaps not surprisingly, in view of the widespread practice of euthanising family pets with a terminal illness, people were slightly less concerned about animals dying than they were about them suffering.

The species concerned also makes a difference, with " .. experiments on monkeys are less likely to win support than those on mice" (Aldhous, 1999). Even when monkeys were not subjected to pain, illness or surgery, there was a drop in approval ranging from 8% for leukaemia, AIDS and cosmetic testing up to a massive 14% for basic biology.

When pain, illness, surgery or death was involved, only leukaemia research managed to attract a majority approval.

This study shows that people can weigh the pros and cons of animal experimentation. The most remarkable result is that a very modest statement about the possible benefits of animal research plus the statements that the research was on mice, would not cause suffering and was aimed at developing or safety testing a drug to treat leukaemia converted 24% support to an astounding 83%.

The lesson is that those who believe animal research should continue would need to detail the steps taken to minimise suffering, and produce compelling arguments to explain why the knowledge they expect to gain justifies the use of animals.

A second survey, using both qualitative and quantitative methods, was carried out by the MORI group for the Medical Research Council in the same year (MORI, 1999). This found that 80% of respondents believed animal research was

necessary as long as suffering was minimal, if it was for medical purposes or for life-threatening diseases and if alternatives were fully considered.

The most common view for most cases in the medical and agricultural and veterinary fields was that animal research was sometimes justified, the only exceptions being life-threatening diseases such as cancer, where the largest percentage thought it was always justified, and improving livestock to increase productivity, which an overwhelming majority of subjects wouldn't have a bar of. For safety testing, the strong majority opinion was that it was never justified. Over 60% were interested in discussing the topic or hearing more about it before forming a firm opinion, but only 14% were very interested and those opposed to animal experimentation were least inclined to want to know more.

Only 16% knew broadly (that is, within the range of 1-30%) what percentage of medical research involved animal experimentation. In other words, 84% thought, incorrectly, that the answer was greater than 30%.

Trust in regulation was very low. Suggestions for improving trust were

- more honesty or openness or access to information and decisions; and
- involvement of an animal welfare organisation (specifically, the RSPCA) in regulation.

How do people form their opinions about animal research? Basically, it seems, by the same sort of osmosis with which they form their views on most things - that is, from parents, friends, colleagues and their own experiences.

Biology classes in schools, colleges and universities play a large part in forming the opinions of youth - whether they attend these classes or not. Not many teachers are successful in convincing most of their students that the animal experiments they do are essential. Sadly, some teachers only manage to convince at least some students that they do not care for, and have no respect for, animals. For non-science students not attending these classes, animal experiments serve to reinforce their image of scientists as cold, unfeeling and bent on acquiring knowledge at any cost. Some teachers in some secondary schools discuss the ethics of animal experimentation in non-science subjects. Unfortunately, the anti-animal experimentation camp is much more organised in providing materials to students and teachers than is the scientific community.
The youth of today tends to be very internet savvy. Unfortunately, much of the material available on the internet is from radical animal rights groups. More moderate groups concerned with animal welfare are relatively silent. More and more scientific journals are putting articles, or at least abstracts, on line but very few of these concern animal research and/or indicate how or why animals have been used in research.

There is little informed debate in magazines of any kind. In 1997, *Scientific American* published a set of pro and con articles on the merits of animal use in biomedical research. The authors of the pro article were incensed that, while they were required to produce references and photocopies from primary sources to justify their assertions, the article on the other side was founded, so they believed, on invalidated misrepresentations of scientific fact. The editors of *Scientific American* refused to print their rebuttal and the authors had to resort to on-line publication on Biomednet to get their point across.

The mass media, in general, do their best to fairly and reasonably inform the public of the issues in such current hot topics as cloning, transgenic technology and xenotransplantation. Otherwise, articles on animal research tend to be either stories of extreme animal rightists running amok or of scientists apparently being unnecessarily cruel (like the branding of elephant seals on Macquarie Island) or conducting seemingly useless experiments (such as doping mice with methamphetamine and blasting them with loud dance music). Before you blame the press for seeking the sensational, think of all the sensational material anti-vivisectionists would glad supply them. Science and medical writers and editors do tend to check their facts.

But, journalists are no more energetic than the rest of the population and look kindly on stories they can use dropping into their laps. Most newspaper stories come from wire services and press releases, supplemented by interviews and, these days, a good deal of internet searching. In other words, as little legwork as possible, unless pictures are required. Unfortunately, the only stories that come down the wire are those of the type I mentioned before. Press releases involving animal research are even rarer. And much material on the internet is blatant anti-animal research propaganda.

If you want the media to play a role in informing the public and influencing them, you must do a bit of lap-dropping.

It might be possible to get a stand-alone story on the pros and cons of animal research published but most editors would look for some sort of hook - that

is, basically, as a follow-up, more in-depth treatment of something already published.

They would also be interested in good news stories of procedures lessening the usage or suffering of animals in research. Such stories could, however, boomerang, somewhat in the same way that the cynical greet ads for new, improved products - it must have been b– awful before.

What I would like to see is every release about a new treatment or new drug or research finding, the research for which involved animals, acknowledging this fact, explaining why it was necessary to use animals, and how their welfare was ensured. This could raise some alarm in some quarters but I would suggest that, if anyone can't do this, or is worried about presenting the facts to the public, perhaps they should ask whether the experiment should have been done.

It is wise to remember, too, that while most, but by no means all, medical and scientific writers do have a medical and/or scientific background, very few have any direct experience of animal research. Also, they are first and foremost journalists. They do not necessarily place the same emphasis on refereed reports and evidence-based conclusions as scientists are wont to do, but they do appreciate stories that contain validation of facts. They like pegs on which to hang stories - a link with some current hot topic or previous story. And, of course, a bit of 'human interest' never goes astray.

As things stand, Animal Ethics Committees are unlikely to influence community views on animal research - for a number of reasons. Many people don't even know of their existence. Those that do are often unclear about how they operate and don't really trust them to police animal research, regarding them as rather incestuous and/or a piece of elaborate window dressing. Animal Ethics Committees must do more to convince people that they really do care for animals used in research and training. They must be prepared to spell out grounds for their decisions and steps they have taken to ensure animal welfare. And they must do more to convince the community they are impartial.

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Animal use statistics: the New Zealand experience and perspective

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Abstract

In New Zealand, the Animal Welfare Act 1999 requires that all those who manipulate live animals for the purposes of research, testing and teaching must do so in accordance with a code of ethical conduct. Institutional animal ethics committees are required to individually assess and approve all manipulations. All code holders must keep readily accessible records on annual animal use statistics, and those statistics are published each year in the National Animal Ethics Advisory Committee's (NAEAC) annual report. The emerging trends in animal use statistics in New Zealand are discussed, along with the 2001 statistics results.

Discussion

Over the last two decades, the use of live animals in research, testing or teaching has been addressed as an important public policy issue in New Zealand. Our system of open government demands, wherever and whenever possible, that information of interest be made available to the general public.

The number of animals used in research, testing or teaching and the nature and purpose of animal use is one such example and ongoing efforts are being made in New Zealand to make this information more meaningful and accessible.

New Zealand has a philosophical and political commitment to the principles of replacement, reduction and refinement of the use of live animals in research, testing or teaching. Institutional Animal Ethics Committees also ensure community input to decision making on the use of animals in research, testing or teaching in both the public and private sectors.

The New Zealand regulatory system for the use of live animals in research, testing and teaching was introduced in 1987 and operated until the commencement of the Animal Welfare Act 1999. This latter Act came into effect on January 1, 2000.

The Act requires that all animal use be governed by a code of ethical conduct and defines manipulation as:

> *…interfering with the normal physiological, behavioural, or anatomical integrity of the animal by deliberately —*
>
> *(a) Subjecting it to a procedure which is unusual or abnormal when compared with that to which animals of that type would be subjected under normal management or practice and which involves—*
>
> *(i) Exposing the animal to any parasite, micro-organism, drug, chemical, biological product, radiation, electrical stimulation, or environmental condition; or*
>
> *(ii) Enforced activity, restraint, nutrition, or surgical intervention; or*
>
> *(b) Depriving the animal of usual care.*

The definition of manipulation does not include:

> *(a) Any therapy necessary for the welfare of an animal; or*
>
> *(b) The killing of an animal as the end point of research, testing, or teaching; or*
>
> *(c) The killing of an animal in order to undertake research, testing, or teaching on the dead animal; or*
>
> *(d) The hunting or killing of any animal in a wild state; or*
>
> *(e) Any procedure that the Minister declares not to be a manipulation.*

The code holders must hold readily accessible records on annual statistics that include:

> *(a) The name of each species of animal manipulated:*
>
> *(b) The number of animals of each species manipulated:*
>
> *(c) The purpose for which each animal was manipulated:*
>
> *(d) The source of supply of each animal manipulated:*
>
> *(e) The status of each animal manipulated (e.g. healthy, diseased, transgenic, pregnant, etc.):*
>
> *(f) The number of animals of each species manipulated:*
>
> *(g) The severity of each manipulation according to the following scale:*
>
> *(i) no suffering or virtually no suffering*
>
> *(ii) little suffering*
>
> *(iii) moderate suffering*

(iv) severe suffering
(v) very severe suffering
(h) The number of animals of each species that died or were destroyed in the course of, or subsequent to, their manipulation: and
(i) The number of animals manipulated which are still alive at the end of the year.

The New Zealand statistics are published each year in the National Animal Ethics Advisory Committee's (NAEAC) annual report. In 2001, a total of 318,500 animals were reported as having been manipulated. The species most commonly manipulated were fish, mice, sheep and cattle, while other miscellaneous species included crustacea, ferrets, wallabies, and bats. 1000 unborn mammals and 3400 birds before hatching were also included in the total.

As point (g) above states, all recorded manipulations must be graded according to a five-point severity scale, ranging from no suffering to very severe suffering. In 2002, 84% of animals experienced no or little suffering. On the other end of the scale, 0.8% of animals experienced severe suffering and 4.6% experienced very severe suffering. This figure is down from that recorded in 2000, where 14.7% of animals experienced severe or very severe suffering.

The number of each species manipulated fluctuates from year to year and 2001 was no exception. For several species, there was a marked increase, for others a marked decrease. The largest percentage increases were in the numbers of deer, reptiles and horses manipulated, although actual numbers are still comparatively small. The largest numeric increase was in fish, while mice and sheep usage dropped substantially. There was a small decrease in the total number of animals manipulated in 2001 compared with 2000 (5,900 less animals were manipulated in 2001).

In considering the annual animal use statistics, it is important to emphasise that every manipulation with a high negative animal welfare impact must be supported by a strong cost benefit justification. The justification is individually assessed and approved by the appropriate institutional animal ethics committee (all of which contain three external independent members) before the work may proceed. The final approval of a research project is often the result of a significant iterative process and every animal ethics committee benefits from the input and perspective of the external members.

New Zealand's commitment to openness and transparency does, however, have the potential to pose security threats to organisations involved in more invasive research and testing. Thus, New Zealand has adopted a policy of publishing data on a "national totals", rather than an institution-specific basis, to minimise the risk of such organisations being targeted by extreme animal liberation groups.

The collection of national animal use statistics is a significant logistical undertaking for both the research community and Government, and thus is undertaken on a national basis in relatively few countries internationally. The experience in New Zealand has demonstrated the complexity of the task, the importance of adequate resourcing, and the impact of legislative change, as well as the importance of collecting data on a consistent basis over reasonable time frames.

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Audits of animal research institutions – the NSW experience

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Abstract

The need for independent audits of animal research institutions is supported in Australia by a variety of groups including regulatory and policy bodies and animal welfare organisations.

Independent audits (or "inspections") of animal research institutions have been conducted in NSW since 1991, with the overarching aim of ensuring that the welfare of animals used in research is safeguarded in accordance with the NSW animal research legislation. These audits involve a comprehensive assessment of each institution's operation under the Animal Research Act 1985. As a result of the findings of inspections, mandatory requirements for improvements in institutions' activities under the Animal Research Act can be imposed.

The audits are viewed at a Government level as being of primary importance in ensuring that the NSW animal research legislation is effective.

Introduction

Within Australia there is widespread support for the concept of conducting independent audits of animal research institutions. This is in addition to the mechanisms already in place for approving and monitoring research at an institution level by Animal Ethics Committees (AECs). The support for independent auditing is from quarters including NHMRC Animal Welfare Committee, the Code Liaison Group (the National body responsible for reviewing the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes) and animal welfare groups under the umbrella of *Animals Australia*.

Discussion

In NSW a system for conducting independent audits of animal research institutions has been in place since 1991. The audits are carried out under the legislation, which encompasses animal research in NSW – the Animal Research Act 1985 (which incorporates the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes*). This system of independent auditing has been viewed at a Government level as being of primary importance in ensuring that the mechanism of "enforced self-regulation", which operates to govern animal research in NSW, is effective. Under this mechanism, animal research institutions self-regulate at a local level via their AECs. Government has a role in monitoring this self-regulation and, where necessary, enforcing compliance with the legislation, by means including conducting audits of institutions.

The audits conducted in NSW are referred to as "inspections". The method of conducting these inspections was based originally on methods used by the Canadian Council on Animal Care and the Association for the Assessment and Accreditation of Laboratory Animal Care.

The primary aim of these inspections is to ensure that the welfare of animals used in research is safeguarded in accordance with the NSW animal research legislation. Within this overarching aim, inspections incorporate three main functions. These are:

- an auditing function to assess compliance with the animal research legislation, including the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes;
- an educative function to assist AECs, animal carers and animal researchers to maintain and raise standards in line with the "3 Rs" of replacement, reduction, and refinement; and
- a regulatory function to enable the investigation of non-compliance with the legislation.

In NSW, all institutions carrying out animal research must be accredited as Animal Research Establishments. Routine inspections of these accredited Animal Research Establishments are carried out approximately once every three years. Where there are problems or particular issues that need following up, then the inspections of an institution may be carried out more frequently.

Inspections may take from half a day up to a week depending on the size of the İnstitution and the type of research being conducted.

The inspection team always includes an Inspector appointed under the Animal Research Act. These inspectors are veterinarians from the Animal Welfare Unit of NSW Agriculture. The Animal Welfare Unit has responsibility for the administration of the Animal Research Act. The inspection team also usually includes one or two members of the NSW Animal Research Review Panel (ARRP). The ARRP is a twelve-member body whose functions, as set out in the legislation, include the investigation and assessment of the conduct of animal research in NSW. The participation of its members in the inspection process assists ARRP to fulfil these legislative responsibilities. Commonly, one of the inspection team members from the ARRP will be one of its four animal welfare representatives, who are nominated by the RSPCA or the Animal Societies Federation.

The inspection is conducted in three phases. The first is obtaining information from the institution on its operations relevant to animal research, the second is visiting the institution and the third is developing a report for the institution. There is a standard checklist of items to be assessed to assist the inspection team in maintaining consistency between inspections (see checklist attached).

Prior to visiting the institution, a range of information is requested from the institution. This is in addition to a substantial amount of information that has already been obtained in association with the institution's accreditation as an Animal Research Establishment. Information that is requested is usually for a period dating back twelve to eighteen months prior to the inspection, and includes minutes of AEC meetings, records of inspections conducted by the AEC, the annual report of the AEC to the institution, and a sample of applications to conduct research that have been considered by the AEC.

On the day or days of the inspection, the inspection team first views facilities and animals. Records related to animal care and management are also viewed. If researchers and animal care staff are available, then the team takes the opportunity to talk to them about the work they carry out. Occasionally research procedures are viewed.

The inspection team then sits in on a scheduled meeting of the AEC. The purpose of this is to view normal operating procedures of the AEC. At the end of the AEC meeting, time is taken to discuss issues arising from the inspection with the AEC and to solicit feedback from AEC members.

An effort is made by the inspection team to meet with the head of the institution to explain the inspection process and to discuss issues relevant to the institution.

The information obtained prior to and during the inspection allows a wide range of aspects of the operation of the institution to be assessed.

Typically assessment would include:

- the constitution and operation of the AEC;
- the level of support provided to the AEC by the institution;
- the completion of research applications by researchers and the consideration of these applications by the AEC;
- the well-being of animals at the institution;
- the standards of animal care and monitoring;
- the facilities for housing and using animals; and
- the standards of record keeping.

In the third phase of the inspection process, the inspection team develops a report. The report is based on a standard format, but one that allows flexibility to cater for the differences in institutions and findings on inspections.

The report is considered at a meeting of the ARRP and final wording is agreed upon.

The report is then sent to the Director-General of NSW Agriculture for approval and the Director-General forwards the report to the institution.

Where serious problems are identified at inspection that, in the judgement of the inspection team, require rapid action, then these are raised with the head of the institution prior to the inspection report being formulated and approved.

Arising from the inspection, conditions may be placed on the accreditation of the institution. In addition, recommendations to improve standards, and commendations may be made by the ARRP.

Implementation of the conditions placed on the institution is mandatory. The institution is required to respond within three months as to how the conditions have been met. Assessment of the adequacy of these responses is made by the ARRP, which then advises the Director-General.

The sorts of requirements that may be placed as conditions usually relate directly to provisions of

the legislation. For example, an institution whose AEC has been meeting without a representative of each category of membership, as required by the *Australian Code of Practice*, may be required to re-examine all applications that were approved at such non-quorate meetings.

Another example would be where housing standards for a particular species fall far short of the principles outlined in the *Australian Code of Practice*. The institution may be prevented from holding that species of animal until the housing standards meet the approval of the ARRP.

In relation to the recommendations arising from inspections, implementation of these is not mandatory, but the institution is required to advise within three months as to how it has responded to the recommendations. If the recommendations have not been implemented, then the institution must explain its reasons for this.

Recommendations tend to be related to raising standards of AEC operation and animal care and management.

Examples of recommendations include:

- suggesting minor changes to housing to better meet the needs of the animals held, such as providing nesting material as well as bedding for rodents;
- recommending that closer attention be paid to animal care, such as foot trimming of indoor housed sheep; and
- suggesting changes to AEC operation, such as recommending that more frequent inspections be conducted.

Commendations are also seen as being important in recognising the good things being done at an institution. The range of activities for which institutions may be commended is wide. Examples include:

- innovations that contribute to improved standards of animal care and management (such as the provision of sheds for shelter from sun and wind in paddocks that do not naturally provide this protection, or the provision of additions in cages to meet species specific needs, such as providing hiding and climbing areas in cages for rats);
- innovations that improve the AEC's effectiveness (such as the production of an AEC newsletter to assist in communication with investigators / teachers); and
- Improvements made at an institution since the previous inspection.

In looking at the outcomes of inspections, some are more easily quantified than others. Where conditions are imposed and implemented then the outcomes are clear, resulting in improved compliance with the legislation, which in most cases will translate into improved standards of animal care and management.

Inspections can also have indirect effects, which do not lend themselves to measurement, such as raising the profile of animal welfare within the institution, resulting in increased resources being made available for animal care and management.

Objective measurements of the overall effects of inspections are difficult to make. In NSW, in the period since inspections began, standards of animal care and management and the sophistication of animal ethics committees in overseeing this have improved significantly. However, it is not easy to quantify how much of this is due to the inspection process and how much to other factors.

An additional outcome of the inspection process is that it allows the Animal Welfare Unit and the ARRP to identify common areas where institutions may need assistance. An example of this, which occurred early in the history of conducting inspections in NSW, was the development of a model research application form for use by AECs. This was developed in consultation with members of AECs in response to problems commonly found on inspections with information being presented in research applications. Numerous ARRP policy and guideline documents have subsequently been developed based on findings during inspections. Meetings held by the Animal Welfare Unit and ARRP for AECs have also commonly had themes to address areas of need as identified during the inspection process.

In terms of "accountability", the system in place provides for comprehensive accountability of research institutions to Government.

In terms of "transparency", general information on the inspection process is publicly available via the annual report of the ARRP and on the Animal Welfare Unit website (www.agric.nsw.gov.au/Aw/index.html). The annual report also records the names and dates of institutions inspected. In addition, an attempt is made in the annual report from NSW Agriculture to quantify the percentage of recommendations made to institutions that are implemented.

However, specific information about the findings and outcomes of inspections related to individual institutions is not accessible to the general public. The issue of what information should be available to the general public was discussed at length during a recent review of the Animal Research Act, but the outcome of this review is yet to be finalised.

Some of the strengths of the system in NSW are:

- the system has "teeth" - requirements for change can be placed on institutions;
- the involvement of a number of people on inspections with varying areas of expertise is valuable in providing differing perspectives and avoiding one personal opinion taking precedence. In addition, the scrutiny of reports by the varied membership of the ARRP ensures a broad representation of views; and
- the thorough nature of inspections ensures that a comprehensive examination and assessment of the institution's operation is carried out.

Some of the areas of strength can unfortunately also be sources of weakness:

- Due to the input of a number of people, it is necessary to be aware to guard against inconsistencies between inspection reports.
- The attendance of a number of people on inspections makes them both difficult to organise and costly to conduct.
- Feedback to institutions is delayed because of the process of consideration and approval of inspection reports.

On balance, the weaknesses of the system are minor in comparison to its strengths. The system of inspections carried out in NSW plays an integral part in ensuring compliance with the spirit and the letter of the animal research legislation, within a system of "enforced self-regulation".

Abbreviations

AEC	Animal Ethics Committee
ARRP	Animal Research Review Panel
NHMRC	National Health and Medical Research Council
RSPCA	Royal Society for the Prevention of Cruelty to Animals

… ***See over page for Site Inspection Checklist***

Site Inspection Checklist

This checklist is designed as a guide only - it may not be appropriate to assess all items on the list and / or additional items may be assessed. The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes should also be used as a guide.

2. Animal Ethics Committee
2.1 Membership
2.2 Minutes
2.3 Meeting Procedures
- 2.3.1 Quorum
- 2.4.2 Frequency of meeting
- 2.3.3 Circulation of agendas/ other material
- 2.3.4 Voting
- 2.3.5 Member participation

2.4 Guidelines / Policies
- 2.4.1 Animal care/ husbandry
- 2.4.2 Research procedures
- 2.4.3 Emergency procedures

2.5 Grievance / Complaint Procedures
2.6 Inspections/ Monitoring
- 2.6.1 Type
- 2.6.2 Frequency
- 2.6.3 Member participation
- 2.6.4 Records
- 2.6.5 Follow up mechanisms

2.7 Research Applications
- 2.7.1 Form
- 2.7.2 Consideration of issues

2.8 Issuing of Authorities
2.9 Annual Report
2.10 Member support
2.11 Communication
- 2.11.1 With Executive of institution
- 2.11.2 With researchers
- 2.11.3 With animal care staff

2.12 Methods for dealing with non-compliance

3. Animal Care and Monitoring
3.1 Well being of animals
- 3.1.1 Physical condition
- 3.1.2 Demeanour

3.2 Routine Care
- 3.2.1 Food
- 3.2.2 Water
- 3.2.3 Cleaning
- 3.2.4 Methods of monitoring
- 3.2.5 Identification of animals
- 3.2.6 Time animals held
- 3.2.7 Records
- 3.2.8 Transport
- 3.2.9 Euthanasia
- 3.2.10 Emergency procedures
- 3.2.11 Health - prophylactic measures
- 3.2.13 Methods of reporting and acting on injury, health or other animal welfare problems

3.3 Animal Production
- 3.3.1 Breeding systems
- 3.3.2 Breeding records
- 3.3.3 Productivity

4. Facilities (Buildings/ Cages / Pens / Paddocks etc.)
4.1 Type
4.2 Construction
4.3 Size
4.4 Lighting
4.5 Ventilation
4.6 Temperature control
4.7 Noise
4.8 Stocking rates
4.9 Bedding
4.10 Environmental enrichment
4.11 Storage Areas
4.12 Waste Disposal

5. Research Protocols/ Procedures (specific protocols may be assessed)
5.1 Type
5.2 Monitoring
5.3 Methods of assessing and alleviating pain/ discomfort / distress
5.4 Completion of research application
5.5 Adherence to protocol application and conditions of AEC approval

Compulsory audits of institutional animal ethics committees: the New Zealand experience

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Abstract

New Zealand legislation controlling the use of animals in research, testing and teaching began its development in the late 1970s. At that time, there was growing support in New Zealand for a regulatory system that was based on the Animal Ethics Committee (AEC) model, which supported the principle of institutional responsibility through approval and supervision by local peer groups. Although this model was successfully introduced, there was no mechanism for reviewing AECs and their effectiveness. The benefits of a mechanism for reviewing the effectiveness of AECs were first discussed in the early 1990s, and a voluntary and independent review system was introduced by ANZCCART. The reviews were undertaken by an independent person with experience in management and quality assurance systems. The Animal Welfare Act 1999 made the voluntary review system compulsory, as it requires that each code holder and its AEC(s) must be reviewed within specified time frames. Under the Act, the purpose of an independent review is to review compliance by a code holder, and by each AEC appointed by the code holder, with the requirements and standards of the Act, the code of ethical conduct and any regulations made under the Act. This paper examines the historical context within which compulsory audits of institutional animal ethics committees (AECs) developed in New Zealand, and current issues relating to the audits.

Discussion

Under the Animal Welfare Act 1999, anyone who uses live animals in research, testing or teaching must apply to the Director-General of the Ministry of Agriculture and Forestry (MAF) for approval of a code of ethical conduct (CEC). The Director-General may approve the CEC for a maximum of five years.

The code should contain the details of the policies, or the protocols, to be adopted and the procedures to be followed by the code holder, and by the animal ethics committee that they appoint. This process ensures that the use of animals in research, testing and teaching is regulated according to the requirements of the Animal Welfare Act 1999.

New Zealand's institutional animal ethics committees (AECs) are established in accordance with the Animal Welfare Act 1999, on the recommendation of the National Animal Ethics Advisory Committee (NAEAC), whose secretariat is provided by the Ministry of Agriculture and Forestry (MAF).

NAEAC advises the Minister on a number of other issues regarding the use of animals in research, testing, and teaching, and has a statutory function to provide information and advice to AECs, but is otherwise not directly involved in the running of AECs.

The AECs are responsible for the evaluation of animal use protocols to determine their ethical acceptability. The justification of each protocol is individually assessed and approved by the AEC before work may proceed. Each AEC contains three external, independent members, including a lay-member nominated by a local or regional council, a member of an animal welfare organisation and a veterinarian nominated by the New Zealand Veterinary Association.

New Zealand legislation controlling the use of animals in research, testing and teaching began its development in the late 1970s. During this time, there was growing support in New Zealand for a regulatory system that was based on the Animal Ethics Committees (AEC) model, developed in Canada, Sweden and Australia.

Before the Animals Protection (Codes of Ethical Conduct) Regulations of 1987, bona fide research workers were exempt from the provisions of the Animals Protection Act 1960. The new regulations required that use of animals in research, testing and teaching must be in accord with an approved code of ethical conduct. In systems of enforced self-regulation, independent monitoring and auditing, to ensure compliance, become particularly important credibility issues.

The 1987 Regulations had no mechanism for reviewing AECs and their effectiveness. Accountability rested merely on the integrity of the AECs and management structures within the

various institutions, a situation in accord with the accountability philosophy of the time. The benefits of a mechanism for reviewing the effectiveness of AECs was first discussed in the early 1990s and valuable discussions were held with the Canadian Council for Animal Care (CCAC).

In 1993, NAEAC (1) approached ANZCCART (NZ), requesting that it assist with setting up a review system for AECs. ANZCCART (NZ) offered a facilitatory and advisory service, with valuable input from Professor Bob Jolly. Following consultation with MAF, NAEAC and other institutions, ANZCCART (NZ) (2) put in place a voluntary and independent review system, with the purpose of:

> *Assisting an institution or individual with a Code and AEC with quality assurance management procedures in the use of animals in research, testing and teaching, within the context of the New Zealand law.*

These reviews were to be undertaken by an independent person with experience in management and quality assurance systems. The reviews were aimed at helping the institutions improve their working procedures, facilities, and accountability in the use of animals in research, testing and teaching. It was noted that:

To be effective, a Review System must be:

- *in accord with legislation;*
- *credible to the public and hence independent; and*
- *conform to accepted quality assurance principles.*

To be acceptable to the institutions concerned it must be:

- *facilitative and educative rather than have a policing role;*
- *backed by scientific information on the care and use of animals; and*
- *cost-effective (2).*

A number of pilot reviews were carried out by ANZCCART before the introduction of the Animal Welfare Act 1999, to ensure support for the concept within the scientific community.

The Animal Welfare Act 1999 made the review system compulsory, as it requires that each code holder and its AEC(s) must be reviewed within specified time frames (section 105). Reviews are conducted by an independent reviewer accredited by MAF, but appointed by the code holder.

Under the Act, the purpose of an independent review is to review compliance by a code holder, and by each AEC appointed by the code holder, with the requirements and standards of the Act, the code of ethical conduct and any regulations made under the Act (3). A satisfactory review report is a prerequisite to obtaining approval for the continuation of a code of ethical conduct for a second or subsequent term (3).

An accredited reviewer may review all aspects of the AEC's decision-making process but is not entitled to pass judgement on the validity or appropriateness of decisions except where failure to comply with the Act or poor process appears to have had a significant bearing on a decision.

Under the Animal Welfare Act, a review must be carried out within two years for a code of ethical conduct being approved for the first time, and again three years later. After that, reviews take place every five years. Under transitional arrangements, existing code holders must undergo a review between 2002 and 2004, depending on when their original code was approved.

The independent reviewers are accredited by the Director-General of MAF. Before granting accreditation, the Director-General must be satisfied that a person is a fit and proper person having regard to his or her:

- competence;
- character or reputation; and
- ability to maintain an appropriate degree of impartiality and independence when conducting reviews.

The accredited reviewers are themselves the subject of an audit, during the first year of review, and then every three years after. Three independent reviewers have been accredited to date. It is anticipated that about six to eight reviews will be accredited for next year's round of audits.

Summary

2002 is the first year that the compulsory reviews have taken place. Eight reviews have now been carried out by the independent reviewers, and MAF and NAEAC are considering their audit reports when reviewing applications by organisations for new codes of ethical conduct. This process has been very successful to date.

Acknowledgements

Input from A C D Bayvel, L A Carsons and G Sutherland in the preparation of this paper is gratefully acknowledged.

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Session Title:

Non-institutional (external) animal users

How best can Animal Ethics Committees (AECs) field external applications?

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Abstract

The Scientific Purposes Code (the Code) deals mainly with institutional AECs, that is AECs set up by, or associated with, institutions to assess animal use applications from staff or affiliates of the institution. However many AECs are asked to assess proposals from applicants who are not employed or engaged by an institution having its own AEC.

Not all AECs accept external applications, which creates a dilemma for the investigators needing to have their work assessed. External applications are increasing in some jurisdictions due to a number of factors such as changes to legislation and greater awareness of animal ethics issues.

Although we all work to a National Code, the different states have varying legislation and adopt different approaches to registration/licensing. There are a number of different models of AECs to cater for external applicants and our aim in this session was to find some practical solutions to some of the generic issues that are common to all these models. Delegates were divided into six groups and provided resolutions to common issues in dealing with external applications.

Commercial non-affiliated AECs were not considered a viable option by delegates due to concerns about accountability, conflicts of interest and profit-making. However fee for service on a cost recovery basis with members paid sitting fees was considered a viable option, provided there were legislative controls and independent audits.

AECs generally have no knowledge of external applicants and this can be overcome by the use of CVs, referees and peer review. Reporting, monitoring and site inspection are key concerns for external applications, especially for remote locations. The use of proxies and/or experienced staff from government agencies for monitoring and site inspections could overcome the problem.

Assessing external applications could expose institutions to corporate risk that raises legal liability issues. Institutions can minimise this risk by ensuring they require referees for the applicant, there is appropriate expertise within the AEC, the work is justified and the conditions of approval cover reporting and monitoring.

There are a number of different models of AEC that can provide this protection, but the delegates deemed the existing institutional AEC the most likely to give the best outcome in terms of animal welfare. The model of a Government agency AEC (e.g. a Director General's AEC) set up to assess external applications was also seen as a viable option.

There was a consensus that whatever type of AEC is used, the key considerations should be the welfare of the animals, equity for all animal users, transparency and public accountability.

Introduction

The Scientific Purposes Code deals mainly with institutional AECs, that is AECs set up by, or associated with, institutions to assess animal use applications from staff or affiliates of the institution. However many AECs are asked to assess proposals from applicants who are not employed or engaged by an institution having its own AEC. Some examples of these 'external' applicants are:

- environmental consultants;
- overseas and/or individual researchers;
- private companies or individuals;
- community wildlife groups; and
- fauna parks or sanctuaries

Not all AECs accept external applications, which creates a dilemma for the investigators needing to have their work assessed. External applications are increasing in some jurisdictions due to a number of factors that include:

- more redundancies = more private consultants;
- greater awareness of need for ethics approval;
- changes to legislation;
- increased registrations/product evaluations;
- environmental issues; and
- registration of users

Although we all work to a National Code, the different states have varying legislation and adopt different approaches to registration/licensing.

There are a number of different options for external users to access an AEC:

1. Individuals form an AEC to assess their own applications (and no others).
2. Use the AEC of an existing (probably large) institution.
3. Use a State Government AEC (if available) that has been specifically formed to handle external applications.
4. Use a commercial AEC (if available) that has been specifically formed to handle external applications.
5. Form a joint AEC serving a number of small institutions or bodies.

Whatever type of AEC is used, the key considerations should be the welfare of the animals, equity for all animal users and public accountability.

Discussion

Our aim in this session was to find some practical solutions to some of the generic issues that are common to all AEC models, but will vary in importance depending on the AEC's terms of reference for external applications.

We divided the delegates into six approximately equal workshop groups based on the different membership categories and backgrounds. We then presented each group with a scenario to address the following issues.

COMMERCIAL/NONAFFILIATED AECs - LEGAL ISSUES

Question:
How would we ensure code compliance and public accountability with commercial/non-affiliated AECs?

Resolutions:
1. It would be important to structure the ethics committee to ensure balanced representation.
2. The competence/character of the AEC members is important and there must be an assessment process.
3. Adequate training of AEC members would be crucial.
4. How/where would they get clients? Would a reputation as an easy touch or a tough committee affect their success as a business? An "easy" AEC could become a target for those who "shop around" when first seeking an AEC.
5. There would be potential for AEC members to compromise themselves – i.e. conflict of interest. The idea of a commercial AEC goes against structures/ethos/processes set out in the Code, especially with respect to the accountability of the AEC to the institution.

COMMERCIAL/NON-AFFILIATED AECs - MONEY ISSUES

Question:
Is profit-making acceptable for such AECs or should they operate on cost recovery only? How could these be controlled?

Resolutions:
1. Fee for service based on profit would be unacceptable for an AEC due to public perceptions and a lack of control over profit-making.
2. AECs that are currently working on a fee for service basis work on cost recovery with quite a large variation in fee schedules between AECs.
3. Profit-making could be perceived by the public as biasing the AEC decision or process and lead to lack of public accountability, transparency of process or undermine the ethics system.
4. Control of non-institutional AECs (and profit-making) could be achieved by legislation. The delegates felt that if fees were to be charged, members should be paid sitting fees and the AEC operate on a cost recovery basis only.
5. Most delegates found "sitting fees" to be appropriate for their AEC members although a much lower percentage actually reimburse their members. It was considered that Category C and D members should receive sitting fees or at least out of pocket expenses.
6. More importantly, control of any AEC (whether institutional or not) would need to be undertaken by an unbiased independent authority such as a Government agency (at the appropriate level). Self-regulation was not seen as appropriate.
7. Regular scrutiny under guidelines was seen as the best method of control over any AEC and an independent auditing process was the most common method. A Memorandum of Understanding could also be used if appropriate.

Question:
How could we ensure there is no conflict of interest arising from commercial AECs approving applications to increase their profit?

Resolutions:
1. Unless an AEC had exclusive market domination or external applicants were forced to access one particular commercial AEC, it is unlikely that a conflict of interest would arise.
2. There would need to be an independent audit process, preferably by a government agency.
3. If a number of commercial AECs were allowed to evolve within the market, could they compete with the institutional AECs? Should institutional investigators be allowed access to commercial AECs?
4. A Government / Director General's AEC was seen as an unbiased and publicly acceptable option for assessing externals, especially in conjunction with an auditing process.

Question:
Should external investigators be required to use one AEC or is it acceptable for them to "shop around" and use different AECs for different projects?

Resolution:
1. Overwhelmingly it was seen as unacceptable to allow applicants to "shop around" as it undermines the ethics system by removing the rapport between the AEC and applicants and increases the difficulty of monitoring and reporting.

PRACTICAL ISSUES WITH EXTERNAL APPLICANTS

Question:
How should the AECs handle the issue of lack of knowledge of applicants' competency, welfare views etc.?

Resolutions:
1. Ask the applicant for a CV, references and seek peer review if possible.
2. Preferably the applicant should be linked to an institution or sponsor that can vouch for their bona fides.
3. Chairpersons can network between other jurisdictions and AECs to check bona fides of applicants (but may be confidentiality issues involved).

Question:
How can the AEC overcome lack of command and control to ensure the applicant fulfils reporting requirements?

Resolutions:
1. Allocate individual sponsor or proxy to assist.
2. Ensure the applicant provides a full report on the activity and preferably publishes findings/results.
3. Investigate possibility of applicants paying a bond before carrying out the work.
4. Charge cost of site inspections to applicants.

Question:
How can the AEC monitor animal use and care, especially at remote locations?

Resolutions:
1. Require Investigators to report regularly and provide video or photographs to AEC.
2. Withdraw approval/terminate activity if there is non-compliance.
3. Ensure the AEC has appropriate expertise to monitor activity, use external agencies to source members e.g. National Parks representative for wildlife studies.
4. Appoint a proxy or independent reviewer to monitor the activity.

Question:
How can the AEC carry out site inspections to ensure AEC conditions are met, especially at remote locations?

Resolutions:
1. Review records regularly.
2. Ensure reporting is a condition of approval.
3. Appoint a proxy Inspector in remote locations e.g. Vet or stock inspector.
4. AEC can reserve the right to inspect at any time, costs to be borne by applicant.

CORPORATE ISSUES WITH EXTERNAL APPLICANTS

Question:
How can an institutional AEC minimise risks to itself and its Institution when it is assessing non-institutional applications?

Resolutions:

1. Actively seek referees for applicant's previous work.
2. Ensure the AEC has a member with specialist knowledge of species or seek specialist advisors.
3. Ensure work is justified, especially if applicant is from overseas wishing to work in Australia. Applicant needs to satisfy AEC they understand the Australian system. Also need to demonstrate capability in species to be handled. May be cultural issues to be addressed.
4. Develop contractual obligations with institutional agency.
5. Monitoring is an issue. If the AEC can't monitor, it shouldn't approve the activity. Distance from AEC is no excuse for not monitoring.
6. Ensure reporting is agreed to by applicant during assessment process.
7. Ensure SOPs are valid for work to be undertaken.
8. Appoint a proxy (e.g. National Parks ranger) to act of behalf of AEC for remote locations and consider use of video reporting.
9. Control situation at all times through conditions in approved application.
10. Charge applicants to cover costs of monitoring in remote areas.

Question:
What, if any, additional implications would there be for Institutions charging a profit-making fee for overseeing research?

Resolutions:

1. Possible liability to institution for not approving an application or not having given proper advice and direction.
2. Legal disclaimer on application suggested.
3. Professional indemnification may not be enough to protect contractual obligations.
4. Exemption under Trade Practices Act exists.

EQUITY OF ACCESS TO AECs FOR ALL ANIMAL USERS

Question:
Do you think the scientific community has a moral obligation to ensure all animal users have access to an AEC?

Resolutions:

1. There is an obligation to ensure all animal users have access to an AEC and the responsibility is at the community level (not restricted to the *scientific* community).
2. External applications should go to ethics committees with the best expertise e.g. wildlife applications to a government agency such as National Parks.
3. Delegates recommended a central body or mechanism to direct applicants to the 'best fit' committee.
4. A Government (e.g. Director General's) AEC could assess those (few) applications with no 'best fit'.
5. Committees should not be constrained by state (or national) boundaries in seeking specialist expertise.
6. External applicant should (at least) pay an administration fee to the AEC's institution.
7. Where it is impractical for the assessing AEC to monitor a project, an external applicant should pay the costs of an appropriate person nominated by the AEC.

EQUITY OF PROTECTION BY AN AEC FOR ALL ANIMALS

Question:
In terms of ensuring animal welfare, what are the strengths and weaknesses of the following models?

1. AEC set up by an individual to assess his or her own applications (and no others)
2. Existing institutional AEC overseeing external applicants.
3. State Government AEC that has been specifically formed to handle external applications.
4. Commercial / private AEC that has been specifically formed to handle external applications.
5. Joint AEC serving a number of small institutions or bodies.

Questions:
How could the weaknesses be overcome?
Which model is likely to give the best outcomes for the welfare of the animals?

Resolutions:

1. AEC set up by an individual to assess his or her own applications (and no others).

   <u>Strengths</u>
   i. AEC knowledge base.
   ii. The AEC would be familiar with the work being conducted by the individual.

iii. The AEC was likely to be geographically located in proximity to the work being conducted, which would facilitate monitoring by the AEC. It was however noted that a large number of individuals conducting research were likely to be involved in wildlife studies which did not lend themselves to local monitoring.

Weaknesses

i. Conflict of interest: This was thought to apply both if the individual (investigator) was a member of the AEC (which in the view of the group would be unacceptable) but also where the investigator was not a member of the AEC. It was considered that there would be an unavoidable degree of bias in the AEC's consideration of one individual's work.

ii. Insufficient activity/skill base: The AEC would have difficulty gaining proficiency in overseeing research projects because of the low workload.

iii. Loss of potential members for busier AECs: The setting up of AECs to oversee one individual or group could remove potential members to sit on AECs that oversee a larger volume of work at institutions.

iv. Cost of regulation: Cost to Government of monitoring a number of AECs overseeing individuals would be greater than for the majority of the other models. The cost to individuals of setting up their own AECs was also a consideration.

v. Legality: In some States/ Territories it may not be legal for an individual to set up their own AEC.

2. Existing institutional AEC overseeing external applicants

Strengths

i. Depth of AEC expertise: The AEC is likely to have a high level of expertise in overseeing research due to the volume of work it would be likely to be overseeing at the institution.

Weaknesses

i. Monitoring of work may be difficult if the individual is remote from the location of the AEC.

ii. Lack of knowledge of individual: The AEC may have limited knowledge of the qualifications and "track record" (including trustworthiness) of the individual.

iii. Lack of familiarity with the research: The AEC may have limited knowledge of the type of research being conducted by the individual and therefore the aspects likely to impact on the welfare of the animals used.

iv. Lack of compliance: Individuals would be outside the "framework" of the institution and therefore not subject to formal disciplinary measures and also not subject to "peer pressure" factors for compliance that normally would have a bearing within the institution structure.

v. Work overload: By accepting the additional work of overseeing individuals external to the institution, the AEC may be subject to an overload of work which could affect its overall effectiveness as well as leading to "burnout" and resignation of members.

3. State Government AEC that has been specifically formed to handle external applications.

Strengths

i. Expertise**:** If such AECs

had a reasonable volume of work to oversee then they would be expected to build up a good level of expertise in overseeing external applicants. Also if research from applicants were predominantly from one discipline (such as wildlife, which was likely to be the case) then proficiency in assessing such applications would be developed.

Weaknesses

i. Monitoring: The AEC would be required to monitor research from throughout the State/Territory that would be logistically difficult and possibly expensive.

ii. Lack of knowledge of individual: The AEC may have limited knowledge of the qualifications and "track record" (including trustworthiness) of the individual.

iii. Expertise: In States/ Territories where there is a low volume of work from individuals, the AEC may have difficulty building up expertise in approving and overseeing applications.

4. Commercial / private AEC that has been specifically formed to handle external applications.

5. Joint AEC serving a number of small institutions or bodies.
(*Apart from the issue of payment for service, models 4 and 5 were seen as raising similar issues and were considered together*).

Strengths

i. Efficiency: The use of one AEC for a number of applicants was seen as an efficient use of resources.

ii. Expertise: A single AEC overseeing a number of applicants could be expected to build up a level of expertise in assessing and overseeing research.

iii. Less conflict of interest: The problem of a conflict of interest with an individual establishing his or her own AEC would not exist with this model.

Weaknesses

i. Payment: Payment by the applicant may create an expectation of approval and place pressure on the AEC.

Question:
How could the weaknesses be overcome?

Resolutions:

1. Conflict of interest: It is thought that regulatory actions by Government (for example mechanisms for approving and auditing of AECs/individuals for compliance) would assist in ensuring that conflict of interest was controlled.
2. Lack of compliance: Where this is a problem, reports could be made to Government and/or approvals withdrawn.

Question:
Which model is likely to give the best outcomes for the welfare of the animals?

Resolutions:

1. Model 2, of an existing institutional AEC, is seen as being likely to give the best outcome in terms of animal welfare, provided the institutional AEC has the necessary expertise and resources (including time to oversee the external applicants).
2. Model 3, of a Government AEC, is also seen as being a reasonable option.

Conclusions

The workshop groups provided some useful guidelines on how best to deal with external applications. Delegates considered commercial non-affiliated AECs not to be a viable option due to concerns about accountability, conflicts of interest and profit-making. Fee for service based on profit would be unacceptable due to public perceptions and a lack of control over profit-making. However, fee for service on a cost recovery basis with members paid sitting fees would be a viable option, provided there were legislative controls and independent audits.

AECs generally have no knowledge of external applicants and this can be overcome by the use of CVs, referees and peer review. Reporting,

monitoring and site inspection are key concerns for external applications, especially for remote locations. The use of proxies and/or experienced staff from government agencies for monitoring and site inspections could overcome the problem, but it was felt that investigators should meet the costs. Reporting conditions should be clearly spelt out in the conditions of approval and the use of videos or photographs from remote activities could be useful.

Assessing external applications could expose institutions to corporate risk that raises legal liability issues. Institutions can minimise this risk by ensuring they require referees for the applicant, there is appropriate expertise on the AEC, the work is justified and the conditions of approval cover reporting and monitoring. The applicants should bear the costs of monitoring and site inspections.

There is a community obligation to ensure equal access to an AEC for all animal users. External users should be prepared to pay for assessment and monitoring of their animal use activities and AECs should not be constrained by state or national boundaries in seeking appropriate specialist expertise for the wide range of applications assessed.

It was agreed that there is a fundamental need for equity of protection by an AEC for all animals used for scientific purposes. There are a number of different models of AEC that can provide this protection, but the delegates deemed the existing institutional AEC the most likely to give the best outcome in terms of animal welfare. The model of a Government agency AEC (e.g. a Director General's AEC) set up to assess external applications is also seen as a viable option.

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Session Title:

What are the animal welfare outcomes?

Practical experience at the coalface of animal research: Modifying a surgical model to improve animal welfare and science outcomes

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ABSTRACT

Researchers attempting to undertake novel studies using animals are frequently handicapped by the limited information available in the literature on suitable experimental techniques. Often the techniques considered for possible use need to be adapted from other studies, and are frequently based on methods first used many years ago. While at the time of first description, these techniques may have been based on best practice, developments in the standards of animal welfare and methods to minimize the pain and distress can lead to a need for reassessment or modification of such techniques

In the present case, the research group wished to develop a model for studying cellular immune responses within the small intestine of sheep. The procedure involved creating an isolated loop of intestine, into which a novel vaccine would be delivered on several occasions. Once a reaction to the vaccine was identified, the isolated gut loop would be directly challenged and the degree of protection provided by the immune response measured.

A need to modify and indeed modernize the experimental procedure was identified during project planning. Previous surgical approaches were reviewed and options for improving the well being of the sheep were considered. Changes were incorporated into the anaesthetic protocol to utilize more recent drugs and to improve the analgesic programme. In the previously described techniques, a full laparotomy was required for each intervention into the isolated gut loop. We considered repeated laparotomy to be undesirable and that it might interfere with the response to vaccination. As a result, we decided to develop a less invasive technique for delivering the vaccine doses and the challenge compounds.

A laparoscopy method was developed where three trochars were inserted through the abdominal wall and injections made into the isolated gut loop via these. To minimize the problem of locating the isolated gut loop within the abdominal space, the gut loop was anchored to the peritoneal wall during the initial surgical procedure.

The method was validated using sheep euthanased at the completion of an unrelated research program. After euthanasia, the sheep were prepared for surgery and experience gained in locating trochars, visualizing the gut target and depositing samples within the gut. A repeatable technique was developed for use in the actual research program.

Evaluating the paper trail: the role of monitoring records

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Abstract

Monitoring of animals used for research purposes is essential to ensure that animals are maintained in circumstances which support their specific physiological, behavioural and psychological needs, that the impact of experimental procedures are managed, that unforeseen complications are promptly detected so that remedial action can be taken, that practices and procedures can be refined to minimise negative impact on animals, and that accountability is provided for the use of animals.

Important elements of effective animal monitoring include a holistic approach with checks and balances in all processes related to animal use, a flexible approach capable of dealing with the inevitable changes and unexpected events that will occur during the course of a project, good communication, co-operation and respect between all parties to ensure that problems are detected and managed quickly and effectively, documentation of the criteria to be used for the monitoring of animal well being, and documentation of the criteria that indicate when intervention (including euthanasia) will occur.

Many different strategies have been proposed for the monitoring of animals used in research. Monitoring records (the "paper trail") are an essential part of any monitoring strategy. Ideally, monitoring records should be specifically designed for each species and for each procedure used in a research protocol, should be relevant for the procedure and species, should be developed as part of the approval process for the project with input from all involved with the monitoring of the animals, and should be treated as "living" documents with the suitability and relevance of the monitoring criteria, intervention points and endpoints being reviewed frequently as the experiment progresses.

This paper summarises an approach to the development of monitoring strategies based upon available literature and practical experience, emphasising their consideration during the planning, conduct and review stages of a project. Processes are also proposed for the involvement of the Animal Ethics Committee (AEC) during the development and implementation of monitoring strategies, in accordance with Australian Code of Practice for the care and use of animals for scientific purposes" (NHMRC et al, 1997).

Introduction

Monitoring of animals used for research purposes is essential to ensure that:

- animals are maintained in circumstances which support their specific physiological, behavioral and psychological needs;
- the impact of experimental procedures are managed;
- unforeseen complications are promptly detected so that remedial action can be taken;
- practices and procedures are refined to minimise negative impact on animals; and
- accountability is provided for the use of animals.

The requirement to minimise unnecessary pain, distress or cannot be achieved unless these adverse effects are detected and monitored in the first instance. The dictionary definition of "monitor" is "*to check, observe or record*" or "*something that serves to remind or give warning*". It is clear that for any system adopted for the monitoring of animals to be effective, it must include not only a strategic approach to the observation of animals, but also a system for the recording of observations. Written records (the "paper trail") facilitate the assessment of an animal as its clinical condition changes, the determination of whether an intervention point has been reached, and the review the effectiveness of the monitoring strategy as a project progresses.

Morton and Griffiths (1985) described the scoring system as a strategy for animal monitoring. This system has since been refined into the binary score sheet system or monitoring checklist (Morton, 1995, 1998a, 1998b, 1998c, 2002). A recent survey of current practices in the United Kingdom for the monitoring of animals demonstrated that, in the absence of practical techniques that could feasibly be used to assess animals objectively, binary score systems or monitoring checklists appeared to be the most effective way of assessing animals

and recording observations (Hawkins, 2002). The survey also revealed that reluctance to use scoring systems was generally due to lack of time to implement them and a lack of awareness that checklists can be continually adapted, tailored to projects, and binary rather than numerical.

At first glance, formal monitoring strategies and checklists can appear very daunting. This paper summarises an approach to the development of monitoring strategies based upon available literature and practical experience. Processes are also proposed for the involvement of the Animal Ethics Committee AEC during the development and implementation of monitoring strategies, in accordance with the "Australian Code of Practice for the care and use of animals for scientific purposes" (NHMRC et al., 1997). Formal monitoring strategies should be considered at all stages during the life of a project - at the planning stage of a project during the consideration of the application to the AEC, during the conduct of the experiments, in the event of adverse events or unexpected deaths, and at the review stage so that the effectiveness of the monitoring strategy can be improved.

Planning Stage - Development of a monitoring strategy by the research team

The development of a monitoring strategy (Canadian Council on Animal Care 1998, Lloyd and Wolfensohn 1998, Morton 1995, Morton 1998a, 1998b, 1998c, Morton 2002, Flecknell 1994) requires decisions to be made regarding:

- the clinical signs or observations that will be used to assess an animal's well-being or clinical condition as the project progresses;
- the system for the recording of observations;
- the frequency of monitoring;
- the clinical sign or combination of clinical signs that will indicate that intervention (including euthanasia) is necessary;
- the actions that will be taken if a problem is detected; and
- the persons who will conduct the monitoring and their training.

1. Define appropriate signs or monitoring criteria

The clinical signs or observations that will be used to assess an animal's condition must be defined. These include general signs of ill-health or an abnormality, and signs specific for the experiment or procedure to be performed.

So that appropriate clinical signs may be selected, researchers must first be aware of what is normal for the particular species and strain of animal that will be used. The animals should be observed during the acclimatisation period so that the researchers become familiar with the normal behaviour of the particular group of animals, or the individual animal.

The general signs of abnormality in the animal should then be identified. Signs of pain and distress vary not only with the species, but also between strains or breeds within the same species, and even among individuals within a strain or breed. Broad groups for a general preliminary screening may be:

- general appearance (e.g. coat);
- posture;
- movement/activity;
- food and water intake;
- defaecation and urination; and
- body temperature.

Finally, abnormal signs relevant to the specific experiment or procedure to be performed should be identified. A simple approach is to consider the procedure that will be performed, identify possible adverse effects that may occur following the procedure, and then the probable signs associated with these adverse effects. For example, adverse effects following intestinal surgery may include peritonitis. Specific clinical signs that would be expected in an animal with peritonitis (depending on the species) include boarding of the abdomen, grunting or vocalisation on abdominal palpation, and fever. Animals should therefore be observed for the development of these signs. In situations where the adverse effects of a procedure are not known, useful information resources include published reports of a parallel experimental condition, previous experience of colleagues, information from veterinarians and animal technicians, or the results from pilot experiments. One approach could be to consider how one would assess the well being of a companion animal. Extrapolation from human to animal can also be used, that is, ask the question "what would a human feel if he/she had to undergo this procedure". This is an especially useful tool when teaching students about the concept of monitoring criteria.

2. Determine appropriate points when intervention is necessary

In experiments involving animals, any actual or potential pain, distress, or discomfort should be minimised or alleviated by choosing the earliest endpoint that is compatible with the scientific objectives of the research. Researchers should

determine which observations are the most significant predictors of further deterioration in the animal's condition, and then identify the earliest point at which those signs appear. It is important to realise that, because many animals do not readily exhibit clinical signs of pain or distress, many criteria used to monitor animals are indicators of more substantial adverse effects rather than mild or moderate pain suffering or distress. In addition, in many prey species such as the rat or mouse, signs of pain or distress may be transient and interspersed with normal behaviour (Roughan and Flecknell, 2001). A "sick" rat is often described as one that is hunched in the corner of a cage, with a rough coat. However, a rat behaving in this manner is no longer able to suppress pain-coping behaviour.

3. Determine actions

Actions that will be taken when a particular sign, or combination of signs, are observed in an animals should be defined. Such actions or interventions may include:

- more frequent observation;
- consultation with a veterinarian;
- administration of specific treatment (e.g. an analgesic agent);
- euthanasia of the animal; and
- removal of the animal from the protocol.

4. Determine monitoring frequency

The frequency of observations should be such that areas of concern and potential problems can be detected earlier rather than later, and therefore animal suffering can be alleviated earlier rather than later. The frequency of observations should increase if there is potential for increasing pain or distress. For example, in some experimental infections, hourly observations may be necessary to identify the point at which the selected "endpoint" has been reached and the animal's pain or distress must be terminated.

5. Training

All persons responsible for making observations of the animals from which an endpoint will be determined, should be competent in evaluating the normal physiology, behaviour and body condition of the animals under observation, and the anticipated specific changes from normal. Provision of appropriate training prior to the commencement of a project should be addressed by the research group, the AEC and the institution. Training should be provided on a needs-assessment basis, and should encompass not only techniques but also the responsibilities of the researchers with respect to monitoring of animals. Training should incorporate workplace assessment, with further training as necessary.

6. Team approach

Monitoring strategies should be developed with input from all involved with the monitoring of the animals used for the research project, and persons with relevant experience with the species to be used and the procedures to be performed. This team approach should include the researchers, research students, veterinarians, and animal technicians. Going through the process of development of monitoring strategies can be used as a training tool for students.

Planning stage - Documentation of the monitoring strategy

1. Monitoring checklist

The monitoring strategy should then be documented into a monitoring checklist, as recommended by Morton and others (Canadian Council on Animal Care 1998, Lloyd and Wolfensohn 1998, Morton 1995, Morton 1998a, 1998b, 1998c, Morton 2002). Thus, the monitoring checklist should include the following elements:

- general signs of abnormality for the species, strain or individual;
- specific signs of problems which may arise from the procedure performed;
- documentation of points where some sort of intervention is required;
- documentation of endpoints where euthanasia is necessary; and
- provision for details of any treatment given so that their effectiveness can be assessed.

Other factors that can be included are details of any special husbandry requirements for the care of animals and identification of any samples that should be taken from an animal should its euthanasia be necessary in absence of the research team.

The descriptions of the monitoring criteria should be phrased so that a "negative" sign is used to indicate "no problems", and a "positive sign" is used to indicate that there may be a potential or actual problem because of the clinical sign or behaviour. For example, the term "isolation" should be used rather than "social interaction", or "laboured respiration" rather than "respiratory pattern".

The inclusion of an NAD (No Abnormalities Detected) box in the checklist should be considered. This box could be used by an experienced person who would have little difficulty in assessing whether or not an animal, or group of animals, was unwell. If an animal was unwell, the detailed checklist should then be used to make judgments over actions to be taken. The Chief Investigator for a project must ensure that misuse of the "NAD" box by inexperienced people does not occur.

2. Specificity of a monitoring checklist

Ideally, a monitoring checklist should be specifically designed for each species and for each procedure. Monitoring criteria will differ according to the type of experimental work, as well as between species and individuals. For some projects, several different monitoring checklists may be necessary in order to cover different phases of the work. A monitoring checklist must be relevant for the procedure. For example, a generic checklist for mice could be used as a starting point, but should not necessarily be used for all projects involving mice.

3. Simplification when possible

Simple checklists can be developed for use during periods in the project where the welfare of the animals is of less concern, for example, during the acclimatisation period, or when an animal has recovered from a particular procedure (Appendix 1). A simple checklist would incorporate an "NAD" box, with the more detailed monitoring checklist used if any abnormality was detected.

Planning Stage - Involvement of the AEC

Agreement on the monitoring strategy should form part of the application process to the Animal Ethics Committee. The AEC can be involved in the fine-tuning of the monitoring criteria and intervention points in consultation with the research team. Thus, all criteria for monitoring and subsequent actions are agreed to, and documented, prior to commencement of the project. The AEC must also ensure that the researchers have the appropriate experience and/or training to effectively implement the monitoring strategy.

Conduct of experiments

1. Recording observations

Once the project has been commenced, the first few animals undergoing a novel procedure must be observed very carefully to determine whether or not the predictions of the likely adverse effects were accurate. The initial study should be timed so that the critical period for the animals occurs during normal working hours. This will assist in ensuring that appropriate observations are made, and that suitable advice is readily available (for example, from veterinarians or senior researchers).

Animals should be checked for all criteria listed in the checklist. A "negative" sign should be recorded if the sign is absent, or a "positive" sign if the abnormality is present. If unsure, record a "positive slash negative" (+/-) sign. Gradations of the "positive" sign can be used to indicate severity of the abnormality. Other signs that were not predicted at the planning stage may be important. Thus, animals should be examined for any other abnormal clinical sign. If abnormalities are observed which are not included in the checklist, these should be recorded. Therapeutic medications should be recorded, so that their effectiveness can be assessed, for example, in terms of pain relief, or the reversal of abnormal clinical signs.

A single checklist could be used for an individual animal, or a group of animals, depending upon the nature of the study and the species involved.

Monitoring checklists invariably take time to complete. Nevertheless, suitable recognition must be given to their importance in the overall monitoring strategy, particularly during the review stages. Rather than abandon the use of monitoring checklists, or use them reluctantly or carelessly, researchers should develop systems to address this issue. For example, use of the "NAD" box can reduce the time taken for an experienced person to complete the checklist. As described previously, simple checklists can be used during the acclimatisation period, or when an animal has recovered from a particular procedure.

2. Keep records with the animal

To ensure that all involved with the care of an animal can make informed decisions about the animal's welfare, monitoring checklists must be kept in the facility with the animal. This practice can easily be overlooked, with the checklists kept with other experimental records in the researcher's office.

3. Assessment of animals and subsequent actions

Use of monitoring records such as a monitoring checklist allows comparisons between time points and reduces the variability in interpretation of signs. Thus, it is easier to assess an animal as its clinical

condition changes, and to determine whether an intervention point has been reached.

If the criteria in the checklist have been framed correctly, an abnormality will be recorded as a "+" sign. It is therefore is more easily and quickly detected within the checklist. Subsequent actions are determined by the nature of the abnormalities, and the actions or endpoints that have been agreed to, and documented in the checklist.

Problems must always be dealt with immediately upon detection. At the very least, the detection of an abnormality, or a combination of abnormal signs, would result in an increase in the frequency of observations. The aim of the checklist is to detect problems before they result in pain or distress to the animal, or the death of the animal.

If an animal dies unexpectedly, an autopsy should be performed so that the cause of death can be determined and the monitoring strategy altered if necessary.

4. Use of pilot studies

Preliminary or pilot studies can be very useful in determining monitoring criteria, intervention points and endpoints, and the frequency of observations required to set an earlier endpoint, especially when the effects of a procedure are unclear. Conducting a pilot experiment also provides the opportunity for all persons to become experienced with the expected signs and symptoms.

Conduct of experiments - Involvement of the AEC

The records of animal monitoring should be inspected and reviewed by the AEC during its routine inspections of research projects in progress, and during inspections of animal facilities where research animals are housed.

The AEC must be advised of any problems or adverse events. These requirements are included in the Australian Code of Practice for the care and use of animals for scientific purposes (NHMRC et al, 1997) that states that "an autopsy should be performed when an animal dies unexpectedly" and that "investigators should promptly notify the AEC of any unexpected adverse effects which occur during the period of the approved project and which impact on the welfare of the animals". While the Code currently uses the word "should" rather than "must", most AECs would view with concern any adverse event that was not reported, or if an autopsy was not conducted when an animal died unexpectedly. Reporting to the AEC permits the committee to assist with any investigation of the incident to prevent its recurrence, and to prevent any compromise to animal welfare and the experimental model. It also serves to educate the AEC by advising it of any problems with procedures that have been approved.

Review of the monitoring strategy

It is during the review process that the value of written monitoring records is particularly highlighted.

1. When?

The monitoring strategy should be reviewed as the project progresses. This is particularly important for new procedures or when the effects of a procedure on the animals may not be clear. There should be a review in the event of any unpredicted or unexpected problem. Review should also be scheduled for strategic points during the entire project, for example, following use of the first group of animals, at the conclusion of a particular section of the study, or even on a regular weekly basis.

2. What?

A monitoring checklist should be treated as a "living document" with the suitability and relevance of the monitoring criteria constantly reviewed. Signs that are found to be relevant to the procedure performed can be added. Signs that are found to be irrelevant can be deleted. A review should include the effectiveness of the criteria used to determine that an action must be taken, including euthanasia, especially if animals are found dead during the experiment. Could the deterioration in the condition of the animal be detected earlier using less severe signs? A review should include the effectiveness of any therapy that was administered. Was the animal's pain alleviated? Did the abnormal clinical sign resolve? The experimental protocol should be amended or refined in the light of any adverse events.

Review - Involvement of the AEC

There should be involvement of the AEC in the review process. At a minimum, AEC approval should be required for any changes to intervention points or humane endpoints. AEC approval must be obtained prior to the implementation of any amendments to the approved protocol. AEC representatives may be involved in the "day-to-day" evaluation of the

effectiveness of the monitoring criteria or endpoints, particularly if a project is associated with specific concerns or involves a pilot study. The AEC should be involved with the review of the monitoring strategy following an adverse event or unexpected death. The use and effectiveness of monitoring checklists should be actively reviewed by the AEC during its routine inspections of research in progress, when project records are examined.

It is important that there is some degree of flexibility in the procedures adopted by the AEC with respect to monitoring strategies for an approved project. Procedures should take account of the inevitable unexpected events that will happen during the course of a project, and should foster and promote the concept of monitoring checklists as "living" documents. If the system is inflexible and requires extensive prior paperwork, it is likely that the review of monitoring checklists "on the run" will be stymied.

Practical examples

This first example (using a hypothetical case) describes how a monitoring strategy can be developed and refined as the study progresses. The aim of the project was to develop a specific lung infection model in the rat, with the animal being infected with bacteria via the trachea. The organism had never previously been used in the rat. In humans, it caused severe lung pathology and even death.

The research team determined that the general indicators of adverse effects or ill health in the rats were lack of inquisitiveness, inactivity, isolation, huddled or hunched posture, ruffled coat, and porphyrin staining of the eyes or nose. It was anticipated that the acute phase of the infection would resolve within 24 hours. Within this time-frame, specific abnormal signs considered to be indicative of lung infection included shallow breathing, increased breathing frequency, and blue extremities. Loss of body weight was proposed as an objective indicator of ill health once the acute phase had passed.

The research team proposed that the frequency of observations should be increased if rapid breathing was observed. The animal would be euthanased if there were signs of laboured breathing and blue extremities. The research team also proposed that, following infection with the organism, the animals would be monitored every hour until the end of the working day, and then the following morning. After 24 hours and once the acute phase of the experiment had passed, daily monitoring was proposed. However, during consideration of the animal ethics application, the AEC was concerned that there was insufficient information on the development of the lung infection or the virulence of the organism in the experimental species, that is, the rat. Thus it was agreed with the researcher that a pilot study would be conducted to more closely define the development of the infection in the rat. The animals would be monitored at hourly intervals during the suspected acute phase, that is, for the first 24 hours.

During the pilot study, rats exhibited signs of inactivity, ruffled coat and rapid breathing. In accordance with documented actions, the frequency of observations was increased to 30-minute intervals. However, at the time of the next assessment, some animals were found either moribund or dead. Autopsies demonstrated overwhelming lung infection. The pilot study was then halted.

During the course of re-evaluation of the model by both the research group and the AEC, and following successive pilot studies using lower inoculum doses, it was evident from the monitoring records that, for this model, "blue extremities" was not a clinical feature of animals found to have significant lung infection at autopsy. An increase in respiratory effort was a significant indicator of irreversible lung infection during the acute phase, in combination with reduced activity and 15% body weight loss. Thus these signs were used as humane endpoints (see Appendix 2). The outcome was the use of a significant lower dose of the organism that resulted in less severe clinical changes in the rat, while still producing sufficient pathological changes in the lungs to achieve the research aim.

Appendix 3 illustrates how a detailed checklist can be linked to a simpler checklist that is used during the acclimatisation period of an animal prior to a surgical procedure, and when the animal had fully recovered from the surgery prior to the final non-recovery procedure.

Conclusion

Monitoring of animals in research is essential to manage the impact of experimental procedures, to consistently detecting areas of concern in the early stages, and therefore to prevent avoidable animal suffering. Important elements of effective animal monitoring include a holistic approach with checks and balances in all processes related to animal use, a flexible approach capable of dealing with the inevitable changes and unexpected events

that will occur during the course of a project, good communication, co-operation and respect between all parties to ensure that problems are detected and managed quickly and effectively, documentation of the criteria to be used for the monitoring of animal well being, and documentation of the criteria that indicate when intervention (including euthanasia) will occur. The recording of observations or the "paper trail" is a critical element of any monitoring strategy. Current literature supports the following advantages of a strategic approach to the monitoring of animals, AND the recording of observations:

- A team approach to the development of the strategy ensures that all relevant persons are aware of their responsibilities.
- Monitoring criteria, and actions to be taken, are agreed to and documented prior to commencement of the project.
- It ensures close observation of animals especially at critical times in the project.
- It ensures a consistency of monitoring according to the agreed criteria.
- Variability in the interpretation of signs is reduced.
- Actions are taken according to documented procedures and endpoints.
- Unforeseen complications can be promptly detected so that remedial action can be taken.
- The effectiveness of therapy intended to relieve adverse effects can be more easily determined.
- Intervention points and humane endpoints can be more readily identified and refined.
- Periodic and strategic review results in effective refinement of the experimental protocol to minimise negative impact on animals.
- It can be used to train new staff, raising their awareness and confidence.
- Monitoring records can increase accountability regarding the use of animals in research.

Whatever approach is taken, it is important that strategies for the recording of observations and the assessment of animals are considered at all stages of the process related to animal use. These include the planning by the research group, the process of approval by the AEC, review at regular times during the conduct of the project by both the research group and the AEC, and in the event of adverse events or unexpected deaths.

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….. See over page for Appendices

APPENDIX 1

The University of Newcastle

PROCEDURES RECORD / TREATMENT SHEETS

Ethics No ..... Species ..... Strain .....……

Group/ Individual Identification ..... Cross Reference# .....

Date	Checked *		Details (procedure or treatment)	Initials
	NAD	Checklist		

* Please mark “NAD” if “No Abnormalities Detected” OR “Checklist” when records transferred to monitoring checklist, or details of procedures or problems in the “Details” column.

\# Use this section to cross reference an animal removed from a group to an individual record sheet.

APPENDIX 2

The University of Newcastle

RAT Identification #					
Date and time of infection:		**Initial Body Weight:**			
Date					
Day					
Time					
Not inquisitive or alert					
Not active					
Isolated					
Huddled, hunched posture					
Ruffled coat					
Porphyrin staining – eyes or nose					
Rapid or shallow breathing					
Increased respiratory effort					
Laboured breathing					
Blue extremities					
Body weight (g)					
Weight change (+ / - %)					
Other signs					
Comments					
Signature					

Frequency of observation: Hourly for 12 hours; then 4-hourly for 24 hours.

Intervention points: Increase frequency of observations to 30 minutes if any abnormalities are seen.

Humane Endpoints: Increased respiratory effort with reduced activity and ≥15% body weight loss

If animal requires euthanasia: Remove lungs and thoracic lymph nodes. Place into sterile container. Collect blood sample (heart or major vessel) into lithium heparin and EDTA (haematology, and biochemistry).

APPENDIX 3

The University of Newcastle

PROCEDURES RECORD / TREATMENT SHEETS

Ethics No: 999 1299 Species: Sheep Breed: Mixed

Individual Identification: Sheep #2 #Cross Reference: Monitoring checklist 2

Date	Checked *		Details (procedure or treatment)	Initials
	NAD	Checklist		
15/3/99	✓		Delivered from Mr Smith's farm.	AB
16/3/99	✓			AB
17/3/99	✓			AB
18/3/99	✓			AB
19/3/99	✓			AB
20/3/99	✓			CD
21/3/99	✓			CD
22/3/99		✓	Surgery performed. (See monitoring checklist)	AB
29/3/99			Transferred from monitoring checklist.	AB
30/3/99	✓			AB
31/3/99	✓			AB
1/4/99			Animal euthanased - completion of project.	AB

* Please mark **NAD** if "No abnormalities detected" OR "**Checklist**" when records transferred to monitoring checklist, or details of procedures or problems in the "Details" column.

Use this section to cross reference an animal removed from a group to an individual record sheet.

Project audits

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ABSTRACT

Under the Victorian prevention of Cruelty to Animals Act 1986, authorised officers inspect licensed scientific establishments to identify whether there is compliance with licence conditions and also to investigate complaints. One of the processes used in Victoria to identify whether there is compliance with the licence conditions and investigate complaints is the auditing of Animal Ethics Committee (AEC) approved projects. Project audits can also provide important feedback on record systems and AEC procedures to the researchers, animal house staff and the AEC and can help to identify whether any identified non-compliance is related to systemic problems in these areas.

The procedure is as follows:

- Identify one or more groups of animals that were issued to the project of interest from the animal house records if the animal house keeps such records. Please note that it is a requirement of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes that the person in charge of the animal house keeps records of the allocation of all animals (section 4.5.8(i)).
- Identify the history of the use of these animals in the project as described in the researcher's records. Please note that section 3.1.9 of the Code clearly requires researchers to keep records of the use and monitoring of animals in scientific and teaching activities.
- Compare the issue and use of the animals against the AEC approved project.

From this procedure the following questions should be able to be answered:

- Do the animal house records provide the information they are supposed to?
- Do the researcher's records provide adequate description of the conduct of the project?
- Does the AEC paperwork adequately describe the project?

The answers to these questions will allow regulators, animal house staff, researchers and the AEC to test the record systems, investigate problems and identify ways to improve the approval and conduct of projects.

Systematic environmental enrichment in a zoo setting

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Abstract

The application of the 3 Cs of behavioural enrichment, Complexity, Choice and Change should be a basic rule in the daily husbandry of captive animals to ensure their psychological well being. In practice planning and evaluation are important to ensure the effectiveness of the process. The process of effective enrichment implementation involves goal setting, a knowledge of the wild behaviour of the species as well as the captive and individual behavioural profiles, assessing devices, putting together a workable enrichment schedule and fitting that into the daily husbandry routine, evaluation of the effectiveness of the programme by observation and changing it as necessary with re-assessment as an ongoing process. Ideally, this process would be put in place for all species but it is particularly important when there is a behavioural problem to be treated. Bears as a group are particularly prone to developing a pacing stereotypy in captivity. The example of a pair of sun bears at Taronga Zoo will be explored through the implementation of the enrichment process and evaluating its effectiveness in their on-going management.

Introduction

Firstly what is environmental enrichment? It is a difficult term to define adequately but a general working definition is that it covers all the techniques used to stimulate natural behaviour in captive animals. In a zoo setting this includes the behavioural design of exhibits but, as well, explores the stimulation of locomotive, feeding, sensory, social and cognitive aspects of animal behaviour.

Dr David Shepherdson, one of the founders of the modern concept of zoo environmental enrichment and main researchers in the field, lists the benefits of enrichment under three headings. (Shepherdson, 2001).

Animal welfare: This emphasises the importance of maintaining the psychological as well as physical well being in captive animals. Enrichment can enhance this in the following ways:

- Increase physical fitness
- Provide mental stimulation
- Promote species typical behaviour
- Improve reproductive success
- Develop learning, adaptation and coping skills
- Enhance immune function

Animal management tool: The use of operant conditioning with positive reinforcement is one of the techniques making an enormous difference in the following ways:

- Facilitate shifting
- Reduce stress during husbandry procedures -
- Alleviate wear and tear on exhibit
- Facilitate introduction

Visitor Experience: Surveys show that zoo visitors stay up to 10 times as long to watch animals involved in active appropriate behaviour. They also do notice and comment on behavioural problems. Enrichment can enhance the visitor experience in the following ways:

- Offer educational experience
- Promote conservation via an emotional connection to the animals
- Present a positive impression of the animals' psychological state and therefore a positive impression of the institution-

However the question can be asked, "Are these benefits generally achieved and is all enrichment effective to this level?"

This is illustrated in a quotation is taken from the recent Disneyworld enrichment website (www.csew.com/enrich):-

> "If asked the question, "Do you have an enrichment program or a training program at your zoo?" a staff member might point to a plastic ball floating in a sea lion pool. "Yes, see, we're providing enrichment for the sea lions." That same person might talk about a diabetic monkey that has been trained to take insulin injections. "Yes, we have a training program." But what happens if the keeper that trained that monkey leaves the zoo? Does the ability to inject the monkey leave with that keeper? Do the sea lions receive enrichment every day or just on the days that a highly motivated keeper works?

What is the goal of adding a ball to the sea lion's pool? Was it successful in enriching the sea lion? How do you know? …… These are all difficult questions to answer and perhaps even more difficult to ask."

To most zoological institutions, a fully effective programme for all species is still a future goal. Most existing programs are reactive rather than proactive, focussing on species where there are behavioural problems or on species, which react well and obviously to enrichment initiatives. Staff may need to make choices as to where limited resources of time and money can best be used. Keepers have to find ways of fitting more into an already very busy schedule. So, too often, enrichment is left to the motivation of good keeping staff, of which, fortunately there are many.

The three C's of enrichment are: Complexity, Choice, and Change. Ideally every keeper would keep these three concepts firmly in mind as they moved around the zoo and every day try to provide something of each for each animal in their care.

However, at least until enrichment is firmly established as an essential aspect of animal husbandry, an organised programme needs to be implemented.

- Enrichment with specific goals works better.
- Enrichment scheduled into keeper routines happens more often and provides more variation.
- Implementation rules and minimum standards help to make the process become routine.
- Evaluation tells us what works, how well and for how long.

A full proactive enrichment program for each species ideally involves a number of steps and we will follow this through using a pair of sun bears as an example.

THE PLANNING STAGE

Firstly, it is important to know as much as possible about the behaviour of the species in the wild, information which is quite often difficult to come by (Veasey et al., 1996).

1. Wild behaviour information on the sun bears (Kurt, 1990) is grouped under the enrichment category headings:

Physical environment: Sun bears are cryptic forest dwellers from highland to lowland regions of South East Asia.

Locomotion: They are adept climbers and spend much time off the ground. They can move rapidly and silently though steep and difficult terrain. Bears often stand bipedal to view distant objects.

Activity patterns: Sun bears are mainly nocturnal; they rest and sunbathe during the day on a platform made of branches several meters above the ground. Unlike many other bear species they remain active all year round.

Feeding: Like most bears, sun bears are opportunistic omnivores, eating a wide variety of food including fruit and nuts, sprouts, roots, growing tips of palm trees (which bring them into conflict with local farmers), termites, bees and honey, grubs, earthworms, birds and small mammals. They forage by skimming the forest floor for food, making extensive use of their long tongue and claws. They show great manipulative skill.

Social behaviour: They seem to be less solitary than some bear species, often moving in pairs. They have an elaborate courtship lasting from two days to a week. Normally two cubs are born and raised in seclusion. The cubs stay with the mother until almost fully grown.

2. The captive history of the particular animals is also important for planning:

The Sun Bears' histories: In early 1997 these sun bears arrived at Taronga Zoo from Cambodia, the first legal transaction of animals from that country. They already had a traumatic past – they were taken early from their mothers, kept under very confined conditions and were destined for the restaurant table. On arrival they already had behavioural problems. The male had a paw licking habit (a sign of pre-mature weaning), the female a begging behaviour where she stood on her hind legs and flipped her tongue at visitors. They were very focussed on their keepers and they reacted with fear to sudden or loud noises and any unusual occurrence.

They settled well into their exhibit and in time became less worried by the zoo and visitor noises and the original behavioural problems lessened. Then in their second year a pacing stereotypy developed in the male and rapidly increased to take up a major part of his day. It was found by observation that pacing was triggered by loud noise, keepers' present or passing the exhibit; it was also found to be anticipatory

– increasing before feeding times and before den access was given. More information on stereotypy is given in Appendix 1.
It was also found that time spent by the bears foraging was low, less than 10% of the day.

Meetings were held with all involved staff to discuss how better to manage the bears.

3. Setting Enrichment Goals:

The goals for the bears were set:

- To lower levels of stereotypic pacing
- To increase the level of feeding and foraging

4. Brainstorming for enrichment ideas:

Captive bears are very food motivated so the project was started with mainly food devices. Since then the list has been expanded into other categories.

Food	Sensory	Exhibit	Novel / Toys (not food related)	Social
Devices	*Sight*	*Substrates*	Balls	Interaction with keeper
Treat boards	Mobile	Leaf litter	'Sinkers'	Training
Honey logs		Woodchip	Branches	Sight / sound
Pipe feeder	*Smell*	Pebbles	Boxes (in den)	Other
Ball feeder	Faeces	Bedding	Plastic containers	
Icicles	Herbs		Rope	
Jelly bamboo	Oils	*Furniture*	Bamboo	
Pinecones		Baskets	Hose	
Smears	*Sound*	Climbing	Log with bark	
	Wind chimes	Retreats		
Methods	Tape	Barriers		
Woodpile		Planting		
Scattered	*Touch*			
Buried	Brush	*Water*		
In pit	Textures	Pool		
On bungy		Waterfalls		
Planting		Misters		
Rotted log				
Beehive				

Ways were looked on how the ideas could be resourced, and the buying, designing, and making of items proceeded to make up enrichment "bank". A system was worked out as to how the items could be filled and a regular supply maintained.

5. The keepers revised the husbandry routine:

- more frequent and smaller feeds, up to 9 a day
- gating the bears a second time during the day to enable a change of the exhibit and enrichment.
- giving the bears den access in again in mid-afternoon

6. Another avenue tried was consultation with a specialist vet for a homeopathic remedy

The program was implemented in mid 2000.

EVALUATION
Evaluation was an essential part of the whole project.

1. Evaluation by direct observation is time consuming but the best way of obtaining detailed behavioural data. Established sampling techniques are used to collect quantitative data. (Hawkins, 2002). Taronga zoo, unlike many other zoos, has an Animal Watch programme that uses trained volunteers to observe animal behaviour, so this has been the main method used in this study (Hawkins 199#).

2. Another method is the use of rapid rating: scores have been developed that can be used by staff to assess reactions to enrichment and effects on goal behaviours where there is not time or personnel to observe at length.

Scoring codes for Evaluating Enrichment (Mellen and Sevenich, 2001)
Direct: from direct observation of reactions to enrichment

1. animal runs/flees from enrichment
2. animal appears to ignore enrichment
3. animal orients to/ looks at enrichment but does not physically contact enrichment.
4. animal makes brief contact (e.g. sniffs/licks/pecks enrichment)
5. animal makes substantial or repeated contact with enrichment

Indirect: keeper unable to observe reaction but uses indirect evidence of use.

1. no evidence of interaction (e.g. pristine, untouched enrichment)
2. minimal evidence of interaction (e.g. moved short distance)
3. moderate evidence of interaction (e.g. moved and urine marked)
4. substantial evidence of interaction (e.g. turned over, urinated on, moved to other side)
5. significant evidence of interaction (e.g. emptied or ripped apart, pieces scattered)

Achievement of intended behavioural goals:

0. enrichment encourages undesirable/dangerous behaviour
1. no reaction, did not encourage goal behaviour
2. animal reacted but behaviour unrelated to planned goal
3. some reaction, some goal behaviours observed
4. moderate reaction, achieved moderate amount of goal behaviour
5. strong reaction, encourage many or substantial amount of goal behaviour

---

3. A third method of evaluation is by the use of records. Reliability of this method is dependent on good record keeping. One example: If the decrease of aggression was the goal, a comparison of the number of wounds recorded before and after could be used to evaluate the change.

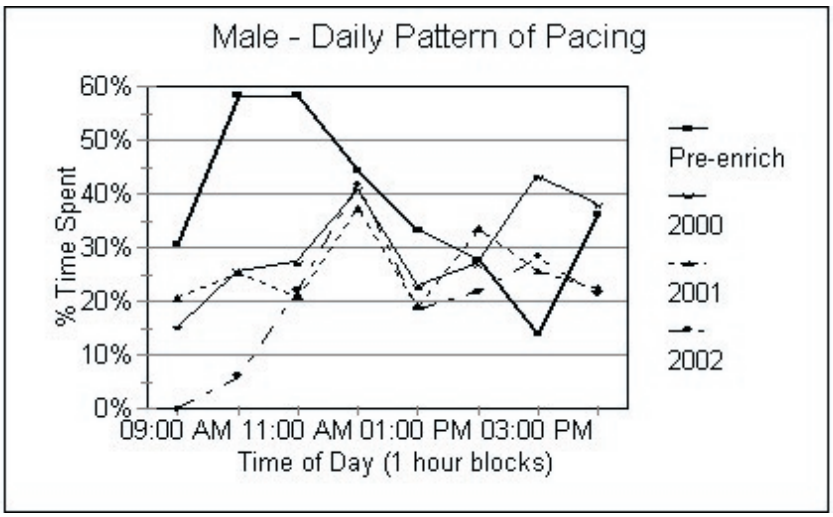
In the presented study there were three aspects to the evaluation:

- Evaluating the problem – looking at patterns of activity, triggers for the pacing. Quantitative data was collected on the activity pattern of the bears, together with anecdotal records of what events caused the start and end of pacing bouts (Figure 1.).
- Evaluating the reactions to new enrichment activities. Data was collected on the time to the first approach to the item, time spent and number of times and spread of activity at the item and type of activity seen at the item.
- Evaluating the effects of the changes on the goal behaviours. Data on activity patterns was again collected with emphasis on the goal behaviours. This data could then be compared to pre-enrichment results (Figure 2).

Results and Discussion

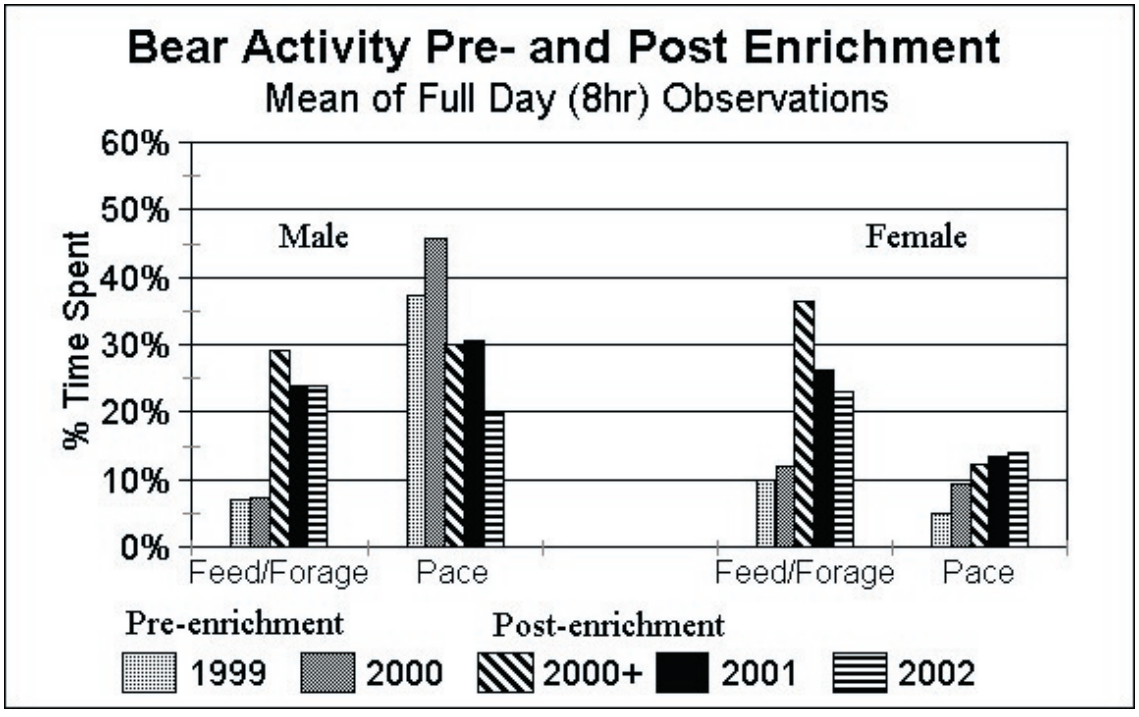
The results of the evaluation of changes to goal behaviours, done by direct observation, are summarised in two graphs.

The first graph (Fig 1) shows the changes in the male sun bear's daily pattern of pacing over the years of the study. The data points are the mean of all the observations done in each time period and are expressed as the percentage of that time spent pacing.



These results show that before the coordinated enrichment programme was implemented the peak of the male's pacing activity was between 10am and 12pm. The implementation of the changes was immediately effective in decreasing this level and this improvement has been maintained. There has also been an improvement in the late afternoon (3 - 5pm) due probably to giving the bears access to their den earlier in the afternoon. The peak period for pacing now is between 1 and 2pm and the level at this time has remained constant throughout the study. This time coincides with the keeper lunch break so no feeds are given during this hour.

Figure 2 summarises the changes in goal behaviour for the sun bears over the years of the study.



After implementation of the program there was an immediate improvement in the male's pacing and a large rise in the foraging time of both bears. Over the next year the improvement in pacing was maintained then this year there has been a further drop in the male's pacing though the female's, while still low, is creeping up through the difference is not significant. Foraging times have remained much higher than the pre-enrichment levels though there has been a drop from the level immediately post implementation. This is probably due to an increase in foraging skills.

Where possible evaluation should separate the effects of different changes made. From a scientific viewpoint the ideal would be testing each change separately as multiple working hypotheses (More & Chepko-Sade, 2002) but this comes into conflict with the need to maintain a high level of daily complexity and challenge in the bears' environment.

The homeopathic remedy was evaluated by comparing pacing levels at for two months before and after its application: though the keepers felt the bears were calmer it did not significantly change the level of pacing for either bear.

Table 1. A summary of the evaluation results on the effect of the homeopathic remedy on the behaviour sun bears. Activity results are means of collected data and are presented as the percentage time spent in that behaviour.

Male sun bear

PRE-TREATMENT		Time obs.		Lie / Rest	Feed/Forage	Pace
Oct - Feb 2001	AM	11:00 -1:00	19 days	6.0%	19.1%	27.3%
	PM	3:00 - 5:00	15 days	3.7%	21.3%	20.1%
POST TREATMENT						
Feb – April 2001	AM	11:00 - 1:00	29 days	5.7%	21.2%	28.7%
	PM	3:00 - 5:00	18 days	6.4%	18.5%	22.6%

Female sun bear

PRE-TREATMENT		Time obs.		Lie / Rest	Feed/Forage	Pace
Oct - Feb 2001	AM	11:00 -1:00	19 days	16.0%	18.0%	20.0%
	PM	3:00 - 5:00	15 days	8.0%	27.0%	8.0%
POST TREATMENT						
Feb – April 2001	AM	11:00 - 1:00	29 days	21.0%	20.0%	14.0%
	PM	3:00 - 5:00	18 days	11.0%	25.0%	5.0%

In late 2000, the bears were given access to their dens earlier in the afternoon than normal – this was to give them more choice at a time when the stream of visitors was passing the exhibit to lower zoo exit. Evaluation of the male's pacing at this time of day has shown on average a lower level of pacing behaviour in the late afternoons in 2001 and 2002 as compared to the 2000 pre- and post- enrichment levels (Fig 1).

PROVIDING AN ON-GOING PROGRAMME

Bears in captivity are high maintenance animals. They are highly intelligent and learn quickly to manipulate enrichment items effectively and there is an on-going need to keep abreast of their changing requirements – altering conditions, increasing the challenge of enrichment, re-assessing; thus continually repeating the above process.

Below is listed some current works and future plans for the bears.

- Exhibit changes:- This year it has been possible to make some major exhibit changes. The climbing trees and logs have been replaced. The waterfall has been repaired and is working again. Further planting both in the exhibit and public areas will create visual barriers. A further climbing structure incorporating another resting hammock is being made.
- Increasing the number of enrichment items available in all categories. Non-food items are being further explored and specifically designed 'bear' toys made and tried.
- Making more challenging feeding devices. The bears are becoming so efficient at using the present ones they become less of a challenge so foraging times are decreasing.
- Introducing a monthly schedule so communication between keepers is better, daily variety is increased and repetition, leading to habituation, is decreased.

Conclusion

Approaching behavioural problems in a systematic way does give better results and in the example given has resulted in substantial progress towards achieving the goals. The behavioural problems of the sun bears will probably never totally extinguished but we will continue to try.

From a scientific view point the testing of each change individually would have allowed us to separate the effectiveness of different enrichment initiatives better but this has to be balanced against the animals' need for daily challenge and complexity.

The relevance of all this to the welfare of animals in research is that environmental enrichment is increasingly being applied to the animals in research facilities. The problems are different, with the emphasis on enrichment that can be applied simply to large numbers of animals, but it is still important to know that what is being done is effective. It is therefore good to think through what you are trying to achieve, to set goals and find a simple way of evaluating the success. The scoring methods (Mellen and Sevenich, 2001) may well be able to be adapted for this.

So, overall the process would be similar to that described above. Enrichment for laboratory animals has been shown to have benefits for the animals, the staff and the researcher (Cunneen, Fagan, Lynch, Wile & Hopkins, 2002).

Acknowledgements

I acknowledge the collaboration of Lesley Small, Senior Carnivore Keeper (Asian Division), with whom I have worked on the sun bear project since its inception; and the other keepers assisting her with their care.

I thank the Animal Watch volunteers, who have carried out the hundreds of hours of observation on the bears, entered the data and regularly (twice a week) filled the enrichment devices.

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APPENDIX 1

STEREOTYPIC BEHAVIOUR AND ZOO ANIMALS

Stereotypy is a repetitive behaviour performed without a recognisable function. Pacing is a locomotion stereotypy where the animal continually walks a repetitive pattern.

Predictions can be made about what species are more likely to develop stereotypies and of what type (Morris 1964) and this seems to be linked to the species foraging strategy. Ungulates are more likely to develop oral stereotypies, post feeding, and carnivores pre-feeding locomotory stereotypies. In carnivorous species the likelihood of pacing can be linked to wild home range size and daily movement patterns with differences between the sexes (Clubb & Mason, 2002).

Session Title:

Thorny issues and ethical conundrums

Speciesism

Susan M Maastricht
Children's Cancer Institute, Australia

In the early '70s, Richard Ryder, author of *Animal Revolution*, coined the term Speciesism, in an endeavour to describe what it is that allows humans to do the things that they do to animals. It created a notion of a value for each animal in comparison to all other animals, including humans.

When I spoke to Bernie Rollin recently about this word and what it means, he was somewhat off-hand about it, suggesting that it was simply another piece of semantics.

He may be right, but it is inescapable that 'speciesism' is alive and well and walking beside us in most aspects our lives. It is true that without speciesism or lets be clear, a system that allows humans to view animals as of different (less?) value than themselves, virtually all of our interactions with animals would not occur. We would not farm animals, eat animals, ride animals, do research on animals or indeed confine animals in zoos or our back yards, as pets.

Even beyond the notion of animals having lower worth than humans, human speciesism separates the non-human animal species onto a scale of value or worthiness.

It is worthwhile for us to consider from where this value system comes – how did the notion of speciesism evolve?

Nature
If we look at nature, it would seem that speciesism is inevitable. In the wild, some animals are predators and some are prey. Some animals are both predator and prey and the value system adjusts dependent upon the perspective. Essentially, the life of the food source is used without remorse, albeit with thanks from the predator species.

Interestingly, the natural scheme may be changed, by placing the animals in another environment, where the need for development of predatory design and skills is not required. Humans have a particular knack of creating this changed circumstance.

History
Since time immemorial, animals have been 'used' by humans. Traditionally they have been a mode of transport, a work tool, a source of food and a source of clothing and shoes. They have been written into our books, our oral history and our art. Early images for children show animals in a subordinate position that is acceptable, and so the imprinting begins.

Culture
The differences between cultures in terms of how they view animals are dramatic. Western society has a long-term relationship with animals as companions and therefore shows a particular regard for the well being of many animal species often above that of humans. Eastern society has had considerably less contact with animals as companions and often the level of compassion for animals is lower than in most western societies. The day-to-day contact with the animals as a source of warmth, companionship and love seems to have created a cultural difference that has led to questioning of animal use. Interestingly however, in western society, not all animals are equal, as we will see shortly.

Religion
You could view this as simply one part of culture, but even within cultures, religious teaching will change the way in which animals are viewed. Buddhists would mourn the passing of an ant, Hindus will protect their cattle with their lives, and Muslims will avoid contact with pigs because they are unclean. Not all animals are therefore equal.

Economy
Third world countries face a crisis to feed the human population and so the lives of animals become worthless other than a source of food or a means of planting and harvesting food. It is only in the wealthier countries that the issues of animal welfare/animal rights achieve status.

In many farming communities, economic survival is difficult. Many practices are continued without addressing animal welfare simply because the cost burden on a struggling industry would be too high. Animals are therefore sacrificed to human well being.

Accepted practices
Apart from farm practices, which will be discussed later, there are many accepted practices that allow animal use for the benefit of humans. This can include use of:

- mouse traps in average houses;
- riding of horses in collected and often difficult positions – interesting recent discoveries about how horses see, shows that the 'on the bit' position renders the horses virtually blind;
- dog breeding and genetic modification using breeding methods – Shar pei classic example of human over intrusion into dog design; and
- in some countries, bull fighting and cock fighting continue – in Australia, dog fighting is alive and well and probably happening in your suburb.

The media
In many ways the media has much to answer for in terms of hyping the emotional response of the community to the ways in which animals are viewed. The emotive story of the puppy farms in western Sydney, raised community ire and action to stop this practice. The many stories of beached whales, followed in graphic and almost appalling detail, helped in the generation of funds and assistance. But in the same breath, the story of the dingoes that killed the young boy on Fraser Island resulted in knee jerk kill of dingoes on the island and the case of the 'killer' shark that was chased by a flotilla of small craft after the loss of the father of three in Western Australia demonstrates how close humans remain to a pack mentality at the direction of at best, a questionable industry.

The law
Even the law has contributed to speciesism. By law, in the case of an emergency, emergency personal will insist that humans must be evacuated from building/premises and any animals located in that building/premises will be left behind. The bush fires are excellent examples of this situation and in 1989, when the earthquake occurred in Newcastle, I was not allowed into the animal areas for 2 days after the quake. In the research environment, justification for animal use must include a description of the statistics that will apply. But somehow there is a value judgement on the statistics – why is it okay to use 2000 mice or 10 sheep or 2 dogs or 1 primate?

Legislative control
The research industry has been one of the most rigorously regulated industries particularly over the last 20 years. Despite this, in the USA today there is no requirement to report the usage of rodents as part of the annual statistics gathering, at a federal level. Farm animals remain exempt species in terms of research and the focus of care has been on the companion animals and primates. This is classic speciesism and it would be interesting to consider why.

The provision of meat for human consumption is another area of significant anomalies. The animals are often held in inadequate conditions before slaughter and then at the time of slaughter are loaded through a chute, nose to tail, with the stunned and then bleeding animals ahead and nowhere to go back. The actual anticipatory impact on the animals from the smell of death and blood is subjugated to the greater need for food.

Abattoirs
In the research laboratory animals cannot be killed in the presence of other animals because the resultant stress would have animal welfare impact and may have research result impact. Interestingly, a recent paper has shown that in rodents, the killing in the same room had less impact than did removing the rats from the room.

Agricultural practices
In the farming community, economic pressure, a disregard for farm animal pain and prophylactic/ production practices have supported the unchanged continuation of practices such as mulesing, castration and tail docking without anaesthetic or analgesics. Such practices would never be permitted in companion animals and indeed the RSPCA would become involved should it occur.

Vertebrate pests
Some animals are regarded as pests of considerably less value than agricultural species or native species and so are subjected to killing that bears no resemblance to euthanasia.

Rabbits have been infected with myxomatosis and calicivirus in an endeavour to find a successful biological weapon of their destruction. The chronic wasting that is seen with myxomatosis and the acute haemorrhagic disease of calicivirus could never be considered a good death.

The use of 1080 poisoning for foxes would never be used if the person laying the bait had seen a case of inadvertent 1080 poisoning. The frantic and uncontrollable 'running' to death is traumatic to the observer and must be excruciating to the fox.
The use of mousetraps that break the mouses back, often with survival is a questionable approach to mice in the house. The use of flamethrowers to kill plague mice, as occurred in South Australia a decade or so ago, seems inexplicable if euthanasia is considered in the destruction process.

Recreational Use of Animals

Fox hunting
Recent lobby for Fox Hunting in the UK demonstrates just how well speciesism resides in our communities.

Fishing
Recreational fishing inserts a large hook into the mouth of the fish and then a battle to exhaustion between human and fish. Finally the fish may lie gasping in the bottom of the boat for examination by the angler and ultimately may be returned to the water bruised and wounded or left to die in the boat. Clearly fish do not feel pain and it is okay to put them through this trauma for our sport.

Shooting
The need to hunt remains as a demonstration of machismo. Shooting inanimate targets doesn't do it. The live animal is the only prey that will do and whether it is deer, goats, pigs, rabbits or kangaroos, the chase and the shot are the deal. The right of the animal to survive is subordinate to the desire to kill of the human hunter.

Racing
Horses, dogs, camels, pigeons are all used for mans pleasure – the thrill of the race, the gamble, the chance to win. That these animals are used too young, too often and are discarded if they fail, is a sad indictment on human attitudes to animals.

Performing/confined animals
The gambit has always been that circus animals love to perform. It seems that circus people have a special talent for communication with animals, that they are able to proclaim this. The truth is that circus animals are largely confined for transport and are kept in facilities that are too small to meet their biological and behavioural needs. Similarly in many countries, animals are kept in close confinement that would not be their preferred choice and humans make the decisions to do this. When dancing bears kill their owners, when confined elephants kill their handlers, when circus lions kill their trainers, should we note a statement of discontent.

Revere or fear
Humans seem to strike for imbalance rather than balance when it comes to how animals are viewed. There is often an emotional drive to protect a species at the same time that there is reason to destroy. This is often driven by fear, in much the same way that science fiction demonstrates human response to alien invasion. Do you remember the old movie called, The Day the Earth Stood Still. Beings of unquestionably greater power arrived on earth to be greeted by mass hysteria and a 'fight' response from humans and it was only the advanced development of the aliens that allowed them to understand what drives humans and so avoid the world wide destruction of which they were capable. Anything that is different may be of less value and if it scares us, it definitely is of less value. So we end up with an endeavour to save and kill at the same time!

Animal Rights
So should all animals be considered in the same way? Is it possible to do this, or given all that I have discussed, is it better to keep the current status quo.

The RSPCA logo shows humans very much as part of the animal kingdom, but equity between species is not described. The reality is that if animals have rights, humans allow this to occur. How these rights relate to human rights however remains in dispute.

A very clever professor that I met a number of years ago proposed (tongue in cheek, I hope) that we should stop worrying about animal ethics and simply use the mentally retarded, the criminals in prison and the orphans in third world countries for research, as they are clearly of less value and are after all just a burden on society and are a better research model. This is speciesism within the human species perhaps no different from the inter-species speciesism that we currently employ.

So where does this leave us?
Members of Animal Ethics Committee cannot escape their innate attitudes that they bring to the committee table. Perhaps it would not work if they did leave them outside the door as they would not be able to approve any projects. There would be no way to justify the use of animals for the betterment of humans if we are all equivalent and the use of one mouse would be no different from the use of one dog, one primate or indeed one human.

It is amazing the way that humans view the world. As a final statement of the bizarre, we cannot stop the systematic destruction of the habitat required by our precious native animals, but we will spend a fortune in an endeavour to retrieve the thylacine that we previously rendered extinct.

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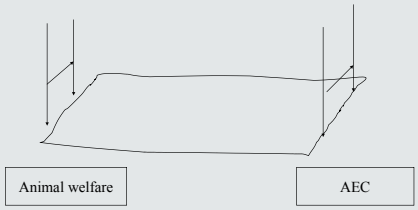
Who could knock the goalposts over? Thorny issues and ethical conundrums

John Schofield
Director of Animal Welfare, University of Otago, New Zealand

[This talk is summarised by a series of diagrams - Editor]

The 'Goalposts' might be Animal Welfare and the AEC



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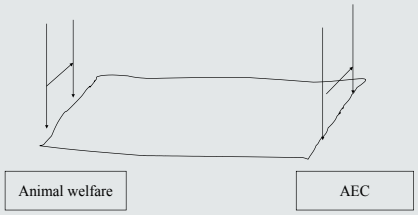
The 'Goalposts' might be Animal Welfare and the AEC



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Definitions:

- **PI = Principal Investigator, or Chief Scientist**
- **RTT= Research, Testing and Teaching**
- **Non-experimental variables**
  - **mouse hepatitis virus, MRM in rats**
- **SPF=specific pathogen free**
- **IVC=individually ventilated cages**

3

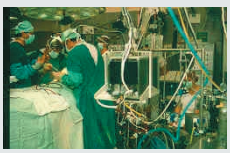
Some thorny issues:

- **The scientists' birthright**
- **The AEC as control point in RTT**
- **The gatekeeper at the cage-face**
- **The role of the AEC in non-experimental variables**
- **Environmental enrichment in animal production colonies**

4

The scientists' birthright ?

- **To have unlimited access to expt animals and service facilities**
- **To have no constraints on animal use**
- **To be above challenge by an AEC or others….**



5

The scientists' rights ...

- **why can't I purchase these cheaper animals?**
- **who are you to question my competence at this manipulation?**
- **what do you mean, I can't use them while still in quarantine?**
- **how dare you tell me what I can't do!**

6

The AEC as a control point in RTT for the following:

- **Animal supply**
- **Quality of animals used by PI's**
- **Quality of animal husbandry and housing**
- **Management of pain control for invasive procedures**

7

AEC control of animal supply ?

- **controlled= a justification for numbers requires the PI to predict and estimate anticipated need. This can minimize the numbers used**
- **not controlled=can lead to excessive use of animals and acceptance of high morbidity & mortality rates**

8

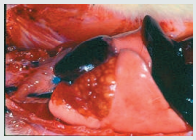
AEC control of animal quality ?

- **controlled= quality appropriate for the proposed study, and suitable for housing in the centralized facility**
- **not controlled=PI may purchase cheap animals that may be contaminated and cannot therefore be housed in centralized facility**

9

AEC control of animal quality ?

- **Murine Respiratory Mycoplasmosis in rats occurs in conventional colonies**
- **Affected animals should not be used for research**
- **Immuno-deficient animals at risk**



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AEC control of quality of animal husbandry and housing?

- **controlled=best practice procedures are promoted**
- **not controlled=variable practice procedures are performed, sometimes by amateurs such as students**

11

AEC control of pain management for surgical procedures?

- **controlled=best practice procedures are promoted with appropriate pain control**
- **not controlled=outdated practices are perpetuated, often with lack of appropriate analgesia**

12

Major survival surgery without post-operative pain control:

- **Smith et al. Aust NZ J Surg 1999, 69: 522-525. Immune cell subpopulations in regenerated splenic tissue in rats**
- **Bhandarkar et al. Aust NZ J Surg 1999, 69: 388-390 Spray of phospholipid powder reduces peritoneal adhesions in rabbits**

(both papers document AEC approval)

13

Major survival surgery without post-operative pain control:

- **Nembutal, halothane and N2O are anaesthetics, not analgesic agents**
- **Based on the 'pain equivalence' concept, all these animals should have been given post-op analgesia**

What standards were the respective AECs working to when they approved this work?

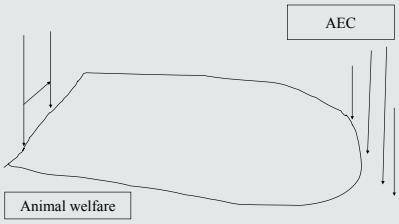
14

Australian code of practice for the care and use of animals for scientific purposes

3.3.31: "When the animal is to recover from the anaesthetic, surgical procedures must conform to accepted standards in human and veterinary practice. Analgesics and tranquillisers must be used when required and their use should parallel that in current medical and veterinary practice"

15

Playing the same field but a different code ?



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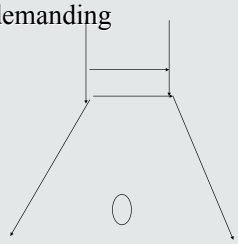
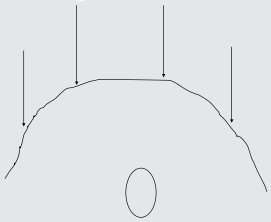
When the AEC lacks control, the animal welfare goals are less demanding



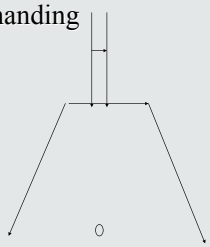
17

When the AEC lacks control, the animal welfare goals are less demanding



18

When AEC is in control the animal welfare goals are more demanding



19

The key question for the Category C and D members?

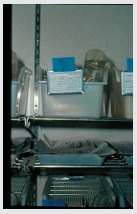
- **So where is the post-operative pain control for these animals in this study?**

No pain control -not approved

20

The gatekeeper at the cage-face?

- **The PI ?**
- **The Facility Manager?**
- **The AEC?**
- **The veterinarian?**
- **Who reports to whom?**



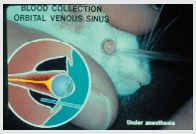
21

Consider the gatekeeper at the cage-face ?

- **the AEC approves orbital blood collection by default or by intention**

BUT

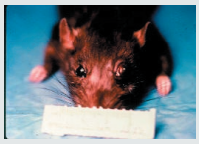
- **facility manager does not permit the technique**



22

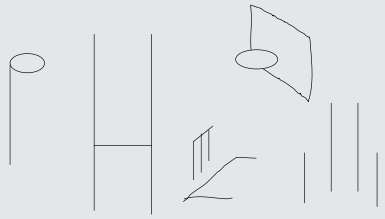
Consider the gatekeeper at the cage-face ?

- Rats are purchased by the PI from a cheap source and they break with eye lesions soon after arrival
- Other animals in the facility become infected
- The veterinarian was not consulted but may be held accountable



23

What are the cage-face goal posts and how are they set?



24

The role of the AEC in non-experimental variables?

- **non-experimental variables can be factors that cause a failure to duplicate studies performed elsewhere**
- **examples include diet, pathogens e.g. MHV, genotype, environment, drugs, reagents…...**

25

The role of the AEC in non-experimental variables?

- For best results the proposed immune study should be performed in SPF mice maintained in micro-isolator or IVC cages
  (because of endemic MHV in the facility)

BUT no cages are available

26

The role of the AEC in non-experimental variables?

- **No role for AEC**
  - AECs should not interfere with research
  - PIs know all about non-expt variables
  - if problem occurs simply repeat the study
- **AECs involved**
  - AECs must know about variables that affect welfare or scientific integrity of study
  - researchers have limited knowledge of non-expt variables

27

Environmental enrichment in animal production colonies?

- enriched animal brains can produce different experimental results in neural plasticity studies
- smart rats need not apply

28

Environmental enrichment in animal production colonies?

- is it ethically acceptable to continue to produce 'dumb' rats?
- should the science control the welfare of rats?

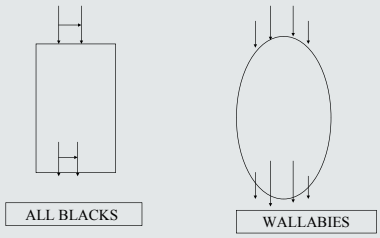
29

In summary, thorny issues are best resolved

when there is mutual respect,
transparent understanding and…..

30

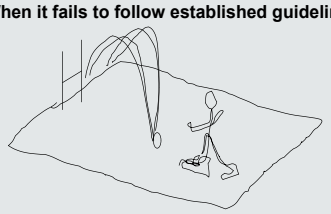
We are all playing the same game



31

When is an AEC not an AEC?

When it fails to follow established guidelines



32

In vitro monoclonal antibody production – ethics and practice

D. Lawrence and T.R. Kuchel
Veterinary Services Division, Institute of Medical and Veterinary Science, Adelaide, South Australia

Abstract

In 1996 the Executive of the Institute of Medical and Veterinary Science (IMVS) and the IMVS Council decided, on the advice of the Animal Ethics Committee, that only after *in vitro* monoclonal antibody production methods had been attempted and failed would consideration be given to allowing mouse ascites collection to occur.

An *in vitro* monoclonal antibody production laboratory was consequently established within the IMVS/Hanson Centre and located at the Veterinary Services Division. The aims of the laboratory are to supply purified monoclonal antibodies to researchers within the IMVS/Hanson Centre as well as external clients including universities and commercially funded laboratories.

Between May 1997 and September 2002 our laboratory received 250 requests for *in vitro* monoclonal antibody production from a total of 132 hybridomas. Hybridoma cells were cultivated in a bioreactor system or gas permeable bag and the secreted monoclonal antibodies purified by affinity chromatography. The Animal Ethics Committee received no requests for permission to produce monoclonal antibodies by ascites collection during this time.

Introduction

The applications of monoclonal antibodies are numerous and diverse. They are extensively used in fundamental research, medicine and biotechnology.[1] In addition to being highly specific; monoclonal antibody assays offer precise measurements and low false-positive results.[2]

There are now many *in vitro* culture systems available which enable the user to produce monoclonal antibodies at a higher concentration than the traditional static tissue culture flasks. As more researchers gain access to core facilities that operate these systems the number of requests for ascites production should decrease.

Replacement, Reduction, Refinement

The principles of replacement and reduction of animals used in research are achieved by utilising *in vitro* monoclonal antibody procedures in preference to ascites protocols. The principle of refinement of techniques used to reduce the impact on animals during induction of antibody-producing lymphoid cells can be achieved by i) the injection of antigen by sub-cutaneous or intra-peritoneal routes in mice; and ii) the use of adjuvants only when deemed essential, ensuring the total volume of inoculum does not exceed 0.2 mL in mice and blood sampling of animals occurs no more than twice.[3]

Cost

The current charge for the supply and housing for three weeks of 20 Balb/c mice in the IMVS Animal Care Facility is $407. This price does not include tapping and downstream processing of ascites. The monoclonal antibody laboratory's current charge is $750 for 10 mg. of purified monoclonal antibodies plus $15 per mg. thereafter.

Culture Equipment

The Miniperm bioreactor, i-Mab gas permeable bag and Cellmax Artificial Capillary System are used in our laboratory for the *in vitro* production of monoclonal antibodies. The gas permeable bag is a relatively cheap (< $100) method of producing monoclonal antibodies. A suspension of hybridoma cells in 500 mL of medium is introduced into the bag and incubated until the viability of the cells has fallen below 10 – 20%. The contents are subsequently harvested and purified by affinity chromatography. Cells and antibodies reach a higher concentration in the Cellmax system than the Miniperm bioreactor and gas permeable bag. The Cellmax can be GMP compliant when used with the appropriate commercially prepared liquid media. The majority of submissions are cultured in the Miniperm bioreactor.

High Density Cell Culture

The design features of the Miniperm culture vessel make it possible to culture cells to considerably higher densities than in conventional culture procedures in which the oxygen and nutrient

requirements can only be met by diffusion.[4] Cells can reach concentrations of 10^7 – 2 x 10^7 / mL. The Miniperm bioreactor consists of two connected modules – a larger nutrient module which contains 350 – 400 mL of media and a smaller production module with a volume of 35 mL into which the hybridomas are introduced. There is a finger shaped silicone rubber membrane in the nutrient module, which is permeable to oxygen and carbon dioxide. The outer surface of the production module consists of a very thin silicone rubber membrane, which is also permeable to oxygen and carbon dioxide. The modules are separated by a dialysis membrane with a MWCO of 12.5 kD. Neither cells nor antibodies can pass through this membrane.

Cells are dependent on the continuous supply of large quantities of nutrients and oxygen and on the removal of metabolic waste products and carbon dioxide. Therefore, the cells must be kept in suspension at all times and must be agitated constantly and intensively.[4] This is achieved by rolling the Miniperm bioreactor on a bottle turning device. The turning speed is adjustable from 0.05 to 20 rpm. Our laboratory uses a turning speed of 1 rpm for most hybridomas.

Culturing of Hybridomas

Hybridoma cell lines must be handled aseptically in a laminar flow or class II safety cabinet.

Hybridomas are submitted to the laboratory as a cryovial of frozen cells on dry ice or as a small tissue culture flask of viable cells. Cells are usually submitted in RPMI plus 10 – 20% fetal calf serum. They are sequentially adapted into serum free media and cultured until a sufficient number have been attained for introduction into the bioreactor system. Media is added to the nutrient module and the bioreactor is placed on a bottle roller at 37°C with 8% CO_2.

The first media change occurs after 3 – 4 days. Media is subsequently changed 4 – 6 times per week. The first harvest is taken after 4 – 8 days by drawing up the sample from the production module using a 50 mL syringe. Subsequent harvests are usually taken twice weekly. A viable cell count is then performed.

The sample is centrifuged and the supernatant stored at – 70°C. A proportion of the cells (usually about 5 x 10^6 / mL) is re-inoculated. Most hybridomas can be cultured continuously for several months.

Purification

Monoclonal antibodies are purified from the bioreactor harvests by affinity column chromatography (Protein A).

The Protein-A column is washed with binding buffer (0.1 M borate / 0.15 M sodium chloride, pH 8.5). Several harvests are pooled, adjusted to pH 8.5, filtered and applied to the column. Monoclonal antibodies present in the sample bind to the Protein A. The column is washed again with binding buffer. The monoclonal antibodies are eluted from the Protein A with 0.1 M citrate, pH 3.0. The eluate is adjusted to pH 7.4, concentrated to about 5 mL and dialysed against two changes of phosphate buffered saline, pH 7.4. The sample is filtered through a 0.2 um membrane and assayed for protein concentration. The final product is dispensed into cryovials ready for dispatch to clients.

Results

Between May 1997 and September 2002 our laboratory received 250 requests for *in vitro* monoclonal antibody production from a total of 132 hybridomas. Depending on the rate of secretion and the amount requested, between 0.25 to over 200 mg. of purified monoclonal antibodies were produced.

The Animal Ethics Committee received no requests for permission to produce monoclonal antibodies by ascites production during this time.

Discussion

The main advantages of the ascites method are the high yield of antibody, in the range of 1 – 20 mg. / mL and that it is not excessively labour-intensive.[1]

However there are a number of disadvantages: the procedure is extremely painful for the animals used, the monoclonal antibodies produced generally show only 60 – 70% immunoreactivity due to contamination with endogenous host antibodies and other proteins and hybridoma cells can become infected with viruses from the host.[1]

Advantages of *in vitro* methods are: the monoclonal antibodies produced generally express an immunoreactivity of 90 – 95%[1], the ethical issue of replacement of animals with bioreactor culture systems and the ability to scale up monoclonal antibody production by extending the culturing period or increasing the number of bioreactors.

The most significant disadvantage is the cost of setting up a core facility to service the requirements of researchers.

References

1 Marx et al, Monoclonal Antibody Production. The Report and Recommendations of ECVAM Workshop 23. ATLA 25, 121-137, 1997.

2. Life Technologies, Guide to Hybridoma Technology.

3. NHMRC Guidelines on Monoclonal Antibody Production.

Session Title:

Ensuring team decision making in Animal Ethics Committees

Team decision making in Animal Ethics Committees: opening remarks

Peter W Johnson
Animal Welfare Unit, NSW Agriculture, Sydney South, NSW

Animal Ethics Committees have a pivotal role in the monitored self-regulation of animal use in research and teaching in Australia. Good meeting procedures can help an AEC to achieve ethical consensus and positive outcomes - but what makes an AEC work effectively to fulfil its terms of reference and meet the principles of the Code of Practice? Other sessions at the 2002 ANZCCART Conference will deal with handling difficult ethical questions, proficiency in principles and terminology relevant to the types of protocols that the AEC will assess, dealing with protocols from outside the institution and meeting community expectations of the AEC. Many of these things may not happen unless the AEC first develops a functional internal working relationship that establishes some fundamentals such as:

- All members are given equal opportunity to assess and comment on the business before the committee.
- All members receive equal opportunity to ask questions and to state their point of view within the forum of the committee.
- The operating procedures of the AEC facilitate discussion and decision making with the consensual support of the members.
- A mechanism exists to remove conflicts of interest and avoid bias that could influence the objectivity of the committee.
- Strategies are in place to deal with situations where individuals may seek to dominate the AEC and influence decisions in favour of personal interests or points of view.

Structuring and running a meeting to achieve effective communication and outcomes: principles and practical processes

Pam Swepson
Principle Policy Officer, Queensland Department of Primary Industries, Fire Ant Control Centre, Brisbane, Queensland

Abstract

If an AEC agrees on a structured process for its meetings, then it is not dependent on the Chair to ensure that all members contribute to the decision-making. The 'nominal group' is such a process because it maximizes the opportunity for each individual to fully contribute to the discussion AND the decision making.

Introduction

As Peter Johnson said in his introduction:
An AEC can reach an ethical decision for each application if it can

- Ensures that that all members have equal opportunity to ask questions and to state their point of view.
- Facilitate discussion by all and decision-making by consensus.
- Deal with dominant individuals.

A structured process/meeting procedure

If a committee adopts a structured process that maximizes the input of all members at all stages, then all members can take responsibility for running the meeting, which the Chair facilitates.

The **Nominal Group** process is one that maximizes the quality of the decision-making by a group.

It is so called Nominal, because it:

- reduces the amount of face-to-face interaction between members which can lead to competition for airspace and domination by some and intimidation of others, but
- maximizes the opportunity for input by individuals at all stages.
- Gets quicker as people get used to it.

Steps in the Process

1. **Allow individual thinking AND writing time to generate all issues/concerns** about an application (either before the meeting or during it), and if possible, in their order of priority.

- *Gives equal opportunity to fast and slow thinkers.*
- *Reduces the competition for air time*
- *Written notes reduce the inclination for quieter members withhold their ideas.*

2. **Collect all issues from all people on a whiteboard in a systematic, but non-confronting fashion**.

- one item at a time from each person (rotate person who starts first)
- in their own words (short sentence)
- each person adding what they consider to be new items to the public list until individual lists are exhausted.
- Number items as you go.
- Do not combine items at this stage. This requires discussion, which is best avoided. Remind people that the time for combining comes later.

Other members:

- do not judge or criticise these items; either to suggest modification or that they are the same as previous items.
- may ask questions for clarification.

- *Face to face interaction (and opportunity to argue) is limited as people talk to the public list rather than each other.*
- *No one person can lead the group.*
- *A public list emerges which is the result of the group, individual contributions less easy to identify and less individual ownership of items than might otherwise be.*
- *No criticism, therefore people do not become defensive or competitive.*
- *Competition between ideas is reduced by postponing judgement until a later stage.*
- *Lowers the probability of conformity or a premature convergence on a few ideas.*

Prioritise issues to maximise the committees consensus and minimises their differences.

The two votes and one vote method

- Group decides on criteria for voting: i.e. 'What are your most important concerns with this application?'
- Allocate a number of votes to each member, depending on the number of issues. (see formula below, often 2, 4 or 6)
- Working individually and without discussion, members allocate two votes (indicated by raising 2 hands) to the 2, 4 or 6 issues that they consider are the MOST important, AND were not contributed by them to the list, and
- Working individually and without discussion, members allocate one vote (indicated by raising 1 hand) to the 2, 4 or 6 issues they consider are the NEXT most important, and can have been contributed by them to the list.
- Collect the votes by calling out the number of each issue one at a time and asking people to indicate by raising their hand/ hands the number of votes they have given it. Record the total number of votes beside each item.
- Identify the items that receive most votes. If there is no convergence on one or a few issues, cross out the issues receiving only 1-2 votes and repeat the process.

- *Reduces the likelihood of conformity that is often the result of using discussion when one person can sway a group by reducing the amount face-to face interaction.*
- *Use voting to find consensus by taking into consideration, as far as possible, all the possible points of view – not voting to find majority support.*
- *Increases the likelihood of consensus and reduces the weight that people put on their own issues by giving people a number of votes.*
- *People are less likely to change their minds in the light of other people voting.*

Formula for deciding the number of votes.

Divide the total number of issues (i) on the list by the number of participants (p). . The number of votes to allocate is between that number and twice it; i.e. from i/p to2i/p; i.e. if there are 20 issues and 8 members, therefore between 2 and 4 votes, for the MOST important issues and the same number of votes for the NEXT most important issues.

Raise these issues with the Applicant and coming to an ethical decision.

Discussion can then work at this stage to come to the final decision.

If not, then repeat the process as necessary; i.e.
To collect the concern of members about the applicants responses.
To collect suggestions for how the applicant could change their application.

Three other processes to consider.

Team building

Ensure that committee members get to know each other as people, not just roles. 'People' make better decisions that 'roles'. Therefore provide formal and informal processes for interaction; i.e. people introduce themselves to the committee well as tea/ coffee before/after meetings to encourage contact between members.

The job description

The 'job description' for a member could explicitly state that a member is on the committee to represent a particular set of values AND to find a path between potentially conflicting values to find an ethical consensus.

The 'job description' could also ask participants to declare any likely conflicts of interest.

Evaluate the meeting process

Provide an anonymous checklist at end of meeting.

- Did I get as much airtime as I needed? Y/N
- Did I feel listened to? Y/N
- How happy am I with the decisions that we have made? 1-5 Very unhappy – very happy.

Reference

Helping groups to be effective. Bob Dick, Interchange 1987.

Facilitating balanced discussion and effective decision marking: the chairperson's perspective

Timothy F Clancy
Arthur Rylah Institute for Environmental Research, Department of Natural Resources and Environment, Heidelberg, Victoria

ABSTRACT

The complexities of managing the Animal Ethics Committee process are discussed from the perspective of an (recent) AEC chair. Issues that have arisen in recent times have included legislative/regulatory intricacies, processes for recruitment of AEC members, lack of commitment to AEC process by all scientific staff (eg view by some that the process is simply a rubber stamping exercise), balancing requirements of providing reasonable opportunities for discussion of projects with need to cover proposals efficiently and issues related to the transfer of guidelines essentially written to deal with laboratory situations into the field. The specific requirements of AECs regarding their composition leads to the selection of personality types with generally different underlying motivators (eg Thinking-Feeling dichotomy sensu Myers-Briggs Type Indicators) and this needs to be recognised in establishing committee processes. Learning from like-functioned AECs plays an important role in ensuring efficient operating procedures and the NRE Chairs Group is put forward as an example process promoting valuable information sharing.

The animal welfare and wider community perspective on maintaining the effectiveness of Animal Ethics Committees

Mark Lawrie
RSPCA, New South Wales

ABSTRACT

Category C and D members, in virtually all cases, are external to the research institutions represented by the AEC. They bring an important, independent perspective to committees. They have the potential, at least initially, to feel less included. The essential input that they provide is enhanced by committees that extend inclusiveness and by external members, themselves, who develop their interactive skills and actively contribute. The greater the effort that members commit to the process, including committee meetings and facility inspections, the more likely they are to have ownership in the decisions of the committee. The committee and its other members have a responsibility to facilitate this process by assisting in the development of external members.

Category C members bring a greater focus on animal welfare to the committee and Category D members' role is to represent a broader community view. Both C and D representatives need to be able to communicate with other members of the committee and critically analyse the contribution of other members providing veterinary and scientific information. There is a clear emphasis in the Code that information presented in committee be expressed, as necessary, in terms able to be understood by lay members. It is important that C and D members are able to assess the animal welfare and "community" commitment of category A and B members. Similarly, it is important that the scientific understanding of lay members be ''sized" by Category A and particularly Category B members.

The following publication offers useful material in understanding the dynamics of lay members:-

http://www.melbourne.net/animals_australia/specials/aecguidelines.html

Session Title:

Personal perspectives on animal ethics

Personal perspectives on animal ethics: candid ten minute views from a Chairperson, members of AECs and scientists on how the process has impacted on their beliefs, their lives, and their work

Chair:
Lyn Scott
Manager Research Ethics/Animal Welfare Officer, Melbourne Research and Innovation Office, The University of Melbourne, Victoria

AEC Contributors and Key points made:

Category A (Veterinarian)

Carol Ginns
Ludwig Institute for Cancer Research, Royal Melbourne Hospital, Victoria

The Guidelines for AEC Members in Victoria (2000), assert that "Category A persons shall ultimately, consider whether proposals are justified weighing the scientific value of the study against the potential effects on the welfare of animals". So, for me, these are the goalposts, and they haven't moved, I have just learned some of the rules of the game; avoid being picked for either team, accept coaching from many sources, appreciate a good goal and finally, accept the umpire's decision. Input from the Animal House Manager at AEC meetings should be mandatory.

Category B (Scientist - Pro AEC system)

Graham Jenkin
Department of Physiology, Senior Research Fellow, Monash Institute of reproduction and Development, Monash University, Victoria

Having undertaken my Postgraduate training at the Babraham Agricultural Research Centre in Cambridge UK, I was acutely aware of the shortcomings of the British system of licensing of researchers (The Home Office agreed "not to disallow me to undertake research on animals").

After my arrival in Australia in 1978 I embraced the close interaction between scientists and animal welfarists and the first edition of the "Code of Practice" produced in 1969. Since that time, I believe that Australia has set an example Internationally on how all groups in the community can work together to achieve acceptable compromise in the regulation and conduct of animal based research. Despite numerous revisions of the Code and a perceived lack of progress in achieving welfare aims in some instances, I believe that the system we have adopted still works well. I do not believe that the goalposts have moved: there is, however, a need for continuing vigilance on all sides of the debate to ensure that standards are upheld. Welfarists need to keep up the pressure; scientists need to be open and accountable, and bodies like the NHMRC Animal Welfare Committee and ANZCCART need to continue to provide a vital link between scientists, welfarists, the general public and, of course, Animal Welfare Committees.

As a Category B person and a past Chair of a busy Animal Ethics Committee, I believe that: Category B persons can in an unbiased way chair AEC's, and in most instances are the appropriate persons to do so. The system is in danger of over regulation/ administration. If the mound of paperwork gets too large, we will loose the support of some groups. The system must remain adaptable and not be over regulated. The Code is subject to interpretation by AEC's and that is appropriate, so do not make the code so proscriptive that it becomes unwieldy.

My take home message is:

- The system in Australia works well.
- Lets all work together to ensure this continues.
- Keep the system flexible and not over restrictive.
- The new generation of scientists are even more accepting of the system; work with them so we can all achieve our goals. Minimise paperwork and administration, save trees.

Category B (Scientist – a second opinion)

Juergen Landmann
Tick Fever Research Centre, Queensland Department of Primary Industries

AECs have been known to hinder research unfairly. Two important examples:

i) where there was no consideration for the big picture when a permit for five mice was not allowed for a project which could have helped prevent 90,000 abortions in cattle/ year; and

ii) where the AEC decision process was

so slow that research was unable to make use of funds allocated for an important liver fluke parasite distribution survey, thus ensuring that the study was unable to take place.

Animal welfare groups seem to target scientists unfairly - are we easy targets? Why not target horse racing - could you get the Melbourne Cup through an AEC?

Scientists are professionals, they should be treated as such and restrictions placed on them only if they offend. You can obtain a firearms licence and you don't need a permit every time you use a gun, but if you break the law then the penalties can be harsh.

Category C (Animal Welfare)

Cynthia Burnett
Humane Education Officer, Animals Australia

Impact on my Beliefs: As a healthy vegetarian and animal welfarist with an animal rights leaning, I do not believe in the need for animals to be farmed for food and find research on livestock to increase productivity an anathema. In terms of animal use for medical research, I find this an extraordinarily difficult, complex issue. Nevertheless, from an ethical viewpoint ALONE, it seems to me highly unethical to place the burden of ensuring the health of one species at the expense of another simply because we have the power to do so. It seems to me that in some areas of medical research (e.g. cancer) decades have passed with very little to show in the way of results and so I question whether science is using the best possible approach here.

I began serving on AECs about 4 years ago. To do so, I had to accept that research would be done, regardless of whether I was on an AEC or not. At that time I held the belief that any interference in the lives of sentient animals (in particular) should be very well justified. Having seen what I have seen in AECs, this belief remains and has indeed strengthened. I also believe it is better to serve on an AEC and to try to be a voice for the animals affected by research than not to be there at all.

Impact on my Life: Working on AECs has affected my life in terms of the considerable time I devote to preparing, reading, and attending meetings and site visits. In particular, I have chosen to do a lot of reading on subjects and issues that would not normally be part of my reading material. While respecting the confidentiality of service on an AEC, I have been able, in general ways, to enlighten family, friends and work colleagues when they question me on a range of issues. Thus, AEC service can play a role in public education.

Impact on my Work: AEC service has had an impact on my work in the animal welfare/rights arena. Among some colleagues in this domain, I, along with many other Category C members, have been criticised for "sleeping with the enemy". On an AEC as a Category C, one has to put aside one's usual approach to animal welfare work and realise that the AEC is not a forum for arguing whether animals should be experimented upon or not. The fact is they are. The question is: how can Category C people contribute best to protect their interests.

Category D (Lay Member)

Glenn Albrecht
Environmental and Life Sciences, Newcastle University, NSW

Over the last few years my participation in the ACEC at Newcastle has turned me into a schizophrenic. There are at least two Glenn Albrechts who turn up to and leave meetings. For the sake of brevity, the views of the two Albrechts on 'Goalposts" shall be presented in Table format (**See next page**):

Dr Albrecht (a)	Dr Albrecht (b)
An increasingly rational system	An increasingly irrational system
Better process through legislation and policy	Process becoming so complex so as to be unmanageable
Better procedures and record keeping making goals achievable (Athos system will be able to do our tax returns!)	Even with more staff and technology we will be unable keep pace with change and complexity
Better application of the 3 Rs	Irrelevance of the 3 Rs: - Greater expense - Greater risks - More animals used - Failure of animals to model human condition We need a new 3 Rs: Re-think, Re-evaluation, Re-direction
Better communication of the aims and justification of animal-based research	Failure to justify and communicate to the public/lay members
Consensus-based decisions working well	Deep seated disagreements and genuine ethical difficulty with what is happening: - Exponential increase in GMOs - Research on Wildlife - Cloning (the Thylacine!) No outlet for such views
Sense of satisfaction that I participate in a system that is effective in reducing animal use, animal pain and suffering	Sense of frustration that small gains are made in unimportant areas while the 'big issues' remain 'off limits' - Production animals - Sustainability ethics - Distribution of research effort (big laboratory, small conservation)
Gradual reform in welfare and legal approaches to animals	No role for real ethics in AECs hence no progress in Animal Ethics!
AECs have a role to play in educating the research community about ethics	Avoidance of big ethical issues and failure to be advocates for: - Human stem cell use as substitute for animals - Viagra as substitute for parts of rare and endangered species (tiger penises!)
High conversion rate of kicking goals over/ through the goalposts	Not even playing the same game as the 'other'

Executive Officer Perspective

Tim Anning
Executive Officer, Animal Ethics Committee, The University of Melbourne, Victoria

I came to my current role from a number of perspectives (a user, an animal house manager, and now an EO/administrator) and so have a number of comments to make in relation to these.

Managing the heavy administrative burden, including organizing AEC Meetings for a large number of people from both inside and outside the University, taking AEC minutes, interpreting decisions made while being mindful of internal/external regulatory requirements, people needs, email correspondence, Australia Post collection points and times, and tight deadlines, are all the lot of an EO, as is also the onus of remaining impartial regardless of one's own beliefs, in helping to resolve problems, negotiate consensus outcomes, and keeping the ball between the goal posts.

Clear benefits have emerged from the AEC system, including:

- There has been a major move away from the use of animals in teaching.
- People within the system are more conscious of everyone else's perspective, though for those outside the system, these often remain a mystery.
- Institutions have raised the profile of ethics significantly – it is now recognized as an area of core strategic importance, and resources are being increasingly committed to ensure that staff "get it right".
- Aspiring scientists have been trained in an environment which identifies the importance of ethics and so are becoming more involved and taking the trouble to understand the system.

Not withstanding these encouraging trends, the system is still under pressure to deliver on community expectations. The EO's role is to participate in a process, which strives to be transparent to the public, and responsive to individuals seeking answers to concerns.

The emergence of transgenic technology is posing an interesting challenge for administering the system and one that will require some innovative approaches in the future.

Session Title:

ANZCCART Student Award

Building partnerships between animal ethics committees and researchers: a successful case study

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Abstract

Scientific research and development is progressing at rate that has never been seen before, and whilst many would argue the benefits of this there are also a number of consequences that need to be further debated. One of these consequences is the increased use of animals in experimental protocols. Whilst society is somewhat accepting of the need to use animals in biomedical research the expectation that regulations will be in place to limit numbers and suffering remains. The presented case highlights an ever-growing requirement for a partnership to be formed between such regulating bodies as the Animal Ethics Committees (AEC), and researchers. The case involved complications with anesthetics used during a routine experimental which had been approved by the appropriate AEC. The complications required members of AEC to work together with the researchers involved in order to find the best solution that was both ethically and scientifically justified. The communication between the two groups that was required to solve the problem resulted in the formation of a partnership. This partnership led to a successful outcome based on the positive communication that occurred between the two groups. I therefore believe that this case should set a precedent for improving communication and forming partnerships connecting ethics committees and researchers.

Introduction

Animal experimentation in scientific research and development has become an important aspect of our society today, which is often accompanied by a heated and passionate argument. With respect to animal experiments, it has been suggested that Western culture holds two relatively conflicting views (Joles and Vorstenbosch 1999). The first being that humans regard themselves as intrinsically different from, and superior to, animals and as such perceive a right to use animals as commodities (Joles and Vorstenbosch 1999). The second view however, states that the importance of animal experiments in the life sciences can be explained by the fact that humans and animals are, in important respects, biologically alike (Joles and Vorstenbosch 1999). If this was not the case, animals could not model the systems in humans that medical scientists are interested in. This conflicting view of animals and humans has at times created ethical tension, as it may seem inconsistent to claim significant biological similarity between animals and humans and yet request that preferential treatment be given to one or the other (Joles and Vorstenbosch 1999). Such ethical quandaries have caused much debate both by the public and also by governments.

The Australian Senate Select Committee on Animal Welfare published a 290-page report in 1989, which provided comprehensive coverage of the public debate into animal welfare and experimentation. This report concluded "there is no doubt that the majority of the population supports biomedical research involving the use of animals, provided that effective controls are operating to keep the number of the animals and the level of pain and distress to a minimum."(ANZCCART 1998) This control has been gained by incorporating legislation and a number of regulatory bodies to oversee animal based research in Australia. Amongst these bodies is the Animal Ethics Committees (AEC), which operate at all Universities where animal, based research and teaching are undertaken. The role of AEC's is to ensure that all animal-based research and teaching within an institution is carried out in accordance with the relevant laws and institutional guidelines, and that it takes account of legitimate public concerns (ANZCCART 1998). In accepting an application, the AEC must also way up the impact that the research will have upon the animal, with the significance and value that the outcome of such research might impart to the community. The AEC should only approve those studies that provide greater outcome benefits than perceived costs to the animal.

Researchers perceptions of the AEC and vice versa, have a long-standing history of being of a somewhat antagonistic nature. Some researchers tend to perceive AEC's poorly due to misunderstanding of the nature of the committee and its role in research. AEC's can also view researchers as being focused on experimental results rather then animal welfare. While this may hold true of some present and past researchers, I believe that this trend is changing. With the influx of young, environmentally and

socially conscious scientists, comes the opportunity to develop a unique partnership between two groups that historically have been in conflict. As biomedical research advances towards a future of genetic manipulation and the forging of new frontiers in science, I believe this partnership will prove invaluable in assessing the significance of the outcome of animal research and weighing this up against the cost to the animals' quality of life.

The following case study presents a recent ethical situation that was resolved quickly and efficiently and without antagonism through the interaction of the ethics committee and the researchers involved. I believe that this case should set a precedent for future developments of direct partnerships between a member or members of the Ethics Committee with researchers. This partnership will allow for a more thorough understanding of the problems faced by the two bodies and the development of the best outcome for both animal welfare and for the research involved.

The Case

This case study commenced with an application for animal ethics approval to perform experiments with QS mice, involving some surgical procedures. The initial application detailed the use of Avertin (tribomoethanol) as the anaesthetic agent of choice. However, the ethics committee requested that the anaesthetic be changed to ketamine/xylazine or ketamine/metedomidine, due to recently reported adverse affects following the use of Avertin. The research was further complicated by the need to consider the effects of the anaesthetic on embryo development, as the females undergoing surgery would have 1-day-old embryos in their oviducts. After extensive research and communication it was agreed by both parties that the combination of ketamine/xylazine/acepromazine would be used. This combination however proved unacceptable, as a high number of unexplained deaths occurred. It was at this point that a combined effort between the Animal Ethics Committee and the researchers began. This partnership led to a successful outcome based on the positive communication that occurred between the two groups. How this partnership was built is the subject of this communication.

Building partnerships

The surgical procedures to be conducted on the QS mice were vasectomy and uterotubal ligation. Both of these procedures had been performed by the chief investigator a number of years ago using the anaesthetic agent Avertin. However, upon our initial application to the ethics committee for approval to use this drug, the committee brought to our attention recent publications reporting that tribomoethanol or Avertin produced acute peritoneal inflammation and fibrinous serositis of the abdominal organs (Zeller, Meier et al. 1998). The committee then forwarded information on the use of alternatives such as ketamine/xylazine or ketamine/metedomidine.

The complexity of our research was amplified by the fact that the female mice would have their uterotubal junction ligated on day 1 of pregnancy, which meant that there would be early stage embryos in their oviducts at the time of isoflurane exposure. The research also involved looking at the presence of an enzyme at the time of implantation. This meant that we needed to find not only an effective anaesthetic but also an anaesthetic that would be non-toxic to embryos and have no adverse effects on the preparation of the endometrium for implantation or on the enzyme being studied.

After approaching the committee it was able to supply us with a paper, which recently compared the effectiveness and safety of a number of intraperitoneal anaesthetic regimes (Arras, Autenried et al. 2001). This paper concluded that the best anaesthetic regime was the combination of ketamine/xylazine/acepromazine. We were also able to contact the authors to verify that this combination was being used in mice undergoing IVF transfer in the laboratory regularly with no effect to success rate. This therefore convinced us that this would be the best alternative regime to try.

The first experiments performed aimed to determine the correct dose for our strain and sex of mice as per instructions (Arras, Autenried et al. 2001). During these experiments, two out of three males died, with an autopsy failing to reveal the reasons for death.

At this stage, a member of the committee was contacted, who advised the removal of Acepromazine from the regime. This initial contacted established a relationship with selected members of the committee that were open to working along side the researchers in order to develop an ethical and scientific solution. The new combination (Ketamine/Xylazine) also resulted in the death of two out of four mice, before surgical anaesthesia was attained. Again, autopsies revealed no abnormalities.

Subsequent discussion with Dr Margarete Arras revealed a number of different dose combinations. However, these combinations resulted in more deaths, with no abnormalities detected on autopsy. It was at this juncture that the committee suggested the use of a gaseous anaesthetic such as Isoflurane.

This was immediately accepted for the male vasectomies. However, there was some hesitation on the use of this in female mice as there had been some research suggesting that Isoflurane inhibited early mouse embryo development (Chetkowski and Nass 1988) as well as having an embryo toxic effect (Matt, Steingold et al. 1991). Both of these studies had been completed in vitro and we were unable to locate any research, which addressed the issue in vivo. For this reason it was decided that if the Isoflurane was to be used in the female mice then a pilot study determining its effects on embryo development and implantation was required.

It was during this phase that the discourse to date, between the ethics committee and ourselves (the researchers) proved invaluable. Due to the in-depth knowledge of the research by numerous ethics committee members, the committee was able to provide us with a prompt reply on the request for a pilot study into the effects of Isoflurane on embryo development and implantation. The speed of reply allowed us to perform the pilot study quickly and therefore limit the delay in the proposed research, whilst ascertaining the best anaesthetic for the mice's well being.

The pilot study examined the effects of exposure of pregnant female mice to Isoflurane on embryo development and implantation. A total of thirty-two female mice were mated and then divided into four subgroups. Two of these subgroups were exposed to Isoflurane on Day 1 (Day 0 = day of insemination) of pregnancy. The other two groups were not exposed to Isoflurane and were used as controls. Animals were then sacrificed on either Day 4 or Day 5 of pregnancy. Embryo development and the number of implantation sites were studied as well as the expression of the protein of interest in these females. The pilot study showed that there were no significant differences between any of the groups and their controls. Therefore, it was concluded that Isoflurane did not effect embryo development to the blastocyst stage or early implantation in the mouse.

Conclusion/Discussion

The above case study aims to outline the importance of building partnerships between ethics committees and researchers. The importance of this partnership can be highlighted in terms of a number of ethical and experimental considerations. Firstly, the effective communication between a select subset of committee members and researchers enabled the research to progress with only limited delay. This aspect may have been more appreciated by the research group but also held a number of ethical advantages. Solving the problem quickly meant that the animals were not kept beyond the time recommended by the committee, averting any undue stress that might have been caused by such a lengthy holding. This also prevented undue waste as the experiments involved the use of animals at a specific age. Therefore any lengthy delay may have caused animals to be wasted due to aging.

Effective communication also allowed for the education and development of new researchers involved in the experiment. The main communication during the case was between a Ph.D. student and the select members of the ethics committee. This allowed the student to gain valuable insights into the role of the AEC and also the role that the researcher must take in animal ethics. As stated in the Joint NHMRC/AVCC Statement and Guidelines on Research Practice "Researchers must be aware of and adhere to ethical principles of justice and veracity, and of respect for people and their privacy and avoidance of harm to them, as well as respect for non-human subjects of research. Research must comply with established guidelines... where research procedures are of a kind requiring approval by a human or animal experimentation ethics committee, or by other safety or validly constituted regulatory committees, research must not proceed without such approval." The case presented here highlights how direct contact with AEC's and/or select members can help to illustrate the importance of the above statement for young scientists training for a career in research. This will help to ensure that any future research undertaken by the student will be considered not only in scientific terms but also in ethical terms.

The partnership formed during this case allowed a dedicated member of the ethics committee to work along side the researcher, therefore having direct contact and observation of the research involved. This allowed evaluations to be made of the quality of research and also of the extent of knowledge on the types of techniques being applied in a non-confrontational environment. This type of information is valuable to AEC's as one of the requirements of approval is that the person undertaking the research has adequate experience in the techniques being performed (ANZCCART 1998).

Successful communication between ethics committees and researchers helps to remove any preconceived prejudices held by either party of the other. Traditionally, these preconceived opinions have tended to be of a negative nature. By forging partnerships and opening the lines of communication, both parties can begin to appreciate the role of the other and in this way

it may be possible to foster research that is both ethically as well as scientifically sound.

The development of a partnership may also help to cultivate trust between the two parties. The evolution of trust may aid in an important aspect of Animal Ethics, which is the reporting of usage of animals and any adverse affects that are experienced during procedures. The above case outlines the importance of reporting adverse affects as if the initial unexplained deaths had gone unreported then more animals may have been lost. Although one would hope that all researchers report adverse affects correctly, this may be, to some extent a naïve assumption. For example a researcher that may fear having important research terminated may be reluctant to report any adverse affects. By trying to foster partnerships and build trust between the two groups it would be hoped that in the future less researchers will fear their AEC in this manner and in fact look to them in cases of adverse outcomes for guidance in resolving the situation for both the animal and their research.

Finally, as AEC's in Australia and New Zealand work towards setting the goalposts for animal ethics in the future, I would ask that they also look at just who is kicking the goals, and perhaps try to foster an image of AEC's and researchers working together in order to achieve both ethically and scientifically sound research. I believe that it is communication and partnerships between AEC's and researchers that will help to set the goalposts for a future in animal experimentation that balances both the importance of the research as well as the importance of animal welfare.

Acknowledgments

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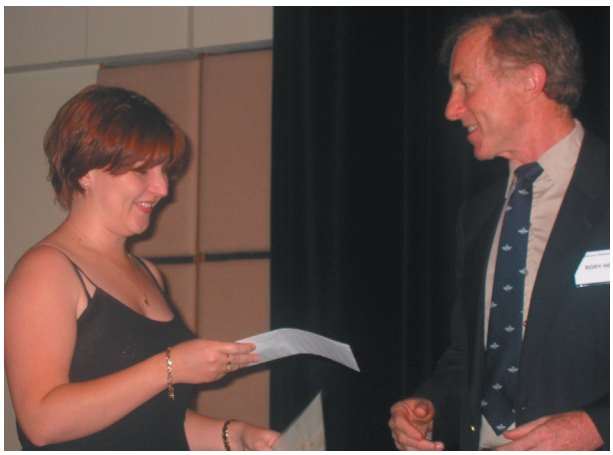

Tammie Roy being presented with the ANZCCART Student Prize by Rory Hope
(Photo by Louise Gilbert)

Poster Session

Animal Ethics Committees are not just animal care committees

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Abstract

Ethical conduct is conduct in accordance with rules and standards, and scientists are bound by law to act ethically in their use of animals in experimentation. The rules and standards by which they are bound are laid down by society. However, in my own experience, many scientists do not pay sufficient attention to the justification of the numbers of animals or to the impact that their experimentation will have on the animals.

Introduction

I am an animal scientist and also a member of an Animal Ethics Committee that almost exclusively examines applications relating to the conduct of scientific experiments. I write this article from the point of view of a member of the Committee As a start, I think that it is useful to define ethical conduct. The Macquarie Dictionary (1985) defines the adjective "ethical" as "in accordance with the rules or standards for right conduct, (especially) the standards of a profession". Scientists are bound by codes of ethical conduct that relate to honesty in the reporting of scientific experiments, acknowledging the work of others, authorship and so on. These are generally accepted by scientists as being a part of scientific life. And, like it or not, scientists are also bound by legislation as well as a code of conduct in the ethical use of animals in research and teaching. So, why try to buck the system, which is not going to change; why not work with it to make it work smoother?

The Animal Ethics Committee

Animal Ethics Committees (AEC) comprise a minimum of one member from each of four categories, veterinary, scientist, welfare and independent. This is because Society has laid down the standards of conduct for the use of animals and this use must take into account the veterinary, scientific, welfare and community concerns that are expected to be addressed. In fact, I believe that these members actually represent constituencies within society and bring to the AEC the views and concerns of these constituencies. However, in my experience, scientists submitting applications for approval generally do not understand the true role of the AEC and see it as something between another administrative hurdle to be overcome and an impediment to the conduct of science.

The responsibility of the applicant

It should go without saying that it is the responsibility of the applicant to be able to demonstrate the ability to design and conduct scientific investigations. However, in my experience, many do this poorly. I believe that the applicant also has to have a reasonable understanding of the welfare, veterinary and community aspects of the ethics of the conduct of experimentation.

Firstly, the science. I find that a lot of applicants do not adequately describe the experimental design and, especially, do not justify the numbers of animals to be used. There are two ways that the numbers of animals can be justified. The first of these is to use the experience gained in past experiments either by the scientist or by others as found in their published work. The second is to use either statistical texts such as Cochran and Cox (1957) or published papers such as Berndtson (1991). Both of these present methods of determining numbers in the light of the differences that are expected and the coefficient of variation of the character to be measured. As a scientist sitting on an AEC, I expect to see a justification for the number of animals to be used spelt out in these terms. Too many times, applicants justify the numbers of animals by simply stating that they have consulted a biometrician or that biometrical assistance will be sought. If serious biometrical assistance has been sought, the biometrician should be able to provide the justification for the numbers.

I also believe that the applicant has to have thought hard about the justification for the experiment. The first component of this is the addition to knowledge that the information will make. The second is the impact that it will have on the animals used to gain the knowledge. In my own experience, where much of the experimentation involves farm animals, many applicants make light of the impact on the animals, believing that this impact is non-invasive or only involves "normal animal husbandry". On our application forms, we have a section where the impact of the experiment on the animals is to be spelt out in detail. However, even a non-invasive experiment with a species like the sheep involves the normal husbandry practices of ear-marking, ear-tagging, tail docking, mulesing and, as is often the case for the male portion of the flock, castration. All of these operations are performed without anaesthetic. Certainly, there are industry standards and codes of practice, but applicants

generally fail to acknowledge the impact that these have on the animals in their care. Other operations that can have an impact on the animals but which also fall under the heading of normal husbandry are mustering and shearing, but rarely do they rate consideration.

If the scientist is unable to do either one of the above, there is no point proceeding with the ethics approval process.

The Animal Ethics Committee

Once the science and the reason for doing the experiment have been accepted, the Committee now has to weigh up the benefits that will come out of the work against the impact that it will have on the animals involved. While this might appear to be a bit simplistic, if the impact on the animals is high then there must be a high likelihood of a high level of benefit from the experiment.

The Committee must be assured that the treatment of the animals and the outcome can be justified from a veterinary standpoint and from a welfare standpoint, taking into account the species-specific physical and mental well being of the animals. The Committee must also be assured that the treatment of the animals and the likely outcome of the experiment are within the confines of community acceptability.

Harmful animal use in teaching

Cynthia Burnett
Humane Education Officer, Animals Australia.

ABSTRACT

Of the three “Rs” the one that possibly causes researchers, educators, AEC committee members and students the most angst is that of “replacement”. This poster display looks at the issue of harmful animal use in TEACHING in light of three matters:

1. Australian and international legislative measures to replace the harmful use of animals (“alternatives”) in teaching
2. the increasing availability of print and electronic information relating to the harmful use of animals in teaching and
3. the continuing increase in student conscientious objection, both in Australia and overseas, as a pathway for change.

Legislative measures include those already in place and those currently under consideration in Australia, the UK, Europe and the USA. For example, ten States in the US have passed student-choice Bills allowing conscientiously objecting students the right to alternative teaching and learning pathways in relation to dissection. Are Australian AECs aware of such developments?

With the advent of electronic communication, vast amounts of information on alternatives in teaching are now available to educators and students alike. For example, there are websites entirely dedicated to the issue of appropriate “replacement” in the life sciences. There are “humane education” email discussion lists through which interested students and educators share first hand experiences of replacement in their courses. It is advantageous for AEC members to understand the effect these initiatives are having on student populations in particular.

Recently both in Australia and the US, experiences of conscientiously objecting students have resulted in significant changes being brought about in individual course programs and whole university faculties. This is an issue of concern that is on the increase and will need to be taken into consideration by AEC members at one time or another. Are we ready for this?

Fitting WR into the three Rs

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ABSTRACT

The three Rs (Replacement, Reduction and Refinement) have stood the test of 40 years of judging animal welfare matters in research and teaching as a guide to ethical decisions on animal use. However, the initial conception and application was in the context of laboratories and/or well known animals, such as sheep, cows and dogs, not to mention mice, rats and guinea pigs. The current NH& MRC (1997) guidelines covers wildlife research for the first time and it has been of great assistance to AECs involved with native fauna. Yet there are problems for those who sit on AECs and those who fill out protocols as to what the three Rs mean for fauna surveys, assessments of feral pest control, and threatened species recovery programs. “Replacement” is not possible because the object of study is the animal itself for its conservation or control, and not as a model for testing an idea. This does not cause a conceptual problem. “Refinement” is a regular aim of all NPWS AEC deliberations from capture techniques to the marking of animals to be used in long-term field studies, but here the recurrent problem is the novelty of the animals being studied, particularly species about which so little is known and the taxonomy is still fluid. However, it is “Reduction” that causes the most problems, principally because the word “use” has proved to be so difficult to apply to field situations. For example, to look at an animal can constitute use, but does this properly apply to every bird watching exercise? Also, if the animals are in large numbers, e.g. waterbirds, flying foxes, native bush rats, it looks as though “use” may be growing, not falling, depending on whether one is counting before or during a drought or before or after a bushfire. Almost all the animals “used” in the protocols submitted to the NPWS AEC are either observed but not touched or, caught momentarily, (such as in a net) or overnight, (such as in a cage trap) and then released unharmed, with usually little more than species, sex and age recorded. It is the task of AECs to intelligently apply the three Rs and integrate them with an equally valid community ethic, namely conserving our wildlife, so that best practice is applied and continues to be developed for the care and handling our unique Australian fauna.