anzccart
HUMANE SCIENCE

ANZCCART Conference 2015

Animal Ethics - The Gold Standard

Conference Proceedings

21 to 23 July, Gold Coast, QLD

www.adelaide.edu.au/ANZCCART/

2015 ANZCCART Conference Programme

Tuesday 21st July 2015

9.00am	**Conference Registration Desk Opens**
9.00 – 11.00 am	Tea and Coffee available for all delegates in the conference foyer area
11.00am	**Conference Opening** **Prof Richard Russell,** Chairman of the ANZCCART Board
Session Chair	*Richard Russell (Chairman, ANZCCART)*
11.30am	**Margaret Rose**- Applying the concept of wellbeing to the advancement of refinement
12.00 noon	**John Schofield & Jim Webster –** What colour is your animal ethics application?
12.30pm – 1.30pm	**Lunch**
Session Chair	*Mandy Paterson (ANZCCART Board Member)*
1.30pm	**Bridget Brox** – Herding small cats: Behavioural observation and welfare management.
2.00pm	**Christian Bowman** – Being a Category C Member and how to utilize one to widen the perspective of an AEC
2.15pm	**Judith Anderson** – What makes an application user friendly for a Category D Member of an AEC
2.30pm	**Paloma White** – Regulated to their eyeballs: Changing regulatory frameworks and the administration of animal ethics committees
3.00 – 3.30pm	**Afternoon Tea Break**
Session Chair	*Geoff Dandie (CEO, ANZCCART)*
3.30pm	**Discussion Groups by AEC Membership Category**
4.00pm	Discussion of hypotheticals
4.30pm	**Feedback from Category Groups to Plenary**
5.00pm	End of Formal Sessions for Day 1
5.30pm – 7.30pm	**Cocktail Function**

Wednesday 22nd July

Session Chair *Richard Russell (ANZCCART Chairman)*

9.00am **Ian Frazer** – Modelling cancer immunotherapy from mouse to human – Mice don't always lie!

9.30am **Michael Batzloff** – TBA

10.00am **Darryl Jones** – Does a bandicoot die in a trap if there is no AEC member present? Dilemmas and responsibilities of field work

10.30am **Morning Tea**

Session Chair *Nicola Pritchard (Member, Local Organizing Committee)*

11.00am **Ian Peak** – Competency and training and the code

11.30am **Francesca Fernandez - Enright** – Research Institutions: How to provide appropriate training to investigators using animals in their research

12.00noon **Bridget Brox** - Pursuing good science: Animal welfare training for university students

12.30 – 1.30pm **Lunch**

Session Chair *Ian Peak (Member, Local Organizing Committee)*

1.30pm **Annie Tarala** – Teaching using animals at the University of Western Australia

2.00pm **Dani Maver** – Title TBA

3.30pm **Robert Cassidy** – Title TBA

3.00pm **Afternoon Tea**

Session Chair *Geoff Dandie (CEO, ANZCCART)*

3.30pm **Geoff Dandie** - Introduction to afternoon workshop

Workshop discussions

4.30pm Feedback from Workshops and Discussion Forum

5.00 pm End of formal sessions for day 2

7.00pm Bus transfer to Dinner venue
(Due to driveway repairs, buses will depart from the loading bay in the street, adjacent to the hotel driveway – our apologies for the inconvenience)

7.30pm – 11.30pm **Conference Dinner** - 78th Floor of the Skypoint tower

Thursday 23rd July

Session Chair *Pete Hodgson (ANZCCART Board Member)*

9.00am **Virginia Williams** – Hidden holes – Are there gaps in the AEC system?

9.30am **Ali Callum** – Us and them – Are we equals in ethics? Consideration on the interface of animal and human ethics.

10.00am **Denise Noonan** – What is the gold standard of competency for animal – based research investigators?

10.30am Morning Tea

Session Chair *Ian Peak (Member, Local Organizing Committee)*

11.00am **Olaf Meynecke** – Animal ethics in marine science – Minimising impact, maximising output

11.30am **Ali Callum** – Reaching for gold and beyond: Refinement of ventral laparotomy procedures and application of this learning to other surgical methods.

12.00pm **John Schofield** – The Cetacean code:- Unlocking underwater language

12.30 – 1.30pm **Lunch**

Session Chair *Mandy Paterson (ANZCCART Board Member)*

1.30pm **Erika Vercuiel** – Animal research in South Africa – developments and achievements of the Animal Ethics Unit, National Council of SPCA's

2.00pm **Geoff Dandie** – Research models: - Are animals the gold standard?

2.30pm Conference summary and conclusion.

3.00pm **Conference Ends**

3.30 – 4.00pm **Afternoon Tea**

Presentations given

on

Tuesday 21st July

Applying the concept of wellbeing to the advancement of Refinement

Margaret Rose[1, 2] and Josephine Joya[3]

Prince of Wales Clinical School, University of New South Wales [1], Centre for Value, Ethics and Law in Medicine, University of Sydney [2], Research Ethics & Compliance Support, University of New South Wales [3] UNSW Sydney NSW 2052 AUSTRALIA.

Although, to date, strategies to identify and alleviate the experience of pain or distress have been the primary focus to achieving Refinement, it is noteworthy that Russell and Burch[1] contended that we should "aim at wellbeing rather than a mere absence of distress". Further, they concluded that the "psychosomatics of experimental animals" was probably the single most important area by which Refinement would be advanced. This at a time when the mind<>body relationship was contentious, poorly understood and generally not recognised as significant in non-human animals.

The notion of wellbeing implies a positive mental state, positive experiences, successful biological function and a capacity to respond to and cope with potentially adverse conditions[2].
Recent advances in neurobiology and ethology have provided evidence that animals experience negative and positive emotional states. Whilst there is increasing evidence of the impact of negative emotional experiences on the validity and interpretation of data, the role and significance of positive experiences merits investigation.
This paper will argue that the concept of wellbeing is pivotal to achieving the goals of Refinement and that a focus on ways to enable cognitive and emotional development will support animal wellbeing, advance the goals of Refinement and potentially enhance scientific outcomes.

[1]Russell WMS, Burch RL. The Principles of Humane Experimental Technique. London: Methuen & Co LTD.,1959.
[2]Australian Code for the Care and Use of Animals for Scientific Purposes. Canberra: Commonwealth of Australia, 2013.

By agreement with the organizing committee, Prof Rose will be publishing her manuscript in an international journal at a later date, so the full manuscript will not be included in these proceedings.

What colour is your animal ethics application?

John C Schofield*, Jim R Webster**
*J&L Consulting Ltd, Dunedin NZ , **AgResearch Ltd., Ruakura, Private Bag 3123 Hamilton 3240, NZ

The current system whereby animal-based research must be approved by an independent Animal Ethics Committee (AEC) may be perceived by some as the gold standard. Clearly this system is better than no regulation at all – but how "Golden" is it really? Does it "shine out like a shaft of gold when all around is dark?" A careful review of the controls on animal use for research uncovers or identifies a number of anomalies which challenges the notion that the current system operates at the 'gold standard' level. This presentation explores these anomalies through a debate: the affirmative position defends the proposition: that animal ethics is the gold standard, while the negative position challenges that view. Is the current AEC system really a gold standard- or merely silver, bronze or are we simply being lead?

The title of this conference: *"Animal Ethics- The Gold Standard"*, appears to us to be an intriguing and provocative theme, which begs the response: "Is that a statement of fact or is that a question?" Such a title suggests to us that a debate might be a useful strategy to explore this issue. So this paper presents the two sides of a debate.
The Affirmative will argue that "Animal Ethics is the Gold Standard", while the Negative will argue that "Animal Ethics is not the Gold Standard". Webster went in to bat for the Affirmative, and Schofield for the Negative. We made use of sporting analogies and the awarding of medals: gold, silver or bronze in this presentation, to describe levels of performance.

The Affirmative's arguments are underpinned by four main points:

1. The animal ethics gold standard is based on the collective wisdom of peer reviewed literature.
2. The system is fair and transparent.
3. With broad-based societal participation in the process of committee review.
4. Supported by rigorous monitoring and enforcement.

The Negative's arguments are also underpinned by four main points:

1. There are a plethora of exceptions in the literature to challenge the wisdom of peer review.
2. Transparency is in the eye of the beholder, as transparent as the Official Information Act (OIA).
3. Some societal representatives are less than effective.
4. Monitoring and/or enforcement can be as variable as the weather.

To develop these arguments further, the Affirmative's position is expanded below, followed in turn by the Negative response:

Affirmative: Based on collective wisdom of peer reviewed literature:

- AECs review applications which are generally based on the science literature.
- Only good science reaches the AEC, since many applications already have been funded.
- This basis validates the proposed science.
- It builds on what has been learnt before.

- It uses techniques which are tried and true and therefore withstand the test of time.

It was suggested that anything less rigorous, is simply "Witchcraft"

Negative: The plethora of literary exceptions:
Agreed that the literature should be the basis of all proposals but:

- There can be significant pressure on AECs, when applications have already been funded.
- Principal Investigators (PI) generally only cite references which support their science, avoiding any contrary references. Clearly presenting to the AEC an unbalanced and biased literature review.
- Animal Ethics Committees (AEC) should evaluate the quality and currency of the literature cited.
- What if the PI uses outdated literature? This is highlighted in the classic example of AEC approved burn studies. A number of scientists reporting burn studies still believe that 3rd degree burns are insensate and hence they argue that no analgesics are needed.
- What if the animal model referenced, is proven by more recent modern tests to be invalid?

Affirmative: the system is a fair and transparent:
Transparency is achieved by:

- The AEC review system is open and defined by legislation. It is even-handed.
- Approval is a two-way process; dialogue is encouraged with researchers.
- Published guidelines are available to assist PIs prepare applications.
- Statutory (annual) reporting of numbers (and grade) used, and these are released publically.
- Meetings are "public".
- OIA is available if anyone wants to access the details of animals used in research.

Negative: There is minimal transparency, because AECs have some of the characteristics of Secret Societies:
Some general features of secret societies such as Freemasons, Illuminati, The Skull and Bones, The Rosicrucians, Bilderberg, The Elders of Zion and The Knights Templar include the following eerie similarities to AECs:

- Secret society membership structures consist of graded or hierarchical degrees. Some degrees have distinctive names, such as the Grand Master 1st Degree, with various stages of proficiency commencing with the 7th Degree (novice)
- Likewise the AEC membership names in Australia include : A, B, C and D
- Admit members of both sexes and claim to have no policy of sexual preferment in regard to promotion within the group.
- The assumption by members of a pseudonym or 'magical' name or motto for use within the organization. For example AECs or IACUCs (Institutional Animal Care and Use Committee). Both these terms are unknown to the uninitiated general public.

The Negative asks the bold question: "Exactly where is the transparency?" A clear lack of transparency is demonstrated by the following:

- AEC membership is not disclosed to the public.
- The AEC application forms are secret documents, not generally available to the public.
- The public is excluded from significant agenda items discussed at AEC meetings.

- There is no standard application form in use, institutions develop their own systems.
- The quality of AEC reviews is quite variable.
- External review reports (every 3yrs in Australia and every 5 yrs in NZ) are not public documents. *See Editor's Note
- Frequently details are redacted from documents requested under the OIA.

Affirmative: There is broad-based societal participation:

- In NZ AECs include nominees from the SPCA, the NZ Veterinary Association and from regional councils. These are complemented by scientists.
- In Australia AECs include Category A, B, C and D personnel.
- Therefore the public is well represented on AECs.
- The system clearly illustrates democracy in action, by society participation.
- The science projects which are approved reflect our societal views and opinions.
- Furthermore, not all applications are approved. This confirms that the review process is working well, that it is balanced and even-handed.

Negative: Societal representatives can face significant challenges and difficulties:

- These nominees are secretly selected. The public is not aware of them. Hence the claim of broad-based representation is a fallacy.
- The SPCA/ Cat C members generally lack any formal animal welfare training. They are selected for their affiliation with these welfare organisations, generally not for any special expertise.
- Regional council/ Cat D members often lack a science background, making their participation more difficult.
- The effectiveness of these societal representatives is very much person dependent. Some nominees offer helpful guidance to the AECs, while others are frequently silent.
- Furthermore, the opportunity for whistleblowing is restricted.

Affirmative: There is rigorous monitoring and enforcement of animal based studies:

AEC monitoring strategies can include:

- Progress reports to the AEC.
- End of study reports to the AEC.
- Adverse event reporting to the AEC.
- AECs can control the supply of experimental animals for research. This offers a rigid monitoring system.
- There are systems in place to ensure only experienced personnel use animals.
- Animal Welfare Officers generally are used to monitor and police animal use.
- Regular inspection visits of animal houses and laboratories by the AEC are mandated.
- Post-approval (PAM) monitoring site visits by the AEC.
- Unannounced "surprise" (SPAM) visits by the AEC.

Negative: Monitoring/ enforcement can be as variable as the weather:

- Monitoring guidelines are vague at best.

- PAM visits are expensive/time consuming. Guidelines in both NZ and Australia recommend that external AEC members are part of the site visit team. However, such external individuals are generally in full-time employment and consequently their availability is often very limited.
- Experience indicates that the scientists on AECs are reluctant to visit their peers. Hence site visits can be variable and infrequent.
- Adverse event reporting is variable. There are few national guidelines for such reports.
- At tertiary institutions, the "manipulation" or experimental procedure is approved, but not always the personnel.

In summary, the case for the Affirmative rests on the following sporting analogies:

- The current system is Solid Gold!
- We should get more funding based on our performance!
- Our systems are highly regarded and internationally competitive.
- AECs are like well-oiled teams.
- AEC members are like highly tuned athletes. Fit, well prepared and competent.
- There is long standing and exemplary service by many AEC members

In summary, the case for the Negative rests on the following:

- The current system is clearly not gold; maybe bronze with the occasional silver.
- More transparency is clearly needed – the system should be like "armoured" glass.
- More training is needed for the AEC members.
- More SPAM visits would be recommended.
- AEC membership should be reviewed more regularly so as to refresh committee membership on a regular basis.

In conclusion the purpose of the debate was to ask some hard questions of the system and challenge the issue of transparency.

References:

The Animal Welfare Act 1999 (NZ)
The Australian code for the care and use of animals for scientific purposes. 8th edition 2013. National Health and Medical Research Council.
Good Practice Guide for the use of animals in research, testing and teaching 2010. Ministry of Agriculture and Forestry. NZ.

Editor's note:

*This was a light-hearted presentation designed to challenge delegates and stimulate discussion, so not all comments made in this context are strictly correct. This is an example where the statement made is actually contradictory to the position taken by the Australian Code.
Section 6.2(vii) states: Institutions must: consider publishing a summary of the external review report (eg. as part of an institutional annual report of website) and making the summary report available to the relevant regulatory authority and funding bodies of the institution (see clause 2.1.10).

Herding Small Cats: Behavioural Observation and Welfare Management

Bridget Brox[1], Horton, P.[2] and Eyre, S[2]

[1]Victoria University of Wellington, [2]Wellington Zoo

Wellington Zoo is host to a wide variety of animals and their care and welfare are of highest priority. To better understand changes in welfare for two pairs of small cats (servals and caracals) an observational study was commissioned and began August 2014. Both pairs of cats were housed in temporary enclosures until the "Grassland Cats habitat" was completed at the end of September. They were then transferred to the new, permanent exhibit. Behavioural data was collected for each animal (3 sessions/week over 4 weeks) while in the temporary enclosures and again after they were moved to the permanent exhibit. Data was then analysed and revealed patterns of positive, neutral and negative behaviours. This information was then used to inform changes in the cats' habitats and to their overall care. Follow up observations were conducted in May/June 2015 to re-evaluate the behaviour of each cat. Results clearly show that the four animals have acclimatised to their new, permanent environment and efforts to manage negative behaviour have been largely successful. Overall, this study provided insight into the challenges that zoos face in managing long term welfare of the animals in their care.

Namely, that every animal, even those of the same species, can be dramatically different in temperament, health, behaviour and individual needs. Due to this heterogeneity it is essential to take a multi-faceted approach to achieve positive outcomes in animal welfare for each animal.

Background & Purpose

Wellington Zoo is host to a wide variety of animals and their care and welfare are of highest priority. This report summarises an observational study that was undertaken to collect behavioural data on two pairs of small cats (servals and caracals) in the care of Wellington Zoo. Both pairs of cats were housed in temporary enclosures until the "Grassland Cats" exhibit was completed at the end of September 2014. They were then transferred to the new, permanent enclosures. Observational data was collected before, while they were in the temporary enclosures, and after they had moved to their permanent home. Additionally, follow up sessions were conducted eight months later to evaluate further changes in behaviour. Taken as a whole this information can be used to identify any behaviours that need to be addressed and inform decisions regarding the cats' enclosures and overall care.

Methods

Data Collection

Ethogram

Observational data was collected using a *Small Felis* ethogram suitable for both species (Mellen, 1993). The ethogram included the behaviours listed below (Table 1). After conducting an initial observation (prior to Part 1) selected behaviours were added to the ethogram (Table 2).

Behaviour	Description
Flehmen	Open-mouthed grimace following the sniffing of an object or cat
Urine marking	Urination
Faeces	Defecation
Following	Cat follows within two body lengths of other cat for a distance at least two body lengths
Displacing	Cat directly approaches another cat (within one body length) and within 5 seconds the second cat moves away
Approaching	Cat directly approaches another cat (within one body length) and the cat approached does not move away
Chasing	One cat runs at or after another cat
Sharpening claws	Claws of front paws are used to scratch a surface
Anogenital sniffing	Cat sniffs the anogenital region of another cat
Social sniffing	Cat sniffs any region other than the anogenital region of another cat
Social grooming	One cat licks and/or nibbles on the fur of another cat
Strike	Cat strikes at another cat with its paw
Cheek rubbing	Cheek of cat is rubbed against an inanimate object
Head rubbing	Head of cat is rubbed against an inanimate object
Neck rubbing	Cat vigorously rubs/scrapes lateral portions of neck against an inanimate object or along substrate
Social head rubbing	Head (forehead region) is rubbed against another cat
Lordosis	Female lowers her forequarters while elevating her hindquarters; tail is often moved to one side
Vocalization	Spit, hiss, growl
Mounting	Male over female (lordosis posture)
Face off	Cats simultaneously face one another (within 1-2 body lengths of each other)

Table 1: Original ethogram behaviours and descriptions.

Behaviour	Description
Inactive	Cat is sitting, standing, laying down or walking
Running	Cat runs (without interacting with another cat)
Climbing	Cat climbs tree or other vertical substrate
Pacing	Cat paces repeated short distances
Patrolling	Cat roams the enclosure (often accompanied by urine marking)
Self grooming	Cat licks and/or nibbles on its own fur
Strike/bite	Cat strikes at another cat with its paw or cat bites another cat
Eating/drinking	Eating food or any object, drinking water
Out of sight	Unable to see cat from observer position

Table 2: Behaviours added to the ethogram.

An example of the template used for data collection is provided below (Figure 1).

Serval and Caracal Observations

Date: 12 September 2014
Start Time: 3:45 pm
Species: Caracal
Observer: Bridget Brox

Note: Just feeding when I started

Individual: 140034

Behaviours

Minute	Flehmen	Urine marking	Faeces	Following	Displacing	Approaching	Chasing	Inactive	Pacing	Climbing	"Sharpening" claws	Anogenital sniffing	Social sniffing	Social grooming	Self grooming	Strike	cheek rubbing	Head rubbing	Neck rubbing	Social head rubbing	Lordosis	Mounting	Face-off	Out of sight	Eating	Spit/hiss/growl vocalizations
1																								x		(v) xx
2																								x		
3																								x		
4																								x		
5																								x		
6																								x		
7																								x		
8						x																				
9								x																		(v) xxxxx
10								x (high perch)																		(v) xxxxxxxxxx
11																								x		(v) xxxx
12																								x		
13																								x		
14																								x		
15																								x		
16																								x		
17																								x		
18								x (high perch)																		(v) xx
19								x (by me)																		(v) xxxx (h) x (at me)
20								x																		(v) x
21																								x		
22															x											
23																								x		
24									x (outside)																	
25									x																	
26									x																	
27									x																	
28																								x		

Figure 1: Example ethogram template used for data collection.

Sessions

Data collection was divided into three discrete parts: in Part 1, observations were made while the cats were in their temporary enclosures. Then in Part 2, observations were made after the cats had moved to their permanent enclosures in the "Grassland Cats" exhibit. Eight months after moving to the new enclosures follow up observations were conducted to evaluate further changes in behaviour (Part 3) (see Figure 2).

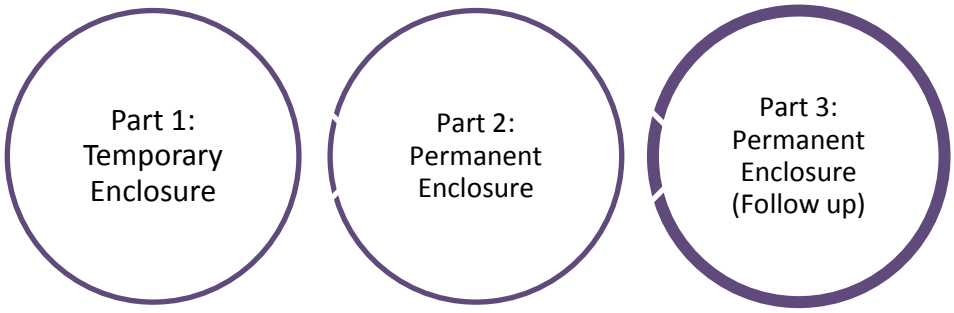

Figure 2: Broad experimental setup: Parts 1, 2 and 3.

During Parts 1, 2 and 3 observations where conducted over four weeks with three sessions per week. Each week one session was completed in the morning (9 AM, 10Am), one at midday (12PM, 1PM) and one in the late afternoon/evening (3 PM, 4PM). Varying days and times provided the opportunity to collect the widest range of potential data. During each session, the observer would record the session start time on the ethogram templates (one for each animal) and start the stop watch. After one minute had elapsed the observer would record (at least) one observation for each cat. On occasion the cats displayed multiple behaviours simultaneously; all behaviours were then recorded. Each session comprised 60 observations per animal (60 minutes) (see Figure 3).

Schedule

Each observational session is listed below (Table 3). During Part 1 observations of both pairs of cats were completed on the same day. However, during Part 2 the servals were placed on a rotating schedule and would spend part of the day "on exhibit" and then be moved to an "off exhibit" area while the younger pair of servals would have time "on exhibit" in the enclosure. Therefore, some of the observations for both pairs of cats were completed on different days. In the end the same number of observations was conducted for each pair of cats. Part 3 observations were completed for the caracals only and matched the observation number, counterbalanced time of day and duration described in both Parts 1 and 2.

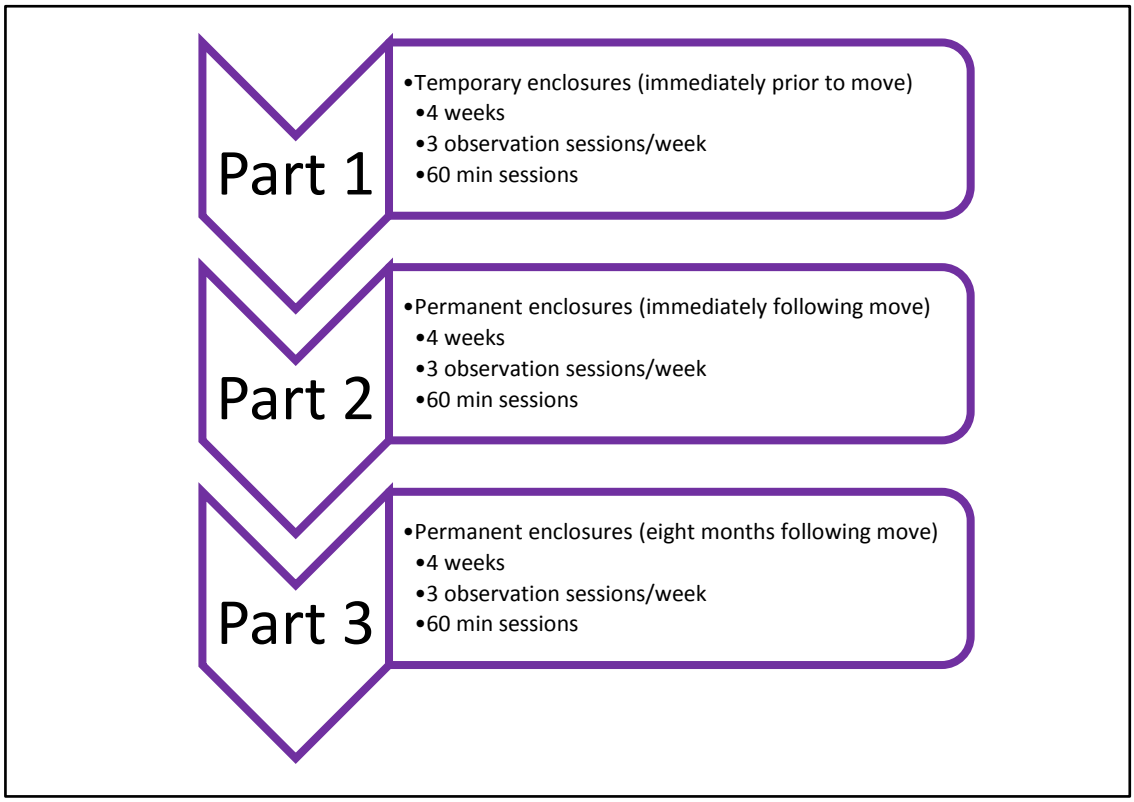

Figure 3: Detailed experimental set up: Session specifics including number, frequency and duration.

Part 1			Part 2						Part 3		
Caracals & Servals			*Caracals*			*Servals*			*Caracals*		
	Day	**Time**		**Day**	**Time**		**Day**	**Time**		**Day**	**Time**
Observation 1	1-Sep	9 AM, 10 AM	***Observation 1***	30-Sep	3 PM, 4 PM	***Observation 1***	4-Oct	9 AM, 10 AM	***Observation 1***	24-May	12:00 PM
Observation 2	4-Sep	3 PM, 4 PM	***Observation 2***	1-Oct	3 PM, 4 PM	***Observation 2***	7-Oct	3 PM, 4 PM	***Observation 2***	26-May	9:00 AM
Observation 3	6-Sep	12 PM, 1 PM	***Observation 3***	4-Oct	9 AM, 10 AM	***Observation 3***	11-Oct	12 PM, 1 PM	***Observation 3***	28-May	3:00 PM
Observation 4	11-Sep	12 PM, 1 PM	***Observation 4***	7-Oct	3 PM, 4 PM	***Observation 4***	13-Oct	12 PM, 1 PM	***Observation 4***	29-May	12:00 PM
Observation 5	12-Sep	3 PM, 4 PM	***Observation 5***	9-Oct	9 AM, 10 AM	***Observation 5***	14-Oct	9 AM, 10 AM	***Observation 5***	1-Jun	9:00 AM
Observation 6	13-Sep	9 AM, 10 AM	***Observation 6***	11-Oct	12 PM, 1 PM	***Observation 6***	17-Oct	3 PM, 4 PM	***Observation 6***	3-Jun	12:00 PM
Observation 7	16-Sep	3 PM, 4 PM	***Observation 7***	13-Oct	12 PM, 1 PM	***Observation 7***	20-Oct	9 AM, 10 AM	***Observation 7***	4-Jun	9:00 AM
Observation 8	17-Sep	9 AM, 10 AM	***Observation 8***	17-Oct	3 PM, 4 PM	***Observation 8***	22-Oct	12 PM, 1 PM	***Observation 8***	6-Jun	3:00 PM
Observation 9	19-Sep	12 PM, 1 PM	***Observation 9***	20-Oct	9 AM, 10 AM	***Observation 9***	23-Oct	3 PM, 4 PM	***Observation 9***	8-Jun	3:00 PM
Observation 10	21-Sep	12 PM, 1 PM	***Observation 10***	22-Oct	12 PM, 1 PM	***Observation 10***	26-Oct	12 PM, 1 PM	***Observation 10***	9-Jun	12:00 PM
Observation 11	23-Sep	9 AM, 10 AM	***Observation 11***	26-Oct	9 AM, 10 AM	***Observation 11***	29-Oct	9 AM, 10 AM	***Observation 11***	10-Jun	3:00 PM
Observation 12	24-Sep	3 PM, 4 PM	***Observation 12***	29-Oct	3 PM, 4 PM	***Observation 12***	30-Oct	3 PM, 4 PM	***Observation 12***	12-Jun	9:00 AM

Table 3: Assessment schedule for Parts 1, 2 and 3.

Data Collation and Analysis

After the final observations were recorded all data were entered into a master spreadsheet for Parts 1, 2 and 3. Recording one data point (per animal) each minute gives a sum total of 720 observations. However, there were a small number of occasions where multiple data points were recorded in the same minute. Therefore, to account for this the total number of observations for each animal was calculated and used to compute values reflecting the percentage of total observations for a particular behaviour.

Serval Individual Data

During Part 1 it was immediately apparent that one of the servals, Kijana, was producing a noticeable amount of pacing behaviour. Therefore, to investigate this behaviour further the pacing data was divided into two parts to distinguish at what location the behaviour had occurred. Both overall and specific pacing data is presented in the Results section. There was no in depth data analysis carried out on any behaviour exhibited by Nkeru.

Data was collected for the servals as specified previously in Part 2. However, no data was collected for the servals in Part 3.

Caracal Individual Data

During Part 1 vocalisations were recorded and are presented in the Results section. Unfortunately, due to the construction of the "Grassland Cats" exhibit it was not possible to record vocalisations in Parts 2 or 3.

Additionally, during Part 2 it became clear that the caracals were spending most of their time on the right side of the enclosure (farthest from their serval neighbours). While it is expected that they would experience a "transition" period in moving to a brand new enclosure they should be using the majority of the space. Therefore, the data from Parts 2 and 3 was analysed to show the amount of time they were spending on the left and right sides of the enclosure. This data was calculated from the time the cats were "in sight" in the enclosure and therefore did not include time spent "out of sight" (i.e. in the den).

Results

Serval Data

Kijana

Percentages were calculated by dividing the number of observations for a particular behaviour by the total number of observations. Total observations for Kijana in Parts 1 and 2 were 746 and 781, respectively.

There were several behaviours that Kijana never exhibited (Table 4) and those that comprised up to 10% of the total observations recorded (Table 5).

Part 1	Part 2	
Behaviour	*Behaviour*	
Flehmen	Flehmen	Head rubbing
Faeces	Following	Neck rubbing
Running	Displacing	Social head rubbing
Anogenital sniffing	Climbing	Mounting
Neck rubbing	Sharpening Claws	Face off
Mounting	Strike/bite	Cheek rubbing
Face off		

Table 4: Behaviours that were never observed for Kijana in Parts 1 and 2.

Part 1		Part 2	
Behaviour	*Percentage*	*Behaviour*	*Percentage*
Urine marking	1.34	Urine marking	5.48
Approaching	1.21	Approaching	1.4
Chasing	0.13	Chasing	0.26
Patrolling	1.88	Patrolling	1.3
Social sniffing	0.8	Social sniffing	0.39
Social grooming	0.13	Social grooming	0.13
Self grooming	2.4	Self grooming	2.3
Sharpening claws	0.4	Faeces	0.9
Following	0.13	Running	0.13
Displacing	0.27	Anogenital sniffing	0.13
Climbing	0.13	Eating/drinking	4.43
Strike/bite	0.54		
Cheek rubbing	0.4		
Head rubbing	0.13		
Social head rubbing	0.13		
Eating/drinking	0.8		

Table 5: Behaviours that comprised up to 10% of the total observations recorded for Kijana in Parts 1 and 2.

Beyond the behaviours listed above Kijana spent the majority of his time either inactive, pacing or out of sight (Table 6).

Part 1		Part 2	
Behaviour	*Percentage*	*Behaviour*	*Percentage*
Inactive	25.07	Inactive	58.67
Pacing	21.85	Pacing	11.73
Out of sight	42.23	Out of sight	14.47

Table 6: Behaviours that were observed most often for Kijana in Parts 1 and 2.

When pacing data was analysed separately, to compare the amount of pacing in Parts 1 and 2, a paired samples *t*-test revealed a marginally significant result ($p = .07$).

To explore Kijana's pacing further the data was organised to show how much time he was pacing in specific locations (Table 7). In Part 1 the "interior" fence refers to a portion of the fence adjacent to the keeper's entrance and the "exterior fence" refers to the portion of the fence adjacent to the stairs near the end of the temporary enclosure. In Part 2 the "den door" refers to a

portion of the fence adjacent to the den doors, the “exterior fence” refers to a portion of the fence on the left side of the enclosure (closest to dens) and the “fence door” refers to the door connecting the serval and caracal enclosures located on the wall that the enclosures share.

Part 1		Part 2	
Location	*Percentage*	*Location*	*Percentage*
Interior fence	59.51	Den door	10
Exterior fence	40.49	Exterior fence	50
		Fence door	40

Table 7. Pacing behaviour divided into specific locations from Parts 1 and 2.

Nkeru

Percentages were calculated by dividing the number of observations for a particular behaviour by the total number of observations. Total observations for Nkeru in Parts 1 and 2 were 753 and 767, respectively.

There were several behaviours that Nkeru never exhibited (Table 8) and those that comprised up to 10% of the total observations recorded (Table 9).

Part 1	Part 2
Behaviour	*Behaviour*
Flehmen	Flehmen
Anogenital sniffing	Anogenital sniffing
Cheek rubbing	Cheek rubbing
Head rubbing	Head rubbing
Neck rubbing	Neck rubbing
Lordosis	Lordosis
Mounting	Mounting
Face off	Face off
Urine marking	Social head rubbing
Faeces	
Following	
Chasing	
Running	
Pacing	
Sharpening claws	

Table 8: Behaviours that were never observed for Nkeru in Parts 1 and 2.

Part 1		Part 2	
Behaviour	*Percentage*	*Behaviour*	*Percentage*
Displacing	0.13	Displacing	0.13
Approaching	3.59	Approaching	2.74
Climbing	0.8	Climbing	0.39
Patrolling	6.64	Patrolling	10.17
Social grooming	0.27	Social grooming	0.39
Self grooming	2.66	Self grooming	3.52
Strike/bite	0.27	Strike/bite	0.13
Eating/drinking	0.13	Eating/drinking	0.78
Social sniffing	0.66	Social sniffing	0.52
Social head rubbing	0.13	Pacing	1.43
		Sharpening claws	0.26
		Chasing	0.26
		Running	0.65
		Urine marking	0.26
		Faeces	0.52
		Following	0.13

Table 9: Behaviours that comprised up to 10% of the total observations recorded for Nkeru in Parts 1 and 2.

Beyond the behaviours listed above Nkeru spent the majority of her time either inactive or out of sight (Table 10).

Part 1		Part 2	
Behaviour	*Percentage*	*Behaviour*	*Percentage*
Inactive	28.55	Inactive	58.67
Out of sight	56.18	Out of sight	19.04

Table 10: Behaviours that were observed most often for Nkreu in Parts 1 and 2.

Caracal Data

Tinka

Percentages were calculated by dividing the number of observations for a particular behaviour by the total number of observations. Total observations for Tinka in Parts 1, 2 and 3 were 774, 764 and 811, respectively.

There were several behaviours that Tinka never exhibited (Table 11) and those that comprised up to 10% of the total observations recorded (Table 12).

Part 1	Part 2	Part 3
Behaviour	*Behaviour*	*Behaviour*
Flehmen	Flehmen	Flehmen
Urine marking	Urine marking	Following
Patrolling	Patrolling	Social sniffing
Anogenital sniffing	Anogenital sniffing	Strike/bite
Head rubbing	Head rubbing	Cheek rubbing
Neck rubbing	Neck rubbing	Head rubbing
Social head rubbing	Social head rubbing	Neck rubbing
Lordosis	Lordosis	Social head rubbing
Mounting	Mounting	Lordosis
	Cheek rubbing	Mounting
	Face off	Face off
	Faeces	
	Running	
	Pacing	
	Following	

Table 11: Behaviours that were never observed for Tinka in Parts 1, 2 and 3.

Part 1		Part 2		Part 3	
Behaviour	*Percentage*	*Behaviour*	*Percentage*	*Behaviour*	*Percentage*
Displacing	1.27	Displacing	0.12	Urine marking	4.44
Approaching	6.1	Approaching	1.4	Faeces	0.25
Chasing	1.14	Chasing	0.25	Displacing	0.37
Climbing	0.25	Climbing	0.37	Approaching	1.6
Sharpening claws	0.13	Sharpening claws	0.37	Chasing	0.86
Social sniffing	2.54	Social sniffing	0.5	Running	0.86
Social grooming	2.29	Social grooming	0.37	Climbing	1.11
Self grooming	3.43	Self grooming	3.85	Pacing	6.78
Strike/bite	2.29	Strike/bite	0.12	Patrolling	9
Eating/drinking	2.3	Eating/drinking	1.4	Sharpening claws	0.25
Faeces	0.13			Anogenital sniffing	0.12
Following	0.13			Social grooming	0.37
Running	0.13			Self grooming	4.32
Cheek rubbing	0.13			Eating/drinking	4.81
Face off	0.13				

Table 12: Behaviours that comprised up to 10% of the total observations recorded for Tinka in Parts 1, 2 and 3.

Beyond the behaviours listed above Tinka spent the majority of her time either inactive, pacing, patrolling or out of sight (Table 13).

Part 1		Part 2		Part 3	
Behaviour	*Percentage*	*Behaviour*	*Percentage*	*Behaviour*	*Percentage*
Inactive	36.85	Inactive	69.44	Inactive	55.66
Pacing	16.01	Pacing	0	Pacing	6.78
Out of sight	23.13	Out of sight	16.77	Patrolling	9
				Out of sight	13.19

Table 13: Behaviours that were observed most often for Tinka in Parts 1, 2 and 3.

Jasiri

Percentages were calculated by dividing the number of observations for a particular behaviour by the total number of observations. Total observations for Jasiri in Parts 1, 2 and 3 were 779, 733 and 760, respectively.

There were several behaviours that Jasiri never exhibited (Table 14) and those that comprised up to 10% of the total observations recorded (Table 15).

Part 1	Part 2		Part 3
Behaviour	*Behaviour*		*Behaviour*
Flehmen	Flehmen	Patrolling	Flehmen
Urine marking	Urine marking	Anogenital sniffing	Following
Faeces	Faeces	Strike/bite	Displacing
Following	Following	Cheek rubbing	Anogenital sniffing
Neck rubbing	Neck rubbing	Head rubbing	Strike/bite
Lordosis	Lordosis	Displacing	Cheek rubbing
Mounting	Mounting	Social head rubbing	Head rubbing
	Face off	Running	Neck rubbing
	Eating/drinking	Sharpening Claws	Social head rubbing
			Lordosis
			Mounting
			Face off

Table 14: Behaviours that were never observed for Jasiri in Parts 1, 2 and 3.

Part 1		Part 2		Part 3	
Behaviour	*Percentage*	*Behaviour*	*Percentage*	*Behaviour*	*Percentage*
Displacing	0.64	Approaching	0.96	Urine marking	0.77
Approaching	3.59	Chasing	0.14	Faeces	0.64
Chasing	0.64	Climbing	0.55	Approaching	1.28
Running	0.39	Pacing	0.68	Chasing	1.28
Climbing	5.26	Social sniffing	0.14	Running	0.51
Pacing	0.77	Social grooming	0.41	Climbing	0.26
Patrolling	0.39	Self grooming	0.68	Patrolling	1.28
Sharpening claws	0.13			Sharpening claws	0.77
Anogenital sniffing	0.13			Social sniffing	0.13
Social sniffing	1.8			Social grooming	0.13
Social grooming	1.7			Self grooming	2.57
Self grooming	6.55			Eating/drinking	2.57
Strike/bite	1.54				
Cheek rubbing	0.13				
Head rubbing	0.13				
Social head rubbing	0.13				
Face off	0.13				
Eating/drinking	2.44				

Table 15: Behaviours that comprised up to 10% of the total observations recorded for Jasiri in Parts 1, 2 and 3.

Beyond the behaviours listed above Jasiri spent the majority of her time inactive, out of sight or pacing (Table 16).

Part 1		Part 2		Part 3	
Behaviour	*Percentage*	*Behaviour*	*Percentage*	*Behaviour*	*Percentage*
Inactive	58.79	Inactive	71.49	Inactive	56.74
Out of sight	13.48	Out of sight	24.69	Out of sight	13.86
				Pacing	10.27

Table 16: Behaviours that were observed most often for Jasiri in Parts 1, 2 and 3.

In Part 1 only, total vocalisations (spit/hiss/growl) were recorded. Time vocalising was calculated by taking the total number of minutes in each session where vocalisations occurred and dividing it by the total session time (720 min) (Table 17).

Part 1		
Cat	*Total Vocalisations*	*Percentage*
Tinka	300	41.67
Jasiri	215	29.86

Table 17: Percentages of total time spent vocalising.

Lastly in Parts 2 and 3, along with behaviour specific data analysis as given above, the amount of time spent in each side of the enclosure was calculated (Table 18).

Part 2			Part 3		
Cat	*Percentage Left*	*Percentage Right*	*Cat*	*Percentage Left*	*Percentage Right*
Tinka	14.53	85.47	Tinka	44.23	55.77
Jasiri	1.48	98.52	Jasiri	22.97	77.03

Table 18: Percentages of total time spent in each side of the enclosure.

Discussion

Servals

Kijana

In Part 1, Kijana spent about 20% of his time pacing in two very specific places within the enclosure. Interestingly, after the move to the "Grassland Cats" exhibit, his pacing decreased by 50%. While this difference was only marginally significant according to formal statistical analysis this change should be considered an important shift in behaviour. Conducting follow up observations would be useful in determining if his pacing behaviour has remained the same or changed (increased or decreased). If his pacing behaviour remains the same (about 10% of the time) or increases it may be beneficial to further evaluate the state of his welfare. This could be done by measuring levels of faecal cortisol to determine if he is indeed stressed/agitated or if this behaviour has become a part of who he is but is not stressful in itself.

Nkeru

Nkeru did not show any maladaptive behaviour in either enclosure during the course of this study. In Part 2 she did exhibit pacing behaviour on one occasion; however, this occurred when there were zoo staff present in the serval enclosure to affix brush onto the fence of the shared wall between the serval and caracal enclosures.

Caracals

Tinka

In Part 1, Tinka spent about 16% of the time pacing along a portion of fence in the outdoor section of the enclosure. However, in Part 2 no instances of pacing were observed. While this is a positive shift in behaviour when observations were conducted in Part 3 instances of pacing were observed again. Pacing comprised about 7% of total observations and many of these coincided with people (zoo visitors and staff) walking past the enclosure particularly where the cats can look through the fence near the keeper gate.

Jasiri

In Part 1, Jasiri exhibited no maladaptive behaviours. However, in Part 2 in the last observational sessions she began exhibit pacing behaviour. In Part 3 Jasiri demonstrated pacing behaviour just over 10% of the time. Like Tinka, Jasiri would pace near the keeper gate. Considering this specific behaviour was observed in both cats at this particular area in the enclosure it may be useful to consider obscuring this portion of the fence in an effort to decrease this stereotypic behaviour.

The data collected in Parts 2 and 3 for both caracals was scrutinised to determine on what side of the enclosure they were spending most of their time. In Part 2, both cats spent their time, almost exclusively, on the right side of the enclosure. This placed them farthest from their serval neighbours. To address this issue straightaway the fenced wall that the two enclosures share was covered. In theory they should learn to explore and utilise the whole of the enclosure. Time spent on each side of the enclosure was again measured in Part 3. Interestingly, Tinka demonstrated a tremendous shift in behaviour. Time spent in the left side of the enclosure shifted from 15% to 45% and time spent on the right side of the enclosure shifted from 85% to 55%. This more balanced use of the enclosure suggests that Tinka has become more comfortable in this space. Similarly, Jasiri demonstrated a shift in time spent between the two sides of the enclosure. Initially, she spent the vast majority of the time (99%) on the right side of the enclosure. In Part 3 she spent more time on the left side of the enclosure (23%) but still remained on the right side of the enclosure most of the time (77%). This shift in behaviour is encouraging however it appears that Jasiri still may be uncomfortable spending time on the left side of the enclosure.

Overall, this process has provided insight into the challenges that zoos face in managing the long term welfare of the animals in their care. Conducting this research highlighted the fact that every animal, even those of the same species, can be dramatically different in temperament, health, behaviour and individual needs. Due to this heterogeneity it is essential to take a multi-faceted approach to achieve positive outcomes in animal welfare for each animal. To this end the data contained in this report can inform decisions regarding animal care for these cats.

Reference

Mellen, J.D. 1993. A comparative analysis of scent-marking, social and reproductive behaviour in 20 species of small cats (Felis). American Zoologist, 33 (2), 151-166.

Being a Category C Member and How to Utilise One to Widen the Perspective of an Animal Ethics Committee

Christian Bowman
RSPCA Queensland (Category C Member on Griffith University Animal Ethics Committee)

As a member of an animal ethics committee who is not currently involved in the care and use of animals for scientific purposes, one faces several challenges – particularly as a first time member. This may include navigating through the scientific language, processes and ultimate the core content of what a body of research is focused on achieving. These challenges can be further compounded by the varying nature of the research applications.

In this presentation, find out how you can widen the perspective of your committee and how a Category C member makes judgements on applications and form opinions on the acceptability of the ethics involved.

To further provide options as to how committees can better utilise a Category C member, some insight into how a typically non-scientific member of an animal committee thinks and how they can see an application totally different from other members will be given.

Key presentation topics

- Individual motivations
- Animal welfare expectations
- Asking the right questions
- A different perspective

Individual motivations

- My love for animals
- Working at the RSPCA
- Contribute personal experience
- Learning experience

Animal Welfare Expectations

- Animal care spectrum
- Decision making process
- Understanding context and outcomes
- Continuous improvement

Asking the right questions

- Developing a set of heuristics
- Understanding applications
  - Aims & Benefits
  - Numbers of animals
  - Supervision
  - Scoresheets etc
  - Euthanasia points
- Is this the most appropriate use of animals in this application?

Learning experience

- Engaging in a conversation in a different language
- Strategic decision making – Keeping project team engagement with AEC
- Benefits to humanity and the environment

What makes an application user friendly for a Cat D Member of an Animal Ethics Committee?

Judith Anderson
AEC Category D Member, Griffith University AEC

A short presentation on the experience of reading animal research applications as a representative of the public for over a decade will be given. Changes to formats that have assisted Category D members and some reflections on improvements we can make will be presented.

It is a privilege to be asked to serve on an Animal Ethics Committee and a responsibility to be current with the community expectations on the use of animals in scientific research.
Having considered research proposals from three universities and a major research institute in Qld, I would start by saying the application formats are evolving and changes made over time have enhanced the understanding of both AEC's and those commissioned with filling out the proposals.

Sub-section of the Code 2.7.3 states: "Institutions must ensure that procedures for applying to an AEC include a requirement for the use of plain English in an application, so that all members of an AEC are provided with sufficient information to participate effectively in the assessment of the application".

That being said, the non-use of lay language can be a major hurdle for Cat D members.
The key questions covered in a lay explanation should be:

What is the question being asked by the research team?
Is it building on previous research? How is it novel?
How are the animals being used?
Are there alternatives to animal use?
What are the short term and long term benefits to science and the community of this research?

This should take just a few paragraphs.

The Cat D member must understand the answers to these questions to make an informed decision.

There are other sections in the application for in-depth discussion of technical procedures, animal welfare and the 3R's. REDUCTION, REPLACEMENT and REFINEMENT Guidance in these matters can be asked from veterinary or research members Cat A or B as the meeting progresses.

In my experience persons without any medical or scientific background can be frightened off AEC committees, as the onus placed on them can be overwhelming. This is not saying we should limit the Cat D's to persons with scientific knowledge, but to be aware that instruction and training are important if they are to fulfil their role with understanding and actually enjoy contributing as a Community representative.

The application is user friendly when the numbers add up; i.e. the animal numbers requested match the numbers of those allocated to experimental groups. I know this sounds basic but testing math skills is not what we signed up for.

It is user friendly when the statistical methods used reflect an understanding of what is being tested. Not "we did it this way last time". We may not have been on the committee last time, or we do not remember the specific proposal mentioned. When the 3R's are considered, adjustments may be in order since "last time". Gold standards have been known to change over time. They are also evolving with new knowledge.

It would help the Cat D members if your statistics were fully explained so that numbers of animals can be justified in the light of the experiment. To be told groups of five are the usual but we are going to use three will flag a reduction. This is a good thing from a 3R's point of view, but what influence does it have on validity? Is the experiment still robust? Are animals going to be wasted in the long run as too few have been used? Statistical methods should determine an accurate picture of the numbers required and that should coincide with the numbers requested. Fewer researchers are now asking for extras 'just in case' and this is a positive. If more animals are necessary, a variation is the right path.

It is best practice when Cut and Paste is used appropriately. It is disconcerting for all members of a committee when a proposal using rats suddenly changes to using mice.

The 3R's, REDUCTION, REPLACEMENT and REFINEMENT, are a cornerstone in the use of animals for scientific purposes as incorporated in the Code. More effort is being focused by researches, including answers demonstrating that they realize the privilege of using animals and need to limit numbers to the minimum necessary to fulfil the aims of the experiment. Consideration of animal welfare through score sheets specific to the project is one aspect of refinement. Not just always using generic score sheets which may or may not identify an animal welfare issue likely to arise in a particular experiment. Attention to the 3R's is aided by asking researchers to specifically address the 3R's on the application form. Cat D members can see at a glance that these issues are being considered and attempts are being made to accommodate this aspect of the Code.

The use of drop-down menus is a help so that only the relevant responses appear. Members of AECs have accompanying instructional documents to refer to in assessing an application. Wading through excess pages is an inefficient use of the time of all committee members.

The use of Standard Operating Procedures can really help Cat D members know what is being done to the animals. However, sometimes Cat D members experience difficulty accessing the University computer network so they can look for SOPs as they are not members of the particular University. This needs to be altered to allow the Cat D member to align the procedure being assessed in the proposal with best practice as determined by the approved SOP. If access is not permitted to the University computer network, then a folder containing all SOP's with room for additions as they are approved, should be made available to Cat D members.

Some Cat D members might appreciate references being provided, but this can be overwhelming. If it is absolutely essential to include the whole paper or papers, then applicants should take the trouble to highlight the pertinent parts. One application I saw recently included submitted references totalling over 150 pages – almost all of which was meaningless.

Much of what I have said could be included in training in the use of the form and the checking of the finished application by the senior investigator.

One committee I was on, Cat C&D members were invited to join the Animal Welfare training program run for animal researchers who were new to the university. Explanation of the Code

gave a working knowledge of the obligations of members of AEC's and researchers. It also included a consideration of the application form, what constitutes a variation, what work requires a new application and use of an unexpected event form. This was followed with demonstrations by the Animal House staff in a laboratory. Animals used in demonstrations were surplus to requirements and would have been euthanized. To actually see methods of blood collection, sexing of neonates and tagging, anaesthesia, exsanguination and other methods of euthanasia, gave important insights into these activities and the respect with which the animals were treated. Once demonstrated, I was more accepting of the procedure. This training program was over two days which I saw as an invaluable tool in doing my job.

Training given by Dept. of Forestry and Fisheries on the changes to the Code was also very helpful.

I would like to conclude with a suggestion that would really assist Cat Ds and probably the AECs as a whole. It pertains to Variations in Methodology and animal numbers. We do not always see the original application when a variation comes forward. A flow diagram showing how the changed animal numbers, altered procedures and different challengers, fits into the overall aim would be invaluable to Cat Ds. This would be an ongoing document presented with each variation and gives a holistic approach, which the lay member can identify with.

Thank You

Regulated to their eyeballs: Changing regulatory frameworks in the administration of Animal Ethics Committees

Paloma White

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Monitoring is a key theme discussed at Animal Ethics Committee (AEC) meetings: how often animals are to be monitored and the means by which they should be monitored, tend to permeate the discussion of most projects. But animals are not the only beings being monitored. Researchers are routinely monitored by AECs through a system of regulatory mechanisms, as are the AECs themselves. These regulatory mechanisms include a system of national and state specific legislation, policies and codes, as well as institution specific policies and procedures all of which regulate animals, researchers, institutions and their AECs.

Drawing on ethnographic material obtained over a two-year period of participant observation with an Australian AEC, this paper will examine one aspect of regulation witnessed during the author's fieldwork - government regulation of the AEC system - to examine how changing regulatory frameworks may shape the practice of ethics at the committee level. This research was conducted at a time of significant change within the animal research ethics field in the state: proposed changes to state legislation had the intention of altering the framework for the establishment of AECs and the appointment of members, as well as dismantling the state Animal Welfare Advisory Committee. At the same time, the establishment of new research institutions and collaborations changed the research landscape, as well as the function and structure of some AECs.

In analysing one proposed regulatory change, this paper will elucidate some tensions that appear to be inherent within the field of animal research ethics in the state generally, and specifically within the AEC that hosted the author. In particular, it will be evident that a tension exists between AEC members' perceptions that the changes may not represent the 'gold standard' of the regulation and administration of AECs, and the idea that nothing will change — that it will be 'business as usual' if, and when, the changes are implemented. At the heart of this tension sit the ideas of transparency and public confidence in a system that has thus far been a robust one, juxtaposed with a growing neoliberal trend within state politics. This paper will discuss this tension in the context of one AEC, and will argue that although the current structure of the AEC system in the state may change, the function of committees and what happens around the committee table will not, because, as one informant remarked, "They are regulated to their eyeballs."

The past two years in the South Australian animal research ethics community can be best described as a period of significant change: the establishment of new research institutes, new collaborations between existing institutes, and the redevelopment and relocation of existing research institutes and infrastructure has seen the establishment of new animal facilities and animal ethics committees (AECs). In addition to these structural changes are the state government's recent legislative changes, which will alter the way AECs are established and how their members are appointed. The result is a change in the structure of individual committees in the state, as well as a significant change to the landscape of AECs in South Australia on a whole.

Drawing on ethnographic material obtained over a two-year period of participant observation with a South Australian AEC (the Committee), this paper will examine how regulatory frameworks are perceived by committee members to transform the AEC system in South Australia. In analysing the regulatory change, this paper will elucidate some tensions that appear to be intrinsic to the field of animal research ethics in the state. In particular, it will be evident that a tension exists between members' perceptions that the legislative changes may not represent the gold standard of the regulation and administration of AECs, and the idea that nothing will essentially change – that it will be 'business as usual' when the changes are implemented. This paper will discuss this tension in the context of one AEC, and will argue that although the current structure of the AEC system may change, the function of committees and what happens around the committee table will not, because, as one informant remarked, "They are regulated to their eyeballs."

In order to contextualise this research, I will begin with a brief overview of the animal ethics committee landscape at both the state and national levels, before briefly outlining the legislative reforms that will form the backdrop for this paper. I will then present ethnographic data, obtained during extensive participant observation within the South Australian AEC system, to show firstly the concerns that one AEC had about the reforms, and secondly the way that those concerns presented themselves as tensions or contradictions, expressed by individuals on the committee, and the committee itself.

Background

The broad range of administrative and regulatory frameworks relating to animal ethics and welfare in Australia has been well documented (see for example Anderson 1990; Dodds 2002; Rose & Grant 2013). This diversity allows the individual states and territories to control their own legislation on matters of animal welfare. In South Australia, the governing legislation

is the *Animal Welfare Act 1985* (SA) (henceforth, the Act), which in Section 4 stipulates the conditions for the use of animals in research and teaching. Under the Act, the use of animals for research and teaching can only be conducted by an individual or institution with a licence issued by the Minister, and administered through the government department responsible for the administration of the Act – the Department of Environment, Water and Natural Resources (DEWNR). There are a number of conditions placed on licences, most pertinently to this paper: consultation with, and approval of, an appropriately constituted AEC and adherence to the national framework - the NHMRC *Australian code for the care and use of animals for scientific purposes* (8th Edition, 2013, henceforth 'the Code').

Until June of 2015, AECs were constituted under the Act, with the Minister issuing AEC licences, formally establishing AECs and appointing all members. This state legislative framework made AECs statutory committees under the Act, setting South Australia apart from most other states and territories across the country. This process is often seen by committee members as a rubber stamp or an administrative hurdle: in most cases that I witnessed during my fieldwork, the Minister delegated the responsibility of the formal appointment process (confirmed in writing) to the Executive Director of the Department. Further, member recruitment was largely handled at the committee level. For example, existing members would identify a person who is interested in becoming a member, or whom they think would be a good member. Occasionally, category B members were approached and appointed as members as an element of professional development and the Institution's responsibility to facilitate animal welfare education for its researchers. Prospective members, after being nominated by the committee, were then forwarded to the Minister for approval and formal appointment to the committee. The government department responsible for the administration of the legislation and oversight of AECs (Dept. Environment Water & Natural Resources), was only used by the Committee to provide a check that the composition of the committee was appropriate and that there were no conflicts of interest.

The Changes

In July of 2014, the state government announced a suite of reforms, with the aims of removing red tape from the government sector, decreasing the bureaucratic burden of state government processes, and increasing government accountability and transparency. To achieve these aims, the Premier launched a review of all government boards and committees with the intent of abolishing, reforming or reclassifying most of them. After a three-month public consultation period, and with direct consultation with the numerous committees and institutions

involved in, or affected by, the government's proposed changes, it was decided to abolish or reform 420 government boards and committees. As a result, the twelve AECs were to be reclassified as institutional committees, with members appointed by the institution rather than the Minister. An omnibus bill amending 43 pieces of legislation to abolish the statutory committees, including AECs, was presented to the House of Assembly in November 2014 (*Statutes Amendment (Boards and Committees - Abolition and Reform) Bill 2014*), eventually passing with amendments in June 2015 (*Statutes Amendment (Boards and Committees - Abolition and Reform) Act 2015*). While the legislation has only recently passed, the transition of AECs from statutory to institutional committees will be managed on a rolling basis, through consultation with the relevant institutions, their AECs and the Department.

Many readers will ask why this is important at all, when South Australia, in the words of one of my informants is an 'outlier' in regard to ministerial approval of AEC members: the system can, and does, work in other states without this additional layer of regulation. But, the approach that the Committee took in its discussions of the changes illuminated three themes that I found to be operating at a number of levels of the Committee's business, which revealed themselves as a series of tensions. Following is an overview of some of those tensions, in relation to the proposed change to the regulatory framework.

The Committee's Concerns

The government's intention to reclassify AECs was first brought to the attention of the Committee at its July 2014 meeting, just a few weeks after the proposal was announced. From the outset, most members of the Committee were apprehensive about the proposed changes, with people calling upon notions of personal pride, of the legality of the changes, and of the government's poor grasp on animal welfare matters in South Australia. In addition to these ideas, three key themes were also raised in the Committee's discussions about the reforms, both around the committee table and in my one-on-one interviews with members. These were: the notion of a declining community spirit; a decline in public confidence in the system; and a decline in transparency and accountability.

Decline in Community Spirit

It was apparent from the initial discussions about the reforms that the committee members felt they were a part of a distinct community of animal ethics practitioners in South Australia. A key feature of this community is the collaboration between AECs and institutions, because the AECs across the state routinely communicate with each other on project specific

issues, opportunities for refinement of procedures, and administrative issues. This communication and collaboration, according to all of my informants, creates a collegial community committed to maintaining the gold standard of animal welfare and ethical practice. However, it was just as clear that the Committee feared that this community may be threatened by the move towards institutionally established and appointed AECs. One member declared at the initial meeting:

> "If the ethics committee is just a creature of the institute, the collaboration and communication between AECs will be lost and there'll be a divergence in standards [of animal welfare]."

While this argument may be seen as an abstraction, drawing on hypothetical situations that may never eventuate, a different member drew upon the same idea at a later meeting, when discussing a cross-institutional project that was causing the Committee some concern. The project being assessed was accepted at another institution, but was not regarded as the gold standard by the Committee or the animal facility. This member drew on the idea of the ministerial appointment and oversight as a means of ensuring the standards are streamlined across AECs and institutions: "This is another example where ministerial oversight is important to ensure there is the same standard of procedures at all the facilities."

The changes from the outset signalled a transformation that was going to be more meaningful to the Committee than simply the manner in which members are appointed. There was concern that self-regulation would diminish the collegial spirit, and eventually animal ethics and welfare practice. In an interview on this topic, the first member elaborated:

> "Consistency amongst ethics committees will be potentially reduced […] If institutions and their committees are independent beings then the need to cooperate and the need to collaborate and the need to make sure that you share [… the] method by which you are achieving the common goal [of animal welfare] and to learn from other committees […], that sort of coordination and sharing approach would diminish with time. It wouldn't diminish straight away […] give it 10 years and all of that would just drift away and just become a nice idea, rather than something we really should do."

For these members, the mere notion of the shift to institutional appointment signalled the move away from the interconnected and collegial community that characterises the AEC system in South Australia, towards a landscape of 'silo' AECs, disconnected from one another, and therefore disconnected from a community of knowledge and expertise that the committee members believe helps to maintain the gold standard of animal welfare and ethical decision making across the state.

Decline in Public Confidence

The collegial spirit of the AEC community was not the only concern of the Committee. It was also concerned about how the public would respond to the issue of animal welfare under a self-regulatory model, insisting that government regulation was the reason that the public has been accepting, so far, of animals used for research and teaching. The Committee's formal letter to the Minister, directed through the Chair, played up the credibility of the system, saying that ministerial appointment of members "provide[s] the community confidence that the potentially fraught relationship between animal welfare and […] research is being responsibly managed." The letter reflected very accurately what I heard around the committee table: members insisted that the relationship between the system, the public and the Committee is thus far amenable because the public is "reassured that there's [government] control over the process […] the reassurance that the public gets would be diminished if there wasn't some sort of political accountability." This member's concerns were typical of other members of the Committee, and tie into the idea that the South Australian system will lose credibility with the public if it were to change. He elaborated: "it is very important to have government involvement in the process. Ministerial appointment of committees and their membership gives credibility to the decisions they make."

It was never actually clear what would happen if the public had reason to question the credibility of the Committee or the system. But one member called up a popular rhetorical device; that of the animal liberation movement, saying that ministerial approval "keeps a lid on the anti-animal use people because what we do and the decisions we make are sanctioned by the government." Yet another member also used the animal liberation movement, a movement which has relatively little presence in South Australia, to bring the public into the discussion of the reforms: "the animal rights activists and the animal liberationists might delay it [the passing of the legislation] if they want the ministerial appointment for AEC members."

The idea of the animal liberationists was intimately linked with the perceived reputation of the Institution, its AEC and the system in general, and became a prominent feature of my fieldwork. In relation to the ministerial appointment of members, one member said:

> "…If there's any chance you'd compromise public confidence in the system, then you're really in trouble, 'cos public confidence in the system is sort of everything […] I know, probably 90% of the population don't know a single thing about the AEC system, but they assume there is something appropriate in place. Those who are interested would obviously want to know about it or be more likely to know about it, and they would be the ones who would be wanting

> to ensure there is public confidence in that system. And they're the ones who'd be making the most noise if there was any good reason for confidence to be questioned."

Reference to the 10% of the population 'who are interested' and 'the ones making the most noise' points to the animal liberationists and animal rights activists. And, although in the mind of this informant, they represent only a small sector of the community, they still have an influential role in shaping the wider community's acceptance of the system. Further, the prospect of what that 10% may think shapes how the Committee perceives itself and its role in upholding a community standard. He went on:

> "So, if you're losing public confidence, I think you're losing everything. And it's probably broader than that too, because the whole system is based around the idea that there is this publicly accountable system in place, which has a sterling reputation. It's [the AEC system] got a really good reputation nationally and internationally amongst those who know about it."

The public submissions to the Minister from the other institutions and their AECs reveal that the unequivocal desire to retain the current system of ministerial appointment wasn't shared by all AECs, and some were explicitly in favour of institutional appointments. When I asked why the Committee had taken such a firm position in its desire to retain the current arrangement, I found evidence of a strong corporate culture, linked to a keen awareness of the public's perception of the Institution, its AEC and the system generally:

> "The [X] Committee… they are public, PUBLIC servants, rather than independent institutions that don't necessarily have that view of the world that the public actually is your employer, and what the public thinks is actually important. Whereas private industry they couldn't care less what the public thinks and an institution like [Y], that's not born out of that sort of sentiment, necessarily, will just have a different perspective on life."

The organisation that I conducted fieldwork with has a long tradition of research in the state, and has a relationship with the South Australian public built on an ideal of trust. It is unsurprising then, that the organisation, and the people representing it through the Chair, category A and category B members, were all wary about the public's perception of the system and the organisation itself if the changes were to be implemented. When I asked the Chair why the Committee's response to the Minister was more strongly in favour of retaining the current arrangement than the other committees' responses, he said:

> "It was certainly the very strong feeling of the Committee that the appointments remain ministerial […] the letter went through our Director of Research for comment, and it was also his opinion, as it turns out, that ministerial appointment was probably the most effective."

The Chair's comment shows how this sentiment was not idiosyncratic of a particular member on the Committee, or type of member (A or B for example), nor was the Committee's response

influenced by the corporate hierarchy. The Committee's formal response, directed through the Chair, and approved by the Director of Research, reflects an engrained corporate culture.

Decline in Transparency and Accountability

The changing regulatory framework signals a change not only of the appointment of members, but a change in the informal accountability networks of the AEC system. The Chair was adamant that it should be the Government that bears the burden of accountability, because the community has given the Government the power of decision making over matters of animal welfare: "in the end, we are holding the Government accountable, the Parliament of the day, the Government itself, that's where we vest our power". Interestingly, government transparency and accountability were stated aims of the reforms, but it appears that in this instance the government will be achieving this aim by simply shifting responsibility from the government to the institution. The burden of maintaining transparency and ensuring accountability within the animal ethics system in South Australia will rest on the shoulders of the institutions. While there has been some commentary on the embedding of the public sector ethos of transparency and accountability into the private sphere to maintain transparency under neoliberal governance frameworks (see for example Braithwaite 2005), it remains to be seen whether this will actually happen when the legislative changes are implemented. The concern of the Committee is, then, whether the system will become more opaque, and thus breach the fine line of acceptance that the community has of animals used for research purposes.

When I asked my participants if ministerial appointment of members was needed, the replies almost always raised issues of transparency and credibility:

> "The government's got to be involved […] for the assurance of the community, there's gotta be someone outside the organisation saying 'yeah, okay, this is okay' […] Ministerial appointments are a bit slow, it's very cumbersome, but it does maintain a check on the composition of the committees."

And,

> "If they [the public] were told the members of AECs were all appointed by the Minister, [they] would go 'oh, okay, fair enough, sure'. If they were told they were appointed by the institution, it's like, 'how do we know they haven't just appointed […] a couple of mates and a few of their cousins to come in and do this for them?' It's lost its objectivity."

Statements like these suggest ministerial appointment is seen as a solution to the problem of public accountability and transparency, to which members can see no other solution. Both responses invoke the idea of the credibility of the Committee and the system, but both also flag

the issue of transparency by assuming that an 'objective check' needs to be maintained on committees and the system; indeed, that the objective check facilitates credibility.

Business as usual

While the Committee was concerned with how the reforms would negatively impact the system of regulation, the structure of committees, and as a result, the relationship between the public, the Committee and the system, there was very little concern about how the reforms would change what they do as a committee, and what animal users do. In fact, a popular phrase around the committee table was 'nothing will change': the informant who was worried about the divergence in standards across committees said, "either way, everything will be the same… it's essentially just a question of whether we will be government appointed or not." This suggests that although his intuition is, that the reforms represent a slippery slope for animal ethics in South Australia, effectively, there will be no change in the practice of ethics.

This contradiction was echoed at multiple levels of the Committee. The Chair revealed that his personal view on the reforms gelled very well with that the Committee; that is that the current regulatory system, including ministerial appointment, should be retained lest the rigorous system be lost. However, as with many of the other members, he qualified his point of view with a caveat:

> "I think it would be less of an issue for this organisation, to come out, to have a rigorous process […] because our main function isn't straight down the research line, I think it's easier for us to [maintain a rigorous process]."

So on the one hand, the rigorous system is threatened by the move towards self-regulation and on the other hand, the organisation, by virtue of its structure, is almost immune to that threat.

Most of my informants, including members of the Committee, government administrators and members of other AECs, agreed that little will change because of the multiple layers of regulation, including licencing at the state level, and the Code at the national level:

> "In terms of AEC operation, approvals, et cetera et cetera, in terms of who's on committees, and that sort of thing, I don't really believe anything will change, well, shouldn't change anyway […] the triennial reviews and that sort of thing are enshrined in the Code […] None of that will change."

This member called on the national framework to argue that committee practice won't change regardless of who appoints members. Although he thought that nothing would change because the national framework is in place, he went on to say that the licencing must still be overseen by the state government department, because the system is:

> "…Operating under legislation which is overseen by that department, which in terms of legal framework, does carry an implicit responsibility to ensure that the legislation is being complied with: [...] Change who's appointing them, fine, but don't bugger up the important issues of oversight and control. Otherwise you risk the whole thing going off the rails or potentially being seen to go off the rails."

So, while the national Code is what will stop things 'going off the rails' on one hand, it is the state legislation, with its provisions for licencing of institutions, a central government department responsible for its administration, and its enshrining of the Code, which gives the AEC system transparency and accountability and, more importantly, allows the public to see that the system is 'on the rails'.

The most poignant response to my questioning about how the proposed reforms would impact the practice of ethics came from a government administrator. This informant was adamant that the changes would not negatively impact the practice of animal ethics at the committee level, or the practice of animal welfare at the research or husbandry level, because:

> "They are regulated to the eyeballs […] Because it's heavily regulated [and] we've got a lot of cross membership of committees, and people get reputations very quickly, if you get a reputation as being a dodgy practitioner here, you may as well leave the state. You're not going to work in South Australia… anywhere."

This response calls on the idea of a community of animal ethics practitioners, in a collegial environment, working together towards a common goal, much the same way as the member who feared the loss of the collegial community did. But, while that committee member thought that the community spirit was endangered by the reforms, the government official thought that it was exactly that collegial community spirit that would regulate the behaviour not only of committees and their members, but also the researchers under their jurisdiction. Removing one layer of regulation, in the eyes of the government official, would have no impact on what happens at the committee table, nor in the animal facility, because committees and researchers have reputations to uphold.

Conclusion

While it is evident that the reforms to the AEC system will only change one relatively minor aspect of the South Australian system, they represent a significant change in how the Committee views its relationship with the public. While the Committee is adamant that the changes will not alter how it functions, the Committee is still symbolically attached to the idea of being a committee established by the Minister, with the Minister approving its membership. This sentimental attachment was revealed through discussions about what the public would think, and

what the animal liberationists might do, but at the same time, 'the public' and animal liberation movement remained relatively silent on the issue of the reforms, and remains largely silent on animal welfare issues related to research and teaching in South Australia, generally. It remains to be seen whether institutional appointment of AEC members will have an impact on the public's perception of the system, or the relationship between the Committee, the Institution and the public. The entire community, including AEC members, the committees themselves, institutions and researchers are all subject to multiple levels of regulation which in some ways facilitate, and in others, constrain, the actions of people in the AEC community.

The Committee had a number of concerns regarding the proposed reforms: a change in the collegial community, causing a divergence in standards of the ethics process; the Committee's relationship with the public; and a decrease in accountability and transparency. These concerns are juxtaposed with the individual members' and the Committee's notion that 'nothing will change'. These tensions are manifested in the words of individuals on the Committee, based on their experience in the system. And although much of the data presented here is based on individuals' perceptions of what will happen when the reforms are implemented, they build to the committee level: the Committee's resolve is that although it believes that the current system should not be reformed at all, when it does change, it won't change what the Committee does. And after a brief discussion at the beginning of each meeting, where the Chair discusses recent developments in the legislative changes, it largely is 'business as usual'. The Committee gets on with it and does what it is there to do assess the projects before it according to the relevant regulatory frameworks – the state legislation and the national Code. And, as long as the national Code remains a living document, and as long as it is protected by state legislation, nothing will change, because they're all regulated to their eyeballs.

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Presentations given

on

Wednesday 22nd July

"Modelling cancer immunotherapy from mouse to human – mice don't always lie! "

Prof Ian Fraser
Translational Research Institute (Australia)

Transplantable tumour models in mice are probably overrated as predictors of efficacy of cancer drug therapy in humans. However, research on mouse tumour immunology has delivered two significant new approaches to human cancer therapy in the last 10 years (Keytruda, and Yervoy). We have used a mouse model of human papillomavirus (HPV) infection in skin to determine why this infection persists, and shown that the problem lies in local factors protecting proliferating skin cells. This finding, and the demonstration that these same factors are active in the cervix when infected with cancer promoting HPVs, allows new approaches to treatment of some chronic viral infections and epithelial cancers.

By arrangement with the organizers,

there is no paper associated with this presentation

Animal models for studying the bacterial pathogens *Streptococcus pyogenes* and *Burkholderia pseudomallei*

Michael R Batzloff
Institute for Glycomics, Gold Coast campus, Griffith University, Queensland, Australia

Vaccines have proven to be a very cost effective method in the prevention of many diseases; however, there is still a large number of disease causing organisms for which the development of a vaccine has proven to be extremely challenging. The difficulty of this process is also compounded by the lack of appropriate models for testing of the vaccine candidates before clinical studies.

Streptococcus pyogenes (group A streptococcus, GAS) is one such organism that presents significant obstacles to vaccine development. We have previously described a 12-mer synthetic peptide (J8), from the highly conserved carboxyl-terminal region of the M-protein of GAS. This peptide, when conjugated to diphtheria toxoid (DT) and formulated with the adjuvant aluminium hydroxide (alum) to form the vaccine formulation (J8-DT/Alum), can induce an immune response in a genetically diverse mouse population. Here we will discuss the development of this vaccine candidate and the animal models used to evaluate vaccine efficacy.

Similarly, *Burkholderia pseudomallei* is another neglected tropical disease that causes significant morbidity and mortality. This bacterium is naturally resistant to many antibiotics and therefore has been a focus for pathogenesis and vaccine research in recent years. Here we will also discuss our research into the interaction of this pathogen with the host model and potential routes of infection.

No manuscript was received for this presentation

Does a bandicoot die in a trap if there is no AEC member present? Dilemmas and responsibilities of field work

Darryl Jones
Griffith University

No abstract or manuscript was received for this presentation

Competency and training and the code

Ian R Peak
Griffith University, Gold Coast Campus, QLD , Australia

The Australian code for the care and use of animals for scientific purposes 8th edition (2013) ("The Code") is one of several key documents that Animal Ethics committees rely on to assess research and teaching involving animals. The code is explicit in describing responsibilities of the Institution, the Committee, Investigators, and Animal carers. The Governing principles include that
Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes.

It is obvious that investigators and carers need training, even in what we may consider to be the least invasive procedures. Once trained, competency must be demonstrated. Institutions must develop guidelines to identify how competence is assessed and ensured. This presentation will highlight the relevant clauses of the Code, as well as other clauses that should be considered when AECs are discussing project applications, during ongoing monitoring of animal use, and at reporting stages of projects.

Requirements for competency and training from other countries will be mentioned, as comparison with The Code. This presentation is intended to stimulate discussion on how different Institutions implement training and competency assessment and assurance.

The Australian code for the care and use of animals for scientific purposes 8th edition (2013) ("The Code") is one of several key documents that Animal Ethics committees rely on to assess research and teaching involving animals. The current edition of the code has several themes running through it, and one of these is the requirement for anyone involved in animal use to be competent, or be under the direct supervision of someone deemed competent.

competence
animal carer responsibilities, 2.5.2(vii), 2.5.5(i)
governing principle, 1.29
institutional responsibilities, 2.1.2(v), 2.1.5(v)(a), 2.1.8
investigator responsibilities, 2.4.4(v)–(vi), 2.4.4(v), 2.4.5(iii), 2.4.8(xix), 2.4.18(ii)
procedures, husbandry and care, 3.1.16, 3.3.1(v)
see also education and training: personnel

It is not often that we take note of an index, but if we do, it is obvious that the code is explicit in describing responsibilities of the Institution, the Committee, Investigators, and Animal carers.

Closely tied to this, as noted in the index, is that investigators and carers need training, even in what we may consider to be the least invasive procedures. Once trained, competency must be demonstrated. Institutions must develop guidelines to identify how competence is assessed and ensured.

There are always several challenges for any organisation in ensuring that it has adequate processes in place to show that it, and all people it has responsibility for, are compliant. Perhaps the major challenge is making it easy for animal carers and investigators to comply. Any system

of regulatory burden that is seen as overly bureaucratic and burdensome may lead to people trying to evade it, or engage only unwillingly with it, paying lip-service only to training and competency. The AEC also has a role in helping develop guidelines to assess and ensure competency. Part of the challenge is pitching the level of education to the level required (training in advanced surgical techniques is not required by everyone!) so the best training and competency assurance programs are modular. How an institution implements training varies with the kind of research and teaching undertaken, and its size.

What may be appropriate is a tiered approach, starting with some level of theoretical training (in rights and responsibilities, legislation, and the processes of ethics application) followed by further theoretical training on the biology of the organisms, then training and competency assessment in basic skills relevant to the research or teaching activity. For animal use that is more complex, or may involve more distress to animals, further training will be required. All this process requires good management of records, and good oversight of individuals to ensure they remain within their assured competency and ongoing assurance of competency requires ongoing observation of investigators.

Why should an organisation care about the training of, and assuring competency of its investigators and carers? Institutions need to be aware that they have explicit responsibilities to ensure investigators have access adequate education programs and resources, and also to have processes in place that ensure competency. Institutions may also need to be aware that the Code requires independent external review of its operations at least every four years (Section 6 of Code), and that it will be reviewed for the following:

> "the adequacy of institutional support, resources and educational programs for the AEC and its members, and for people involved in any aspect of the care and use of animals for scientific purposes, to ensure that they can meet their responsibilities under the Code"

All of this requires commitment from all levels including senior Institutional management to provide adequate resourcing, Welfare Officers or veterinarians, animal carers, and investigators. As an aside, it is interesting that it is sometimes the younger, junior investigators who more willingly embrace the requirements for training and competency assurance than their more senior, long-established colleagues.

Ultimately, investigators and carers who are well educated, well trained, and competent are better able to apply the Governing Principles, resulting in less impact on the animals under our care.

Research Institutions: how to provide appropriate training to investigators using animals in their research

Francesca Fernandez-Enright[1,2]., Penny Potter[1]., Eve Steinke[1].

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According to the latest edition of the Australian Code for the Care and Use of Animals for Scientific Purposes (8th Edition 2013), the research institution "should provide appropriate education and training to members of research teams and ensure that they have the necessary knowledge and expertise for the specific animal procedures proposed and the species used."
The delivery of suitable training to the researchers is therefore critical, and should provide both theoretical and practical skills training in order for the investigators to perform their animal research. Training courses, including ethical, institutional and legal aspects in animal research, must be designed to suit a wide audience, from individuals with no previous experience with animals to more experienced researchers.

How can the research institution be sure of providing suitable education to their staff/students working with animals as stipulated in the Australian Code for the Care and Use of Animals for Scientific Purposes? Should the assessment of competency be a one-off thing, or on-going? What are the common issues encountered during the training of individuals working with animals?

Here we discuss the different ways of educating staff/students in the design and the performance of their animal researches in line with the Australian Code for the Care and Use of Animals for Scientific Purposes, provided by the research institutions.

No Paper was submitted by the Authors for this presentation

Teaching using animals at The University of Western Australia

Dr. Annie Tarala
The University of Western Australia

The University of Western Australia (UWA) is currently undertaking a survey of teaching practices involving animals both nationally and internationally. It is envisaged that this survey will inform decision-making regarding animals used in teaching and could also identify opportunities for further refinement. Survey participants are invited to compare the teaching practices involving animals at their Institution to those currently in progress at UWA.

At present, there are a small number of teaching programs underway at UWA which use mammals or birds. All of these teaching programs are approved by the UWA Animal Ethics Committee (AEC). The UWA AEC consists of at least one individual from each of the four categories of membership who has significant teaching experience. The UWA AEC held nineteen meetings during 2014 in which 101 new applications were considered. Twelve of these submissions were teaching applications. Half of the teaching applications were submitted to the UWA AEC in March 2014 with a further quarter deliberated later at the July meeting. The remaining submissions were presented to the AEC in the intervening months.

Replacement, along with refinement and reduction (the 3Rs), remain the cornerstone of ethical animal use at the UWA. A variety of UWA staff are available to ensure that all animal users are supported in maintaining the highest standards of animal care. These include animal ethics administrative staff, animal technicians (and farm staff), senior animal unit co-ordinators and managers, veterinarians, animal welfare veterinary advisors and animal welfare officers. Ninety-five percent of the AEC approved teaching programs that involve surgery are non-recovery in nature. Non-recovery surgical procedures at UWA are broadly classified as follows:

- Rodents (40%): All of the non-recovery surgical procedures involving rodents provide undergraduate teaching in physiology, pharmacology or neuroscience.
- Sheep and Pigs (20% and 20%): All of the non-recovery surgical procedures involving both sheep and pigs provide postgraduate medical training.
- Goats (5%): Non-recovery surgical procedures involving goats also provide postgraduate medical training.
- Rodents and rabbits (5%): All of the non-recovery surgical procedures involving both rodents and rabbits provide UWA Staff with training in the various techniques required to conduct their research.
- Chickens (5%): All of the non-recovery surgical procedures involving chickens provide undergraduate teaching in neuroscience.

The remaining teaching programs (5%) involve recovery surgery and rats are used to introduce a variety of psychopharmacological research techniques to undergraduate neuroscience students.
All of the information collected during this survey will be kept confidential as institutions and individuals will not be identified. All participants will be provided with a copy of the final report. Individuals interested in participating in this ANZCCART supported initiative are asked to contact Annie Tarala (annie.tarala@uwa.edu.au).

No manuscript was received for this presentation

Abstracts for

Presentations given on

Thursday 23rd July

Hidden holes – are there gaps in the AEC system?

Virginia Williams[1] and Linda Carsons[2]

[1]Chair, National Animal Ethics Advisory Committee
[2]Principal Adviser, Animal Welfare Team, Ministry for Primary Industries

New Zealand's oversight of institutions that use animals in research testing and teaching (RTT) is devolved to animal ethics committees (AECs) that operate under codes of ethical conduct approved by the Ministry for Primary Industries. AECs review and may approve applications to carry out research, with or without conditions, and are also required to monitor compliance with any conditions of approval.

The National Animal Ethics Advisory Committee has an advisory role to the Minister, the Director General of the Ministry for Primary Industries and AECs on ethical and animal welfare issues arising from RTT, but does not have any direct part in the decision-making process. Institutions are audited by independent reviewers at least every five years for compliance with the legislation and their codes of ethical conduct. Such reviews are required to cover a selection of the paperwork since the previous review, as well as interviews with AEC members, researchers and facility staff and also include facility inspections.

Other countries, e.g. the United Kingdom and the USA, carry out unannounced audit visits. New Zealand chose not to use this system when the AEC process was made mandatory with the passing of the Animal Welfare Act in 1999, aiming for institutional buy-in rather than the potentially more confrontational surprise visit.

Is the New Zealand system a gold standard system or a work in progress? This paper looks at some of the issues raised both within and outside of the review system and offers some suggestions to ongoing improvement.

Introduction

In New Zealand, Part 6 of the Animal Welfare Act applies to the use of animals for research, testing and teaching (RTT) purposes, setting out conditions and requirements under which such activity may be undertaken. New Zealand's RTT system accommodates a variety of institutions – universities, commercial organisations, Crown Research Institutes, governmental departments, polytechnics and schools – which carry out a range of activities e.g. complex physiological experiments, pest control methods, animal handling, animal husbandry research, veterinary research, testing of commercial products and production of biological agents using a variety of animal species.

Direct oversight of RTT activities is devolved to animal ethics committees (AECs) that operate under institutional codes of ethical conduct (CECs) approved by the Ministry for Primary Industries (MPI). AECs review and may approve - with or without conditions – or decline applications to carry out research. These committees are also required to monitor animal facilities, as well as compliance with any conditions of approval. AEC membership must include three members who have no other connection to the institution. One must be nominated by the

New Zealand Veterinary Association; one by the Royal New Zealand SPCA; and the other by a local or regional council.

In addition, at intervals of no more than five years, institutions must be audited by independent reviewers for compliance with the legislation and their codes of ethical conduct. Such reviews are required to cover a selection of the paperwork (applications, minutes, reports, complaints) since the previous review, as well as interviews with AEC members, researchers and facility staff. Inspections of animal facilities are also included. The reviewer's report, which must include any critical or key issues, is scrutinised by both MPI and the National Animal Ethics Advisory Committee (NAEAC). The committee's role is above all, an advisory one - to the Minister, the Director General of MPI and AECs - on ethical and animal welfare issues arising from RTT. The final decision on whether CECs are approved, approved with conditions such as more frequent reviews, or not approved, lies with MPI. Following a review, an institution is required to satisfy MPI that any issues raised are being/have been dealt with - most of these will be required before a new code of ethical conduct is issued. The reviewers themselves are audited every five years.

Does the system work?

Other countries, for example the United Kingdom and the USA, carry out unannounced audit visits. New Zealand chose not to use this system when the AEC process was made mandatory with the passing of the Animal Welfare Act in 1999, aiming for institutional buy-in rather than the potentially more confrontational surprise visit. Can we be confident that AEC oversight coupled with the review system means that institutions do meet their obligations under the legislation?

AEC oversight

Firstly and possibly most importantly, the system allows for public scrutiny within the AEC membership. The three external members, representing the veterinary profession, animal welfare groups and the lay public, are there to give a measure of confidence for the New Zealand public that welfare and ethical considerations are not overridden by institutional requirements.

Reviewers

Of those who currently carry out the periodic reviews assessing compliance with the legislation, all but one are veterinarians (the other is an animal welfare scientist with extensive AEC experience), most with audit and/or laboratory animal science backgrounds. The review documents themselves ensure a uniformity of approach and the detailed review reports generally demonstrate good understanding of both the legislative requirements and the practices and policies of the institutions under review. Areas where improvement is needed are readily identified. Annual meetings or teleconferences are held for reviewers so that information on practice can be shared and issues of concern raised.

The review system

The first reviews under the Animal Welfare Act 1999 took place in 2002. Up to 2015, there have been a total of 98 reviews of 35 institutions: 30 first expiry reviews, 26 second expiry reviews, 24 third expiry reviews, 7 reviews of newly constituted CECs and AECs, and 11 special reviews following issues of non-compliance. Seventy-three percent of the first expiry reviews were deemed satisfactory, as were 85% of second expiry reviews and 96% of third expiry reviews. Eighty-six percent of reviews of new code holders were satisfactory, while 100% of special reviews required following issues of non-compliance were satisfactory. It should be noted that a classification of "satisfactory" does not necessarily mean that MPI did not require any actions to

be taken. Rather, it means that any deficiencies were not major and did not impact on animal welfare. MPI sets conditions and timeframes for the amendment of any deficiencies.

So, the review results show that, while it took a while for institutions to accustom themselves to the new requirements, with only 73% satisfactory in the first round of reviews, there has been a steady rise in the percentage demonstrating satisfactory compliance through the second and third rounds. This can be seen as an improvement in the degree of compliance through the RTT industry since the introduction of the current legislation.

Issues raised in reviews - monitoring

Issues of concern raised by reviewers during the audit process can give some insight as to where difficulties in the system lie. Of these, the one that has been consistently identified in some but not all reviews is a failure to adequately monitor compliance with approved protocols. Monitoring is seen as the most effective way that an AEC can ensure such compliance, so that any failures in set monitoring requirements may jeopardise the integrity of the system. NAEAC has clear guidelines on monitoring[1] include the following:

- Monitoring should be focused on manipulations that have the greatest impact on animals, those that involve new procedures or personnel (especially contracted or 'parented' work), and those that are considered only marginally justified.
- Routine, well-established manipulations may warrant only periodic monitoring.
- Reports should be provided during and at the end of any study.
- For projects being carried at a remote location, the AEC should consider contracting the services of consultant veterinarians or auditors to carry out monitoring as prescribed by the AEC.

Animal welfare officers (AWOs) can also be used by AECs as sources of information on compliance. However, institutions are not required to have AWOs in New Zealand, and although most of the larger institutions do have such personnel, others do not. All will have veterinarians either on staff or on call, but these do not necessarily have the welfare knowledge or focus to fulfil the role of an AWO.

Issues raised in reviews - facilities

Inadequacies in the facilities in which animals are housed have also been raised in reviews. In fact some institutions welcome such negative feedback as useful encouragement, particularly when economic considerations have been raised as barriers to improvement.

Issues raised in reviews – AEC process

The integrity of the system also depends on AECs adhering to legal requirements in particular, but also to the procedures that each AEC puts in place to define how it is going to carry out its business. As an example, NAEAC has found that smaller institutions with lower levels of research or teaching of lesser impact may fail to fulfil their stated requirements. They may hold fewer meetings than specified, for instance, which can result in a lower level of experience and knowledge within the committee. The generally low impact animal handling teaching in polytechnics may even be seen as welfare-friendly, with less importance attached to it. Other factors contributing to a lack of knowledge of the animal ethics system include institutional restructures and/or constantly changing personnel, particularly when hand over systems are poor.

There are options available to reduce some of these problems. Smaller institutions may choose to become 'parented' by another institution's AEC, which, while it may incur some financial cost,

[1] https://www.mpi.govt.nz/document-vault/9174

will probably be cheaper in the long run. It should also prevent the loss of institutional knowledge that occurs in small institutions with high staff turnover.

Complaints

Another way to look at the effectiveness of the system is to track the number of complaints. The New Zealand system requires protocols to be established for the making of complaints, whether those be by AEC members, by researchers, by staff or by people external to the institution. This is a difficult area and one of concern. An overview of the reviews indicates that complaints are rare. This can be taken as a positive, but there has occasionally been anecdotal evidence of concerns raised by employees who nevertheless will not lay a formal complaint for fear of their jobs.

Training

We can also look at the training that is provided for those working with research animals, whether that is in the general husbandry sphere or in the carrying out of manipulations for RTT purposes. New Zealand's system requires that staff are "well-trained", and that manipulations should be performed by competent personnel with appropriate training and experience. Application forms for AEC scrutiny require sign off on training and experience and how additional training will be given if required. However, it is up to each institution to decide how such training will take place. Some have formal training programmes; while others rely on on-the-job training.

In terms of the AEC members themselves, NAEAC encourages institutions to send them to conferences such as the annual ANZCCART Conference or to the biennial AEC Workshops run by NAEAC. The feedback after such events indicates the value of the sharing of information between members of different committees.

Institutional culture

The final issue is how the animal ethics system is viewed within an institution. Is it seen as adding value, or as a hindrance or even threat to the institution's research programme? Is the Chair independent of institutional politics? An AEC may need to work to make the case to its institution for being seen to encourage compliance; for the system being seen as creating legitimacy in the eyes of society. NAEAC sees it as important to get researchers on the AEC to give them a wider view; to use science to demonstrate the benefits of humane and ethical science; to reward scientists, animal carers and AEC members for excellent practice. Changes in culture can be slow, but the evidence is that the evolution the humane care of animals in RTT systems under the scrutiny of legislative systems such as that in place in New Zealand around the world continues.

In conclusion, while there are some areas where improvements can be made, the New Zealand system can be generally seen as safeguarding the welfare of animals in RTT.

Us and them - are we equal in Ethics? Considerations on the interface of Animal and Human Ethics

Ali Cullum & Jim Webster

AgResearch Ruakura

The requirement to obtain human ethics approval for a survey for ANZCCART last year has prompted some research on human ethics and how we interface it with animal ethics in projects which have both a human and animal ethics component. In some studies human ethics approval may be essential to a full deliberation on the cost-benefit of the entire project.

To stimulate discussion and thinking on the topic, this presentation will cover the history of medical studies involving humans pre and post the Nuremberg Code and the evolution of current human ethics procedures. We make some suggestions about how human and animal ethics might interface and achieve this goal in a smooth manner. This includes tools such as informed consent, human ethics reports and access to human ethics expertise, and how Animal Ethics Committees might successfully include information about human ethics in their considerations.

Human ethics in Australia and New Zealand have comparable legal frameworks. In New Zealand, the National Ethics Advisory Committee (NEAC) was first formed in 2001 and advises the Minister of Health on ethical guidelines for human ethics committees reviewing studies involving people. There are three categories of ethics committees: Institutional Ethics Committees (IEC) eg. for universities; Health and Disability Ethics Committees (HDEC), eg. for hospital health boards; and the NZ Ethics Committee (NZEC) which functions nationally for all studies not falling under the umbrella of the HDEC or IEC. Human ethics in Australia started in the 1960's and is administered by the government under the National Health and Medical Research Council (NHMRC)Act 1992. The legislation views risk for participants in research and is guided by the National Statement on Ethical Conduct in Human Research 2007.

In world human ethics, the historic starting point was the Hippocratic Oath (5^{th} Century BC) which specified that doctors must not harm their patients. In Prussia, laws governing human research were passed in 1900 AD, and the World Medical Association (WMA), formed in 1946, revised the Hippocratic Oath and promoted ethical guidelines for humans participating in medical research (Declaration of Geneva 1948). Paradoxically in America, animal research historically promulgated more concern than that for humans, with the first laboratory animal regulations being created in 1910. In 1947, as a result of the Nuremberg Tribunal, the ten point Nuremberg Code of international ethical principles for the use of humans in research was generated. The Tribunal examined the crimes against Jews by the Nazis, who used them for unethical research, including live dissection to examine organ function, and sterilization without consent. The code itself is not law, but provides the foundation for the subsequent WMA Declarations of Geneva (1948) and Helsinki (1964), which are the basis of law governing research involving humans in many countries of the world. The integral guiding principles of the Nuremberg code are that all research involving humans may only be performed with their informed consent, must have valid scientific context, and should have been first carried out in appropriate non-human models.

Examples of research studies which have had questionable human ethics, and whose public exposure has preceded changes in international thinking and law are: Henrietta Lacks, HeLa

Cells 1951; Tuskegee Syphilis Experiment 1932-1972; Redwing Studies 1943; MKSEARCH mind altering drugs 1965 and Dioxin (Agent Orange), Holmesburg State Prison 1965.

Henrietta Lacks was a young African American woman who was treated at the John Hopkins Hospital for cervical cancer. In1950, Dr George Gey, a doctor and scientist at the hospital, received a fresh biopsy of her cervical cancer and used it for tissue research in his laboratory. It was the first tissue that he was able to "grow" or culture in the laboratory and the cells proved to be indestructible and were labelled "immortal". The cells founded tissue culture science as we know it today and still used worldwide in biomedical laboratories. They are called "HeLa cells" after their donor, but Henrietta and her family knew nothing about the use of her cells in modern science until years after Henrietta's death in 1951. The family felt they should have some monetary recompense for the use of their mother's cells, but the law in America states that samples taken for clinical diagnosis do not belong to the patient once they have been collected, and Henrietta had agreed to her biopsy being removed. However modern medical ethics principles do indicate that there should have been a very detailed informed consent procedure for Henrietta when her cells were successfully cultured.

Another example of human ethics are the Redwing Studies which were conducted in 1943 by Kabat, Rossen and Anderson to try and understand why World War II pilots blacked out when they steeply banked their planes after having dropped bombs on a target. They hypothesised it was due to an acute arrest of cerebral circulation brought about by gravitational forces and developed the KRA collar or cuff which occluded cerebral circulation in patients. They used 11 schizophrenics and 126 prison inmates for their studies. The prison inmates were encouraged to volunteer for participation, being told it was their "war effort" for their fellow countrymen and the schizophrenics were told it may improve their neurological condition. To their credit, Kabat, Rossen and Anderson did try their collar first on dogs, then themselves, prior to using it on their "volunteers" and discovered no ill effects from its use. The experiments did advance the understanding of brain function, but were certainly not carried out with proper informed consent for their subjects!

The five guiding principles of human ethics for people participating in research in New Zealand are: Autonomy (or informed consent), Justice (or respect and fair treatment), Beneficience (or cost benefit), Non maleficence (or no harm) and Outcome (or justifying participants' input). These principles are similar to the guiding principles for animal ethics and welfare and their cost harm benefit analyses involving the 3 R's and 5 Freedoms. Therefore, if Animal Ethics applications take care of animals in research, and Human Ethics takes care of humans participating in research, why would investigators carrying out animal research need any human ethics approval? For our animal ethics committee, there are two main reasons for considering a requirement for human ethics approval: the first is that the knowledge or data being gained by the study has an effect on the humans providing it; and the second is that the caring for the animals participating in the research has an effect on the humans providing that care.

An example of the first reason is seen by our Animal Ethics Committee when a survey or data collection using agricultural animal systems is undertaken. The survey may simply be collecting data on animal husbandry methods and animal outcomes, or it may be an interventional study (eg. medical treatment for common herd disease) with an associated survey about husbandry methods which would affect the disease incidence. Agricultural business owners/operators sign an informed consent form about their participation in the study, but this is aimed at animal welfare and an understanding of animal welfare legislation rather than human welfare. It does say that the person signing acknowledges their participation in the study, but does not specifically refer to the time and effort the study will involve, nor look at ways in which a person may be

affected by the study. This may include loss of time (increased labour cost, loss of leisure time) because they have to undertake extra animal movements on the farm to allow the study to happen, loss of production (economic outcomes) because of reduced output by an animal who has been manipulated as part of a study (e.g. longer time standing in yard, less time eating and producing), or it may be that if the data outcome is benchmarked against other producers, they feel disadvantaged if their business' data is below the group average (mental stress). In this case there are side effects of the study for the human participants; therefore a separate acknowledgement of this is appropriate with an accompanying human ethics application.

An example of the second reason is that animal carers involved in research with animals may be negatively affected by the actual manipulations being carried out on the animals they care for, particularly those studies with a D or E welfare grading. Or they can be affected by the end point of the project which may involve humane death of the animals. The main effects for these people are the mental stress of seeing animals they care for suffer (even though that suffering is minimized) and of sadness and loss. These feelings are known as compassion fatigue, a recognized syndrome among people whose occupation involves caring (nurses, doctors etc). Should we recognize these negative effects for our animal carers in a more formal fashion by involving separate human ethics considerations with our animal ethics applications? Are we being negligent if we do not do so?

Our company undertakes research using both humans and animals. In general the human studies are classed as minimal intervention or impact (eg. anonymous and voluntary survey), meaning they are unlikely to have a major effect on the participants. The company has an in house system for dealing with the human ethics involved in these studies. For studies which do not come under this category, we can use NZEC who provide a means of impartial assessment for studies not under the cover of universities or health boards.

In conclusion, the aim of this presentation is to promote dialogue about the involvement of human ethics in animal ethics applications. As an animal ethics committee, or committee member, if a human ethics consideration is appropriate:

1. do have someone you can ask about human ethics applications?

2. does, and should, your informed consent document cover human ethics as well as animal welfare and ethics?

3. when human participants sign to take part in a study (animal carers, farmers, veterinarians) is the right information imparted to them by the applicant?

4. does, and should, an Animal Ethics Committee ask these questions?

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What is the Gold Standard of Competency for Animal-based Research Investigators?

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Responsible Conduct of Research and Research Skills (including relevant technical skills) are considered to be some of the core competencies of Research Investigators. In Australia, The *Australian Code for the responsible conduct of research* (2007) details the principles and practice of research integrity and the responsible conduct of research by institutions and researchers. Institutions must provide induction training, formal training and continuing education to all researchers on a range of subjects, including regulation and ethics.

This presentation will discuss how the principles of Research Integrity, Continuing Education, and the requirements of the *Australian Code for the care and use of animals for scientific purposes* apply to Research Investigators using animals for scientific purposes. The Australian Code (Clause 2.2.8) requires institutions to ensure "that investigators are well-informed of their responsibilities under the Code and their legal responsibilities" and "are competent in the procedures they perform or are under the direct supervision of a person who is competent to perform the procedures". Institutions must provide "adequate resources for appropriate education, training, and assessment of competence of investigators, and certification of such competence to the satisfaction of the AEC".

The curriculum or knowledge-based content of Induction training courses has not been detailed in the Australian Code, however there is guidance available on the core components that could apply to all researchers who use animals for scientific purposes. Tailoring of additional content to meet institutional and discipline-specific needs is recommended, as this makes the training more relevant to the needs and interests of the trainee. Delivery of Induction training has historically been face-to-face training seminars and workshops, however increasingly on-line training delivery has become possible and popular. Assessment of competency (knowledge) can be "automated" using on-line learning management systems, or simplified manual approaches used. In this way the institution and the AEC can meet their responsibilities to implement an Induction training program, using the most relevant or readily available resources at their disposal.

Examples of delivery of Induction training, Continuing Education, Practical Skills training and Competency Assessment (knowledge and skills) will be provided.

No manuscript was received for this presentation

Animal ethics in marine science - minimising impact, maximising output

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Animal research in the marine environment is often associated with a number of difficulties. The challenges to work in high seas, deep oceans and highly saline waters in remote places require innovative approaches and well planned research to ensure successful outcomes. For many decades it was common practice to catch marine animals in large numbers with often fatal consequences for the target species. With oceans under pressure from anthropogenic stressors new methods have emerged in recent years that allow studying a species with minimal impact on the animal itself. Some threatened species cannot or should not be harmed but at the same time further research to ensure their survival is vital. Research can also contribute to animal welfare when new techniques are being developed and accepted in the research community. Here I introduce some techniques that are currently available in marine animal research and that are minimising harm to marine animals. My work has focused on marine biology and ecology aiming to improve current knowledge about marine vertebrates home range, habitat dependencies, health, feeding and breeding activities. Research work has been ranging from remote underwater videos, telemetry, video and satellite tagging, remote visual observations to tissue sampling. This work included over 10 different types of marine animal research ethics over the past 8 years and covered a wide range of different technologies to study fish and marine mammals. The outcomes of two case studies are being presented including telemetry tagging of fish and collection of mucous samples from whales, demonstrating the feasibility of non-lethal techniques in marine science.

Animal research in the marine environment is often associated with a number of difficulties. The challenges to work in remote high seas, deep open oceans and a salty environment require innovative approaches and well planned research to ensure successful outcomes. For many decades it was common practice to catch marine animals in large numbers often with fatal consequences for the target species such as elasmobranches. With oceans under pressure from anthropogenic stressors including over-fishing, coastal development and climate change, new methods have emerged in recent years that allow studying a species with minimal impact on the animal itself. Threatened species cannot or should not be harmed but at the same time further research for the benefit of their conservation may be vital. Research can also contribute to animal welfare when new techniques are being developed and accepted in the research community. Here I introduce some techniques that are currently available in marine animal research that are minimising harm to marine animals. My research is focused on marine biology and ecology aiming to improve current knowledge about marine vertebrates' home range, habitat dependencies, health, feeding and breeding activities. My research methodology has ranged from remote underwater videos, telemetry, video and satellite tagging, remote visual observations to tissue sampling. This work included over 10 different types of marine animal research ethics over the past 8 years and covered a wide variety of technologies to study fish and marine mammals. The outcomes of a case study are being presented, showcasing the collection of mucous samples from whales, demonstrating the feasibility of non-lethal techniques in marine science and how the on-going development of new technology can advance animal ethics.

Ethical challenges – balance between impact and benefit

There are two fundamental questions that need to be dealt with when considering animal ethics:
(A) How relevant or advancing is the research question to the science community and public? And
(B) How many animals need to be involved to achieve useful outcomes?

It is important to thoroughly assess the contribution a research question can make to the science community and wider public before the start of a project (and this should not be influenced by the availability of funding). In marine science a lot of baseline data is missing and often applied science is undertaken as it usually receives more funding but no baseline data exist to support the applied research. For instance a conservation question may be raised on how best to protect a threatened species but fundamental data on physiology and ecology is missing to completely understand the species needs. In contrast, similar or same research questions may be followed up again repeatedly in different projects because of their political relevance, for example in climate change research. It may well be possible to solve a problem or answer a question with existing knowledge and information. This should be explored by researchers through the thorough review of all relevant literature before the commencement of any new field studies.

The number of animals required for an experiment or research activity depends on the amount of data needed to answer the research questions. There has been extensive work done on how much data is required from a statistical point of view (Kraemer & Blasey, 2015) but less work on how different size of data sets are being perceived in the science community. There is a general understanding within the science community that "more data is better" and looking at the impact of science publications there is a clear trend that articles publishing with large data sets have higher impact or end up in higher impact journals (Acuna, Allesina, & Kording, 2012). We all know that quantity does not assure quality yet it is simply more convincing to look at a graph or map that has many data points. It is important to test the statistical power of an envisaged data set and set a clear strategy for the data points needed to achieve statistical relevance but at the same time to not fall in the trap of a "data frenzy". There are some state of the art software tools that allow researchers to test the potential statistical power in a set of scenarios and help define the data points needed for statistical power (Bratton, Choodari-Oskooei, & Royston, 2015).

Challenges in the marine environment

There is more water than land on the surface of the earth. This of course is well known and not surprising; however, it makes for one of the biggest challenges when undertaking marine research. Both the temporal and spatial replication of sampling is difficult. Often finding the target species poses challenges that are not comparable to terrestrial research. An estimated 91% of all marine species are still undescribed (Sweetlove, 2011). Due to limited accessibility to all parts of the ocean, flexibility in the research plan is fundamental for successful outcomes. Higher flexibility also means higher costs. Marine research projects are proportionally more expensive than terrestrial research due to the demands on research equipment. Corrosion, pressure and the high resistance of water, as well as device communication underwater and retrieval are just some aspects that make equipment expensive. Arguably, all costs need to be doubled when it is to do with marine environments.

Marine animal research of the past

There has been a dark history in marine animal research mostly involving lethal techniques for gut content and physiological research but also for species abundance and distribution measurements. Methods included harpooning, netting, hooking, trapping, poisoning (rotenone, cyanide) and use of shock waves from dynamite blasts (Burn, Langemann, & Parker, 1951; McClay, 2000; Tyler, 1960). Non-lethal techniques were limited to visual observations from land, boat and Scuba. External tagging was undertaken in some cases using catch and release (Norris & Pryor, 1970).

Non-lethal techniques in marine science

In recent decades non-lethal techniques were developed in particular due to the protection of some marine megafauna such as turtles and marine mammals. Advancement of equipment and methods (in particular chemical analyses) and refinement of measurements opened up new types of sampling. Small amounts of tissue from biopsy darts, blubber cores, fin clips, skin, scale, teeth and whiskers to least invasive methods using excreta, scat and mucous provide a facet of information for research. Some relevant techniques include DNA, fatty acids and stable isotope analyses (Dumont & Murrell, 2005).
The advanced analytical methods combined with modelling techniques have improved knowledge on many species using small data sets from non-lethal sampling. The capacity of hardware and software allows interpolation and modelling of population dynamics, food webs and physiological responses based on a small sample number reducing impact on the target species. Modelling also allows for the effective use of secondary data sets (e.g. fish catch data). Other non-invasive marine research techniques include underwater video such as baited remote underwater videos (BRUVS) and remote sensing such as sonar arrays, satellite, radar and thermal sensing, videography and photography from sea, land and air. This technology is often combined with tags (radio-tags, acoustic tags, PIT tags, satellite tags, external ID tags, Dtags, archival, GSM tags). The tags features can include accelerator, magnetometer, hydrophone, temperature, salinity, flow meter, depth, time, location and other add-ons providing insights on movement, behaviour and physiological response of individuals (McIntyre, 2014).

Case study – humpback whale mucous sampling

In the previous section I have introduced a number of non-lethal techniques in marine science following the 3Rs principle: replacement, reduction, refinement. Here I introduce a new method that has emerged recently and is becoming increasingly popular amongst marine mammal researchers. It involves the use of remote controlled drones to sample mucous from marine mammal exhaled air. It is an example for how research on protected species can lead to efficient non-invasive sampling techniques.

As a result of the population increase in some whale species such as the humpback whale there is concern that individuals increasingly suffer from climate change impacts including food shortage and rising water temperature (Ramp, Delarue, Palsbøll, Sears, & Hammond, 2015). This can result in health deterioration including respiratory infections. Previous work on humpback whale health was done using blood and blubber samples (Waugh, Nichols, Schlabach, Noad, & Bengtson, 2014). This can be invasive (blubber cores) or lethal (blood). However, some research on exhaled air from marine mammals has been undertaken with promising results (Acevedo-Whitehouse, Rocha-Gosselin, & Gendron, 2010).

The aim of my study was to develop a method to assess humpback whale health from mucous samples collected from exhaled air to establish a non-lethal method. I used a remotely controlled drone with a mounted mucous collection device (petri dish) to sample exhaled air from humpback whales. Before the field study commenced, the most effective way to collect the samples was developed and a possible extraction method for DNA established. Eleven samples from different humpback whales were collected in October 2014 off the northern tip of the Gold Coast bay, Australia (Figure 1 and 2). Only a small number of samples were required to test the method. I collected 0.01-0.09 g of exhaled air per sample mainly consisting of sea water. The DNA was extracted using a FastDNA Spin kit and hormones were extracted using GeneBLAzerER (Thermo Fisher Scientific) in vitro bio-assays receptors. The DNA results were inconclusive in a first electrophoresis gel test. However, hormones were successfully extracted (oestrogen and testosterone) and assigned to individual whales. Both collection method and analytical methods still require further development but the first set of results were encouraging.

Figure 1: Collection of exhaled air from humpback whales using a remote controlled drone.

Figure 2: Preparation of collected samples on board the research vessel.
Cross contamination between samples and from involved staff posed one of the biggest challenges.

Conclusion and Outlook

Animal ethics is an increasingly important aspect in marine animal research. Meeting current standards and setting new standards should always be part of the research. Another way to reduce impacts of marine animal research is to ensure robust research questions and clearly defined justification of the sample size. The challenges of the marine environment need to be adequately addressed when undertaking marine research. Projects may fail or not produce any outcomes if these challenges are not considered causing unnecessary harm or disturbance to marine animals.

Including ethics standards in marine animal research should not be seen as a hurdle but a way forward to improve the research. All animal research should include impact mitigation. Why not setting higher ethical standards than required? We can learn and move on from the past where lethal research methods were the norm. Some of this work has provided valuable information but a lot of it was not necessary.

There are promising trends showing that non-invasive techniques are becoming increasingly popular (Cressey, 2011). Refining chemical and DNA analyses in combination with remote sensing and modelling can successfully reduce the number of samples required. However, the development of non-invasive techniques receives very little or no funding due to high costs and uncertain outcomes. A way forward can be a partnership with industry or the community to overcome some of the development costs and at the same time the benefits of high ethical standards in animal research can be directly communicated to the public.

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Reaching for Gold and Beyond: Refinement of Ventral Laparotomy Procedures and Application of this Learning to other Surgical Methods

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AgResearch Ruakura

This presentation examines what is considered by many to be a routine surgical procedure, and how we must continue to critically evaluate surgical procedures in order to "reach for the gold standard". Ventral laparotomy is performed to give access to the uterus and ovaries for reproductive research outcomes such as embryo flushing, embryo transfer and ova collection.
Our facility has a herd of female goats that are used repeatedly for reproductive programmes, including surgical ventral laparotomy. Individual goats may have 6 -12 operations during their lifetime. After the programme began in 2009, the staff involved started to question the impact of the procedure on the animals and to look at means of improvement. Improvements to date have included refinement of animal management and handling methods, preparation and restraint for surgery, surgical techniques and post-surgical care.

This process has highlighted the need for ongoing refinement of all our manipulations involving animals. We should not accept existing "routine" methods as the definitive gold standard, but as a stepping stone on the journey towards a platinum state!

In 2009 at AgResearch Ruakura, we started a programme which involves the use of dairy goat does to generate ova, embryos, foetuses and live kids. We had an old sheep Standard Operating Procedure (SOP) for a laparotomy using full anaesthesia which we adapted for the goats. Imagine that you are a goat, what does involvement in this programme mean for you?

First, you have the questionable honour of being screened as healthy and reproductively sound for the programme! This means that you are reproductively mature, you may have had previous successful surgeries and or pregnancies, you are sound in limb and hoof, have good general body health and udder health (if going to have kids) and are not currently in kid. Then you are taken from your peaceful flock grazing environment, separated into a group of 20-24 does, given booster vaccinations for protection from leptospirosis and clostridial infections, drenched with an anthelmintic and started on the synchrony programme. If you are "lucky" you may be an embryo recipient, which means you will receive one or two intra-vaginal devices plus one injection of pregnant mare serum gonadotrophin (PMSG) in the next two weeks. If you are "unlucky" you will be an egg donor and that means you will be subjected to the more intensive superovulation programme: a regime of three intra-vaginal progesterone releasing devices, one injection of gonadotrophin releasing hormone (GnRH), one injection of PMSG and eight injections of follicle stimulating hormone (FSH). These are all intramuscular injections and as a dairy goat you do not have much muscle. For the last 4 days of the programme you will be yarded twice daily and injected (ouch!). So, as a goat are you going to enjoy being involved in the programme?

Answering for the goat from the veterinary, animal ethics and welfare viewpoint, the quick reply is probably "no"! However from a refinement viewpoint there are many small things we can do

which make this regime more acceptable for the goat. For our goats, the first thing we do after the initial selection is weigh them, put a neck collar on them and number them on both sides with spray paint. The up to date bodyweight means we are able to give accurate individual drug doses, particularly for the anaesthetic drugs. The collar means goats are easy to catch and restrain for injections, manoeuvre to anaesthetic induction area etc. The painted numbers enables quick and accurate identification for recording timing of oestrus and other behavioural events which does not involve disturbing the goats to read small numbers on eartags. To make the whole procedure more acceptable, the goats are fed supplement immediately after yarding which encourages them to come to the yards even though "bad" things are happening there. In order to mitigate the impact of repeated intramuscular injections, we use a fine 25 gauge 1 inch needle, and alternate injection sites between rump (right and left) and caudal leg, or gastrocnemius muscle (also right and left). This means that although each site has two or three injections, they are at least two days apart. The fine needle and proper restraint for injections minimizes muscle trauma.

Feeding hay and meal as well as grass means that the animals have a good long lasting energy supply in their digestive system (like eating pasta to load carbohydrates before a sporting event!) and are able to be fed indoors as they recover from their surgery. It also reduces the volume and liquidity of their rumen contents which enables them to have food and water up to 8 hours prior to surgery. They are transported to the surgery building in a covered trailer, and are housed indoors overnight prior to surgery: ensuring animals who are clean and dry for surgery and eliminating the chance of escape for clandestine midnight feasts!

As with many procedures, refinements are ongoing. Originally on the morning of surgery, animals were unceremoniously dragged from the holding pen and manhandled into a corner for intravenous induction of anaesthesia, then their head was held in an upright position and the mouth opened with fingers to allow the anaesthetist to intubate. They were then slung by two people holding their legs onto the operating table. This was backbreaking for the holder and also painful for the goat whose legs are designed to bear their weight in an upright position, not in the opposite direction! Now, the use of a collar enables easier direction of the goat when moving from pen to pen. Once the animal is induced with intravenous ketamine and valium, the holder sits on a chair, extends the goat's neck between their legs and uses a second collar to hold the mouth open for the anaesthetist. This allows easy access to the larynx for intubation and is a comfortable position for the holder. The goat is transported using a custom designed canvas sling which remains on the table and is also used to move the animal into a recovery position. Far kinder than hanging them upside down by their legs! The operating table leg restraints have sponge placed on them to soften the grip around the legs.

On our first day of surgery we did not use intravenous fluids and returned the animals post-surgery to recover on the metal gratings. We quickly realised that the animals were cold on the gratings and their recovery was very slow. Refinement for recovery means we now use padded mats for the goats to recover on, with blankets laid over the body to provide extra warmth. Provision of intravenous fluids (1 litre lactated ringers solution) during surgery improves tissue hydration and general body health for the procedure and also speeds recovery from anaesthetic. As an additional bonus for being used for the surgery, goats receive a pedicure whilst they are asleep on the anaesthetic table. This has benefits for the goat and the handler (reduces pedicures

whilst they are awake). As soon as they awaken they move into an area where they can eat, drink and rest quietly.

The preparation for surgery has also been refined. Clipping with a number 40 blade gives a good close shave and vacuuming up the hair means the surgical site is hair free. Meloxicam is given subcutaneously for perioperative analgesia and also preventative antibiotics. The skin preparation protocol has been refined from scrubbing with water and iodine wash to painting on iodine scrub and then removing, after an appropriate time for effective skin sterilization, with sterile saline. This means that the surgical site has minimal free fluid and the iodine does not soak through the drapes and affect the uterine tissues exposed on the drapes, therefore reducing the risk of damaging tissues and causing internal adhesions. Initially alcohol was used as a final skin treatment, but it was felt that this could also soak through the drapes and affect internal tissues and the ova or embryos.

Once into surgery, the site of the laparotomy is ventral, but no longer midline. We found that we had wound breakdowns with midline sutures and resulting abdominal hernias. It is also difficult to perform repeated openings of the same midline site. Therefore paramedian incision sites are used. These heal much better (more muscle) and it is easy to make 4-6 different incision sites on each side of the abdomen, allowing repeated use of the same animals. Goat tissues react adversely to catgut, and we have found that vicryl sutures are the best. Two muscle layers are sutured, then the skin. An interrupted mattress suture with skin wound edges just apposed gives the best external healing. Wounds are closely inspected for the first 3 days post-surgery when further analgesia and antibiotics are administered (large animal meloxicam and long acting oxytetracycline). These products both last 72 hours and are subcutaneous injections, therefore less invasive than intramuscular injections for the animal. Stitches are removed at 10 days post operatively. Vicryl suture material does absorb, but we have found that the stitches provide a focus for dirt and that local infections result. Therefore stitch removal enables faster wound healing.

In conclusion: over the time we have been running the goat programme we have made continual modifications to our procedures before, during and after surgery. These changes allow a better environment for the animal and the human, reduce animal pain and improve anaesthetic and surgical outcomes. They highlight the fact that there are always improvements you can make to a procedure that will enhance animal welfare. We are by no means perfect in what we do and can always improve further. We are aspiring to the platinum state!

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The Cetacean Code
Unlocking underwater language

J C Schofield

J&L Consulting Ltd, Dunedin NZ

Serendipitous observations and discoveries have played an important part in the development of the life sciences. One of the most commonly used examples, is that of Alexander Fleming, to whom is attributed the discovery of penicillin in 1928. Although a French physician, Ernest Duchesne published similar findings based on work performed in Lyons in 1897, his early discovery has largely been forgotten. This presentation explores how an unusual observation led to the decoding of the communication signals used by whales. As in all animal based research, (with the possible exception of Japanese whale research), an Animal Ethics Committee (AEC) is involved and this institutional review can have a significant impact on the success or otherwise of the study. The AEC in this story had to face numerous challenges, some of which they managed with credit; however, these were possibly outweighed by a series of questionable judgements. The delegates will be in a position to determine for themselves whether the AEC was operating at a gold standard.

No manuscript was received for this presentation

Animal Research in South Africa – Developments and achievements of the Animal Ethics Unit (AEU), National Council of SPCA's (NSPCA)

Erika Vercuiel

Manager of the Animal Ethics Unit, National Council of SPCA's

The functions of the NSPCA AEU include serving on Animal Ethics Committees (AEC's) as the category C person (welfare representative) , intense reviewing of research protocols, conducting inspections at research facilities, enforcing animal welfare law, and promoting the 3R's (replacement, reduction and refinement). We also play a major role in improving South African legislation (revision of the South African National Standards based on the current Australian Code) with regards to animals used in research. We are the only welfare organization in South Africa who is actively involved in the sphere of animal research and also the only organization who keeps statistics on animal use in South Africa.

During the past 10 years, the AEU has advanced dramatically in terms of increasing our involvement with animal research facilities, the increasing amount of facility inspections we have conducted (↑1285%), increasing the amount of committees we serve on (↑238%), growing amount of expertise in the unit and also enhancing the way in which we capture statistics of animal use.

In the field of alternatives, one of the most impressive achievements thus far has been the development of the first South African 3D printed dissection rat. Another unique partial replacement tool is the suture kit with artificial skin that could replace the use of animals for training students in suturing techniques. We constantly look for opportunities to make use of our own South African resources to keep the costs of alternatives to a minimum. We recently had a breakthrough with the Department of Basic Education to give school kids the option of using the dissection model in the classroom, an area where welfare concerns are huge. Currently some primary schools source animals from the wild and do unnecessary dissections, a practice that we would like to see being phased out.

In South Africa we see a variety of animals used for various purposes of research outcomes, but are also faced with challenges unique to our country. Challenges such as
"load shedding" (power cuts), cultural differences, crime and language barriers affect the intensity of our work.

We believe that despite the challenges, the NSPCA's role in the research community is paramount for improving welfare of research animals.

No Paper was submitted for this presentation

Research Models:- Is Animal Experimentation the Gold Standard?

Dr Geoffrey Dandie

The debate about whether or not to use animal models is a perpetual quandary that brings passions to the fore and is not going to be resolved at this or any other meeting. However, the important thing is that we continue to think about it and enter into any debate with an open mind. As AEC members, it is a question that comes up with almost every application that is considered. I say almost every application, because we do occasionally see applications where the answer is a very clear yes or no.

On the one hand, we read stories in the popular press telling us that the use of animals in medical research is scientifically invalid and producing misleading data, while applicants to the committee are constantly assuring us that the work they wish to have approved is the best possible way to examine the question at hand. So, who is right?

It is interesting to note that public debates around these differences tend to focus solely on medical research projects and ignore (for example) wildlife studies. It is also difficult to ignore the history of medical breakthroughs that have been achieved using animal models of disease, yet it is impossible to ignore the fact that animals are living, sensate entities with intelligence and value.

What we often fail to recognise is that the term 'animal model' is in itself an acknowledgement of its imperfection. As with any 'model' system, the use of animals is almost always an approximation of, rather than a specific case of the actual human disease being investigated. Equally, we should always ask where an animal model fits into the overall research strategy. Is this the sole way that a disease process or potential cure being investigated, or is it part of an overall research strategy that includes everything from clinical research involving actual patients right back to *in vitro* and computer models as well?

Contrary to the impression that might be gained from media reports, the current approach to drug development and safety testing adopted by many pharmaceutical companies includes multiple research strategies. They generally start with computer models that look at the molecular structure of the potential therapeutic agent followed by testing candidate drugs using high-throughput *in vitro* screening assays before employing using cell and or tissue culture assay systems to test both efficacy and toxicity. Only when the compound under investigation has passed all these steps will it be trialled in animal models as the final step before entering clinical testing and (assuming it passes at all stages) potentially being licenced for clinical use. The reasons for rigorous testing of potential treatments prior to animal studies are two-fold. Firstly, there is the obvious ethical requirement to ensure that animals are only used judiciously and secondly, there are imposing practical barriers to the use of animals associated with the time required to conduct animal trials and the enormous expense involved as well. So researchers and / or Pharmaceutical companies are not going to rush any product into animal testing without first establishing that those tests are likely to show promising results. It is also true to say that by adopting a staged strategy that involves all available modes of testing, the greatest possible chance of successfully identifying both the potential risks and benefits of any new treatment is reasonably assured …… and isn't that the Gold Standard we should all hope to see adopted?

Introduction:

Let's begin by looking at the question, is animal experimentation the gold standard? In itself, this sounds like a pretty simple question but I suggest that it might not be as simple as it seems. I could even go so far and ask if there really could ever be a single 'gold standard' when it comes to an issue as broad and complex as the scientific use of animals? A closer look at research statistics from across Australia shows that animal – based studies are aiming to answer many different questions across a number of disciplines so it really is difficult to see how one answer might fit in with the vast array of work being done. Even if we try to break down animal based studies into two very broad groups like wildlife research and biomedical research, I would be tempted to suggest that the use of animals would be the 'gold standard' for wildlife researchers but I might also question if this is still true in all cases for biomedical research.

Outcomes from Australian Animal Research:

Australia has a very strong and productive research culture that ranks very highly by international standards and some of that research work involves the use of animals. In this regard, we are not alone. In fact, we are very much a part of the broader international community that undertakes and shares the results of their research with a view to also sharing the benefits that are derived from such work. In the medical field alone, this means that Australians have either been playing a supporting role or in some cases, the lead role in many medical advances over the past century and we will consider some specific examples shortly.

On the other hand and contrary to the impression you might gain from the popular press, animal research is not limited to 'medical research'. In fact, if you examine the animal use statistics, a significant proportion of the animals used each year are used in non-medical research projects. What might surprise many people, is the fact that fish are now the most common type of animal used in Australian research. Some of this use would be associated with using fish species like the zebra fish as a model for genetic diseases or other studies that aim to improve human and / or veterinary health outcomes, while a significant proportion of these fish are also used in areas such as aquaculture research that aim to achieve sustainable fish populations that both feed the human population and also maintain biodiversity associated with fish populations in the wild.

Another very significant group of animals used for research purposes would be wild animals (both native and feral) that are used in wildlife research projects – many of which are aimed at the conservation of rare or endangered species. Examples of this kind of work range from the undertaking of environmental impact studies (as required prior to any development work outside our cities) right through to work aiming to control feral species such as the cane toad or conservation of native species like the Tasmanian devil, which is now under threat of extinction due to the emergence of a unique, infectious facial tumour disease. When it comes to the idea of controlling the spread of feral species, the cane toad is obviously the first thing that comes to mind these days, but work to control the spread of foxes, rabbits, feral cats, camels, or even introduced aquatic species like the crown of thorns starfish that tends to decimate areas of coral reefs every few decades. Interestingly, work of this kind is accepted – almost without question, by the Australian population and clearly must include the use of animals as an integral part of the work and yet, whenever the question of using animals in research is raised, this kind of work is rarely if ever even mentioned.

When it comes to the more traditionally viewed medical research breakthroughs achieved during the past century, the great majority have required the use of animals. Australian medical research can be credited with the development of a great range of medicines, vaccines and treatments.

People with even mild hypertension can now significantly reduce their risk of suffering a heart attack or stroke by simply taking medication to reduce their blood pressure.

No longer do suffers of gastric ulcers have to endure years of treatment in the hope that their ulcers may be cured. All that is now required in most cases is a short course of antibiotics.

Women can now be protected against most cervical cancers thanks to the development of a vaccine, which has already resulted in a 50% decrease in the incidence of cervical cancers in many age groups.

Problems associated with sleep apnoea have essentially been overcome with the use of a small mask and a little positive air pressure during sleep.

Development of bone marrow transplantation and the restoration of immune cells after chemotherapy thanks to the development of the family of colony stimulating factors used today.

Seven out of the ten most common childhood cancers can now be cured. A number of improvements in the treatment of adult cancers have also been developed here as well.

Hib vaccine – prevents fatal infection and possibly childhood leukaemia as well

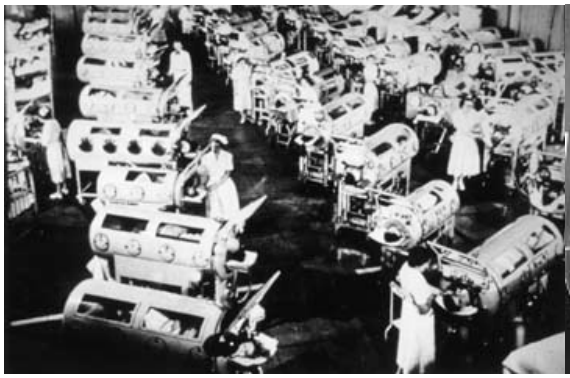
Economic benefits from health and medical research

Medical research is not a cheap undertaking, but it does also bring substantial benefits – both in terms of health and economic benefits as well. A study done by the Australian Society for Medical Research (ASMR) has shown that every $1 spent on Australian medical research, resulted in a $3 return to the national economy. As a part of this, the international pharmaceutical industry puts around $600M into the Australian economy each year to conduct medical trials. Beyond that however, the Australian pharmaceutical industry has now developed to the point where exports are now worth more than $4Billion per year and that makes it a bigger source of export income than the wine industry. Nationally, the Australian Stock Exchange now has a number of biotechnology and pharmaceutical companies listed with a net worth of around $50Billion and this sector has outperformed the All Ordinaries index for the past 15 years. In terms of local employment, CSL and Cochlear alone employ thousands of Australians between them and that alone will have significant flow-on effects throughout the economy.

By way of comparison, the US government invested $3.6B in the human genome project over fifteen years. The nett outcome of that investment was substantial with each $1 invested yielding a return of around $178 to the US economy. So clearly, this is a high cost, high return industry that from a purely economic standpoint, makes a lot of sense – even without considering the health benefits that come out of it.

Australian medical research can also offer cost savings as well. Recent Australian research has offered findings that have significant savings for the health budget. For example, one study has shown that treatments aimed at stabilizing cracks in vertebrae are ineffective so they are no longer offered as the preferred treatment option. It has also been demonstrated that the use of normal saline is just as effective as more expensive, human albumin based, intravenous solutions. This one study has the potential to save over $700M in Australia each year, which is roughly equivalent to the annual NHMRC budget.

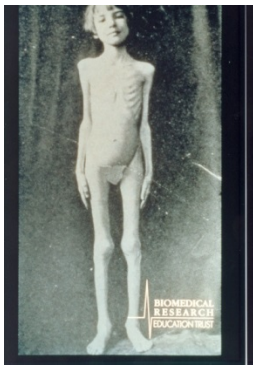
When considering the economic benefits and cost savings associated with health and medical research, there can perhaps be no better example than the development and use of vaccines. As a young aspiring immunologist, I was personally inspired by a talk given by Sir Gus Nossal (then Director of the Walter and Eliza Hall Institute in Melbourne) who cited the example of the development of effective vaccines against the debilitating disease, Poliomyelitis. Sir Gus went on to explain that the cost savings brought about by the development of the Polio Vaccine by Jonas Salk has paid for all medical research done to date and probably into the future as well. While this seemed a rather bold statement, there is little doubt that the costs associated with caring for the vast number of people who could otherwise be affected by, or even paralysed as a result of polio infection would be ever increasing with population growth and the development of other measures that have the ability to keep victims of polio alive for 50 years or more after suffering the devastating effects of the disease. So even the most rudimentary cost / benefit calculation shows that these claims are entirely realistic and an excellent example of the benefits that can come from medical research.



A polio wards in the 1950's

Being young and healthy offered little if any protection

Of course other major 'breakthrough discoveries' such as the role of the pancreas in juvenile - onset diabetes and developed the first treatment for the disease which had until then, inevitably been a condition that caused wastage and eventually death. It was the work of Banting and Best in dogs that lead to these outcomes.



Young girl with diabetes

The same girl after treatment

Banting & Best with Marjorie the dog

As indicated, this discovery was made in UK by Banting and Best who surgically removed the pancreas in a group of dogs and noted that those dogs who survived this procedure developed all the symptoms of diabetes. Importantly, when those dogs were treated by injection of an extract prepared from fresh pancreas, they regained their health. By all accounts, Dr Banting's surgical skills were not the best and have meant that this work has been cited as an example of a project that would probably not be approved by an AEC today, simply because the investigators skills were not good enough. This offers an interesting potential dilemma, with the benefit of hindsight, would you recommend approval of this ground breaking research or rate the welfare of the 20 dogs they used more highly? Hopefully, it would have been possible to negotiate an appropriate compromise, like allowing the work to proceed with an appropriately skilled researcher or qualified veterinarian doing all the surgical procedures.

Balancing Expectations

So this brings me to the central question that faces every AEC each time they meet. Every time a scientist prepares and submits an application to the AEC, they do so with the clear intention of making a difference and using those animals to do something that they consider to be really important and worthwhile. Yet as AEC members, we have to match and balance those laudable aspirations against the needs and welfare of the animals they wish to use. And yes, this will often mean trying to work out some kind of compromise position that will allow science to progress without compromising the welfare of the animals.

The other great paradox that needs to be addressed is the differences in perspective that is typical of scientists as opposed to animal welfarists.

Old School Scientist perspective	**Perspective of some Animal Welfarists**
Animals are anatomically and physiologically very similar to humans	Animals are anatomically and physiologically very different to humans
Animal immune systems, circulatory systems, nervous systems, endocrine systems, etc., all work the same way as the equivalent systems in humans	Animal immune systems, circulatory systems, nervous systems, endocrine systems, etc., all work in ways that are very different to equivalent human systems
There is high genetic concordance between humans and laboratory animals	There are major genetic differences between humans and laboratory animals
Animals may not perceive pain or distress in the same way as humans	Animals do perceive pain and distress in the same way as humans
Animals are an ideal model for undertaking research	Animal data is irrelevant, misleading and cruel

When I compare these apparently disparate perspectives in line with current scientifically based knowledge and what I would like to think is a reasonably balanced approach, I come up with the following 'compromise' list of perspectives for the reasons indicated:

My perspective	**Basis for that perspective**
Animals are anatomically and physiologically very similar to humans	Mammalian systems all rely on the same internal organs performing pretty much identical functions. However, there are some subtle differences and these need to be taken into account when selecting the best model for any particular experiment.

Animal immune systems, circulatory systems, nervous systems, endocrine systems, etc., all work in very similar ways to the equivalent systems in humans	Again, while the similarities far outweigh the difference, those differences can be both informative and challenging so they need to be taken into account.
There are varying degrees of genetic concordance between humans and laboratory animals	There are genetic differences between most members of the same species, so unless you are working with identical twins, this will always be a factor to some degree. The question is how important is that difference and how much variation is acceptable in each situation?
Animals do perceive pain and distress and in the absence of reasonable evidence to the contrary, we need to assume that they do so in the same way as humans	There is good evidence to show that animals do perceive pain and distress although there are also data that indicate this may vary at different stages of development for example. However, as pain and distress are potentially major experimental variables that cannot be controlled, it is essential to prevent or at least minimise their impact by preventing the sensations in animals used or via the appropriate use of anaesthetics or analgesics.
Animals are still an important model for some research, but will probably never provide us with a complete picture of what is happening in any test system.	Animal data is an important part of any testing procedure, but it is not the complete answer, nor should it be considered in isolation.

We also need to be cognisant of the need for balance when it comes to reports about the scientific use of animals that appear in the media and think carefully about the source of stories and the veracity of any claims made in stories that are not presenting a balanced perspective. Certainly we are seeing a number of reports in the media these days that make some pretty interesting claims. Perhaps the most common example of this would be the idea that 97% of animal studies produce meaningless data and so are a waste of animals. What is missing in these kinds of citations is detail and precision. Most of the original articles cited include careful wording like, for example, included provision that the work done in animals did not directly lead to any treatment (thereby indicating their lack of value). Such claims are often based on quite extensive literature searches and are generally technically correct within the strict limits of their claims. However, what such reports do not take into account is that the greatest majority of scientific publications (in any field) present incremental steps forward in knowledge and only very few scientific studies lead instantly to a new treatment for some disease or other. Does this diminish the value of each piece of research undertaken that results in another step forward? I would respectfully suggest that such a dismissal would be like suggesting that you only need the top row of bricks in a wall to hold up a roof, because almost without exception, big discoveries are built on the foundations laid by early research and the smaller discoveries they made.

We also hear claims that data from animal studies is misleading or even dangerous and I have to be honest and confess that this is a claim that I personally, just tend to regard with a degree of scepticism. Yes, it would be foolish to deny that data derived from animal studies may differ from what is seen in human patients, but equally it can be a very good predictor of what might happen in humans. We must not lose sight of the fact that animals are only being used as a model for human disease and like any model, it can be accurate, or it may be partially correct, or it might be misleading so yes, the use of animal models is an imperfect solution. It is also worth

remembering that human clinical trials are also imperfect, so claims that we should only conduct medical experiments in human volunteers would probably be imperfect as well.

The idea that human cell or tissue culture experiments are infinitely superior to animal testing is also an interesting proposal and I would suggest that the use of human cells and tissues in culture based experiment is an important step that should always be part of any testing regimen, but unfortunately the use of cells or tissues in isolation does not always show what will happen in a complete body as it does not allow for the interactions between different body systems that can and do occur. There is an important balance that needs to be attained when testing new drugs etc and that includes both ensuring that it will work on human cells and also determining if and how it may interact with various systems in the body. So both strategies would seem to be important.

Looking at some of the claims and counter claims cited above in more detail, the issue of genetic similarities and / or differences between humans and experimental animal models is one that can be quantified and does vary with the species under consideration. So for example, the degree of genetic homology between humans is around 99.5% (obviously very high, but just short of a perfect match). When you consider the equivalent comparison between humans and chimpanzees, that drops to around 97%. Comparing humans with cats gives us a level of genetic homology of around 90%, between humans and cows of around 80%, between humans and mice at around 75% and even between humans and the humble fruit fly (Drosophila) we have around 60% homology. A score of 60% in an exam will generally give you a good pass, but would you buy a car that only works 60% of the time? So it is a judgement call when it comes to setting boundaries about where you draw the line when it comes to genetic differences between species. Clearly, there will always be homology between living species as there are common features and functions that are essential to life, but it would also seem equally clear that the differences are pretty important as well. So, accepting that not even human to human offers a perfect match, where do you set the limits and are those limits going to be the same every time, after all, those comparison statistics cited above relate to the entire genome of each species. When you get down to the genes that govern the function of individual organs or bodily systems, in some instances, the level of genetic homology increases further while in others it can drop off dramatically as the relevant genetic code might be carried on a different chromosome, so it can be more difficult to predict. Little wonder that the general population can become confused to the point of disinterest by claims and counter-claims – all of which purport to be scientifically based, simply because people can choose to be conveniently selective in their citation of scientific facts.

Changing Public Attitudes and the European Experience

Back in 2010, the EU changed their regulations regarding the scientific use of animals (EU Directive 2010/63/EU), which promotes the 3Rs and the development & uptake of alternatives in a way that essentially meant that the rules in place across Europe were almost the same as in Australia and New Zealand. At the time, this move was widely supported and lauded by many as a ‘significant advance’ for the EU. However, last year, there was a very strong move towards scrapping this amendment and essentially banning the scientific use of animals all together.

As I understand the process within the EU, changes to legislation can be put before the European parliament if they gain sufficient public support as defined by meeting or exceeding a threshold proportion of the population in at least seven member states as shown by signing a petition or some equivalent form of registration of support. The move to fully replace the use of animal

experimentation within the EU gained the support of over 1.2 million people and exceeded the required threshold level of support in nine member states and so the proposal went before the EU parliament. In response, the EU Parliament welcomed the mobilization of support for animal welfare but ruled that for the time being, animal experimentation remained important for protecting human and animal health and maintaining an intact environment. The EU Parliament did however make it clear that even though Directive 2010/63/EU remains in place, there is a clear expectation that there is the goal of working towards fully replacing animal experimentation.

It may be interesting to note that one of the nine Member States showing sufficient support for the abolition of animal experimentation was Spain, where bull fighting regains a legal and popular part of their culture. I will leave you to your own thoughts on that contrast.

Testing the safety and efficacy of new drugs

In spite of the common perception, often perpetuated by the way things get reported in the media, new drugs or potential treatments for disease are not just concocted in the laboratory and thrown into animal trials. The simple fact is that this kind of process is inappropriate, illogical and quite simply a waste of money. So even though there is no strictly proscribed protocol that is set in concrete and must be followed, most new drugs and treatments go through a logical, stepwise series of processes that will (hopefully) demonstrate safety and efficacy of the new drug at the same time as determining any toxicity issues that need to be addressed.

So, the common steps that most drug development scientists would follow would begin with *in silico* testing that would use computer databases and programmes to compare the new treatment with existing treatments, based on molecular composition, structure and predicted ability to bind to the appropriate receptors, markers, proteins, or whatever is required to mediate the desired effect. Perhaps more commonly though these days, candidate drugs are often designed *in silico*, based on the need to bind to or block a particular receptor or cell protein and this is used as the basis for constructing an appropriate molecule to fulfil those aims.

Once past the stage of computer modelling / *in silico* testing, the next step would be to enter one or more phases of *in vitro* testing where cells in culture would be used for high throughput screening assays designed to test that the candidate drug will activate the desired biochemical pathways within target cells. This might mean activating some cells or killing cells for example, or even just changing the way those cells operate so that they produce something or potentially switch off the production of some factor(s). If the candidate drug passes that stage, then the next step might be to look at the potential for toxicity in cell cultures and also to start looking at safe / effective dose ranges in cell cultures as well. The logical step after that is often to look at these kinds of parameters in slightly more complex systems, so rather than using cell cultures, some of these tests might be repeated in tissue culture or even organ cultures (which are often derived from animals) to see if the results obtained from isolated cells are reproducible when those cells are still arranged in tissues or organs as they are in the body.

When the information obtained from human and or animal based cell and tissue culture systems has been checked and fully analysed, a determination will be made about the prospects of success and if everything is still looking good, then the decision might be made to embark on the much more expensive phases of testing that begin with animal models. This is where some really critical decisions must be made as the time taken to undertake this kind of work as well as the

expense involved means that the choice of animal model, the timing of experiments, the dose ranges that are tested and a number of other factors must be decided – based largely on the information gained from earlier tests. If the wrong animal model or inappropriate doses are used for example, the data obtained from these trials can be misleading. We frequently see applications that justify the choice of animal in terms of their lower cost or the fact that multiple animals can be easily housed in a confined area, which are clearly factors that need to be considered, but hopefully the most persuasive justifications would be based around the biological / physiological similarities between human patients (where relevant) and the relevant organ or system in the animal model selected. It is worth noting at this level, that the British Pharmacopeia standard that needs to be met as a qualification for most clinical trials, dictates that a candidate drug needs to be tested in at least two disparate species of animals. This is aiming to reduce the likelihood of an inappropriate model animal being used, but of course, it does not offer any real guarantee.

Assuming that the animal trials all show appropriately positive results and inform researchers about effective dosages, toxic dose limits, degradation kinetics, excretion kinetics, etc., the researcher may decide to apply for permission to conduct clinical trials. In the first instance, this would most likely involve a very small number of volunteers to confirm safety, metabolism kinetics and check for any unexpected side effects for example. Beyond that, if each stage is successfully passed, clinical trials can progressively involve larger number of volunteer patients right through to large scale, double blind, cross-over clinical trials that see the new candidate treatment being compared against the current 'best practice' treatment for that disease in a way that ensure no one (patient, researcher, local doctors & nurses, etc) know whether the old or new treatment is being taken at any stage during the trial. This ensures that the potential effects of bias (operator or patient) are unlikely to impinge on the results. If the candidate drug proves to be as good as or better than current treatments, an application may be submitted for approval and a licence for clinical use.

This means that by the time any new drug comes onto the market, it should have been tested using computer models, cell and tissue culture models, animal models and humans before it is released for sale and use by patients.

Balancing the costs and benefits of research

Hopefully I have been able to illustrate that a lot of research work involving the use of animals can be associated with both high risk and potentially high rewards and it is therefore the difficult job of every AEC member to balance out those potential risks and the likelihood of achieving the rewards that may hopefully follow. Clearly, this is not always an easy task, but it is one that every member of every AEC across Australia and New Zealand takes very seriously. So, bearing in mind that at least half the categories of AEC membership are based on the idea that those members do not have any specific scientific background or expertise, how can AEC members' best try to analyse and assess applications so that they can answer such difficult ethical questions?

Possibly the simplest way is to try to breakdown the application into some simpler questions that hopefully can be answered? First and foremost, is the use of animal essential and what has been done to identify potential alternatives to animal work? Obviously the choice of species listed in

any application has to be looked at quite carefully and justified. How likely is the work to produce the outcomes that are tied to the application is always a big question and of course the most common focus will generally be, do the potential benefits of the work outweigh the potential costs to any animals that might be used?

When considering some of these questions, AEC members might look for guidance from the applicants through the submitted application. For example, how big is the problem that the work is trying to address? In many cases, the bigger the problem; the more likely an AEC might be to consider an application sympathetically. Another series of questions can be based around the question, how realistic are the applicant's aims and claims? Even this can be quite an imposing question to answer, so it might be easier to again break this down even further to a series of sub-questions like: do they have the ability to do the work they are planning? What is the likelihood that any result obtained from the proposed work will answer the questions being asked? Beyond these kinds of questions, it is also important to consider the bigger picture regarding the context of any project. This means essentially asking about the potential value of any data obtained. Will the results of the proposed work potentially provide a major advance or an incremental step forward in solving the problems under investigation?

Are animal models the 'Gold Standard'?

This is of course the big question I set out to address and to be honest, I am still not sure that there is a single answer to that question and this is largely a result of the incredibly broad range of questions that are investigated across Australia using animals. Certainly, my own person belief is that in cases where the direct beneficiary of the research would be the animals themselves or at least other members of their own species, the answer may well still be "yes". The kind of work I am thinking of here would be wildlife conservation studies and potentially even a lot of agricultural and aquaculture studies aimed at improving the lives of animals being bred or raised using these systems. However, when it comes to medical research studies that aim to cure human disease I am not so sure. Clearly, animal studies remain a vital (and still legally required) step in the process required to gain approval for a new drug or treatment, but the animal work is just one part of that process.

Thinking back to the excellent presentation we heard from Ian Fraser on Wednesday morning, much of the work that led to the development of the HPV vaccine involved the use of animal models and they were essential for both convincing Big Pharma companies to put the money into the clinical trials as well as providing a lot of the safety data needed to justify those trials, but those animal studies did not provide all the answers.

Are animal models perfect?

Clearly the answer here has to be "no". Animals are only ever and can only ever be used as a model of human disease or the treatment of any condition or disease and almost by definition that implies that the model is an approximation of that disease. It is also true to say that there are hundreds, if not thousands of examples of potential drugs or therapies that have passed animals trials but failed in human patients. However, it is worth remembering that almost exactly the same number of failed treatments was also tested in human subjects as well and those human trials also failed to predict the failures that resulted when the drug was released for clinical use, so perfection is probably an unattainable goal in this area.

Perspectives and conclusions

There is a lot of handwringing and speculation reported in the media at times about the problem of results from animal tests being unreliable and only predicting the true outcome of treatment in a proportion of cases. Regrettably though, the simple truth is that in biological sciences, there really is no such thing as 100% certainty because there is so much variability between individuals. So the likelihood of any one treatment working for 100% of patients is almost zero. If you think back to Ian Fraser's utopian principle discussion yesterday, where the question was asked – If only 30% of patients are cured by an expensive treatment, should they be asked to pay for it? This really highlights the kind of variability that is seen in the real world, because it is not uncommon to find that only 30 - 40% of patients are cured by any particular treatment.

Humans are a very diverse species who respond to different things in different ways at different times and this is why we do need a range of treatment options available for common conditions. If you take the example of medications for high blood pressure and / or high blood cholesterol levels, which are both very commonly prescribed for Australians over the age of (say) 50 years. Your doctor will need to select from a range of a dozen or more different drugs, all of which are available in various doses and she / he will pretty much take an educated guess at which one or combination will work best for you based on your age, severity of symptoms, other medical considerations, lifestyle, etc., etc., and suggest that you try the prescribed medication for a few weeks and then come back for another check-up. At this stage, it should be clear that the prescribed treatment is either working (in which case all is good and continue taking it) or not working as well as hoped, so they will suggest an alternative drug or change of dose etc. Essentially adopting a regimen of empirical experimentation until they determine what will work for you. This is a simple and really important process because we are all different.

Finally, returning to my initial question, animals are still an important link in the chain but they are still only a model, so we must acknowledge that the use of animal models is an imperfect approximation and not the whole answer. That said, claims that they are dangerous, misleading and a major cause of problems with drugs that need to be withdrawn from the market for safety reasons, also need to be taken with a grain of salt. After all, every one of those drugs that proved to be problematic when licenced for use would have also been tested in humans as well and those human tests also clearly failed to predict the problems. So regrettably, like life itself, science is not always perfect.