The A S C
Animals in Science Committee

Animals in Science Committee
and
Animal Welfare and Ethical Review Body
Hub Chairs Workshop

13 March 2019

Workshop Report

1. Introduction

1.1. The fifth Animals in Science Committee (ASC) and Animal Welfare and Ethical Review Body (AWERB) Hubs Workshop was convened on 13th March 2019.

1.2. The aim of the day was to enable attendees to share and discuss key aspects of the role and operation of an AWERB, tips on dealing with late project licence applications (PPLs) and share thoughts on having open AWERB meetings. Attendees also had an opportunity to explore the function of the harm-benefit analysis, as well as consider how to take forward ethical discussion.

1.3. Workshop attendees included chairs of the regional UK AWERB Hubs, or their nominated representatives, members of the ASC AWERB Subgroup, and presenters. The workshop was chaired by Dr Sally Robinson. The agenda for the day can be found at Annex A.

1.4. This report sets out the points and issues raised by attendees. Presentations provided at the workshop will be made available to attendees to share with their AWERBs.

2. The Role and Operation of an AWERB

2.1. Feedback from the 2018 ASC AWERB Road Shows indicated that AWERBs would welcome further guidance on how they should operate to effectively discharge all their functions.

2.2. Therefore, ahead of this year's AWERB Hub Chairs workshop, the ASC wrote out to Hub Chairs seeking views on how they address the tasks outlined in the 'Guidance on the Operation of the Animals (Scientific Procedures) Act 1986' (set out below), as well as what works well in their AWERBs.

2.3. Ideas by workshop attendees are outlined in this report. The intention of the ASC subgroup is to reflect on the ideas raised and to produce separately a short set of good practice recommendations against each of the tasks of an AWERB:

Advise staff in dealing with animals in licensed establishment on matters related to the welfare of the animals, in relation to their acquisition, accommodation, care and use.

- Having clear Establishment guidelines that outline areas relating to animal use not covered in project licences (e.g. supply/transport and acclimatisation), and these should be provided to new personal licence holders (PILs) and new project licence holders as part of their induction.

- Making training and refresher courses available to all staff who work with animals.

- Providing advice to staff, for example availability of reports from the Named Animal Care & Welfare Officers (NACWOs), Named Veterinary Surgeon (NVS) and Establishment Licence Holder (PeLH).

- Holding open AWERB meetings - these can provide opportunities to disseminate information to all staff. They also give individuals a chance to air views and can act as the forum for discussion of ethical issues.

- Running regular workshops with external speakers who can provide a fresh perspective on matters related to the welfare of animals.

Advise on the application of the 3Rs and keep informed of relevant technical and scientific developments.

- Annual 3Rs symposium/3Rs day within establishments. This might include awards (e.g. best 3Rs poster). One delegate noted that a recent joint 3Rs day between two institutions had brought mutual learning, with one having a formal requirement for biostatistical input and the other, which didn't, now recognising the potential benefits of such.

- As a further means to facilitate knowledge exchange on 3Rs and Culture of Care, some Hubs reported their members participating in an 'exchange programme' with AWERB members attending AWERB meetings in their Hub.

- Some establishments have 3Rs groups which cover a range of expertise. These groups horizon scan in order to draw information into their establishment.

- Invite external speakers to address emerging issues, either at the AWERB or more widely with animal users within the establishment.

- Refinement is often the focus of AWERB 3Rs discussions; more promotion of Replacement would be helpful.

Establish and review management and operational processes for monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the licensed establishment.

- The size of the institution may affect the way it monitors issues. The AWERB of a small establishment with few licences may have more time to undertake monitoring and follow-up of issues. However, AWERBs of larger establishments with numerous licences (some 200+) might struggle. AWERBs should aim to establish a reasonable level of oversight, while not being overly prescriptive. For example, the AWERB may ask for formal reports from Named People that relate to monitoring and follow up of animal welfare observations. Alternatively, the AWERB may establish subgroups with outlined tasks that then report back to the committee, e.g. a subgroup specifically assigned to review management and operational process. Other ideas included having a sub group to review project licences which would in turn free up more of the main meeting time to discuss oversight in relation to management and operational processes.

- The benefit in learning from near misses was noted, as was the importance of recording and disseminating the details.

- The example of an 'Event observation log' was offered, this would go to the Named Information Officer, who would consolidate all reports and

present to the AWERB. This type of log is used for learning from both positive and negative observations/events.

- Introduce a rolling programme of topics that focus on defined subjects over a period of time e.g. training records. Alternatively, have a formal AWERB review audit across all animal use and care, then have a deep dive into selected areas.

- Establish routes where animal welfare issues can be raised safely and effectively by staff (technicians or more junior researchers) outside the involvement of the individual's immediate management chain (for instance via the AWERB Chair).

Advise the establishment licence holder whether to support project proposals, primarily considering such proposals from a local perspective and bringing local knowledge and local expertise to bear.

- Many establishments have procedures for pre-review of project licences which can provide advice on a range of local issues such as: availability of specific expertise; PPL review processes and policies; views on overseas work; and whether regulated work thresholds have been correctly identified.

- Pre-reviews also provide opportunities to identify potential training and collaboration gaps, for instance when working with uncommon species and methodologies.

- Establishments with pre-review processes reported applicants finding the AWERB committee being more effective.

- The project licence application writing may be delegated however it was agreed AWERBs should remind all applicants that they are fully accountable for the content and quality of the draft application.

Follow the development and outcome (retrospective review) of projects carried out in the establishment, taking into account the effect on the animals used; and to identify and advise on elements that could further contribute to the 3Rs.

- Retrospective reviews provide opportunities to assimilate a great deal of information regarding the progress of the work (how are the benefits being realised), share any learning, with accompanying opportunities to inform the 3Rs. For example, many establishments carry out retrospective reviews as an ongoing process throughout the project at 1, 3 and 5 years, as regular reflection on projects improves focus and identifies areas for improvements. Some establishments conduct reviews annually.

- Ongoing review – some establishments have an ongoing review after each study is completed and some others have a review of all Standard Condition 18 Reports as they arise. This allows the AWERB, or a subgroup of the AWERB, to monitor management and operational processes in relation to animal welfare events occurring within specified time frames.

- AWERB Hubs could exchange such information within their region's AWERBs or with other Hubs.

- The Knowledge Hub could include a repository for refinements and other 3Rs examples.

- Some Establishments have a NC3Rs programme manager which had been a very useful source of 3Rs methodology. A further benefit would be for Hub chairs to ensure these regional managers contribute to their AWERB Hub meeting to further promote the 3Rs outside of their allocated Establishments.

Assist with the retrospective assessment of relevant projects carried out at their establishment.

- Assessments should consider more than unexpected harms; they should also reflect on the overall progress of the work and whether the benefits claimed were achieved.

- They should also ask 'what did the animal experience?' Were the harms as predicted, greater or lower? Assessments are opportunities to look for refinements and consider if they can be adopted in other ongoing licences.

Advise on re-homing schemes, including the appropriate socialisation of the animals to be re-homed.

- Excess numbers of animals in need of rehoming was an important ethical question as well as a potential reputational one for the establishment. There was a role for the AWERB in discussing both aspects.

- Project licences should have a separate part of the licence for rehoming, standardised rehoming processes should be in place as good practice. Where in place, these should be communicated to all relevant staff, including the AWERB lay members.

- Difficulty in socialising laboratory animals was noted, including those brought into a group they had not been previously part of, and that this can affect the feasibility of re-homing.

- Even though it's no longer the institution's legal responsibility, it was good practice to follow up how well the animal(s) were doing in their new environment. In one establishment the Named Animal Care and Welfare Officer (NACWO) offers guidance on how to look after the animals and makes contact again after 4-6 weeks to check progress.

Other tasks e.g. Promoting Culture of Care.

- Adding in 'Culture of Care' into all staff objectives including administrative staff.

- Establishments can work between animal technical staff and scientists to develop 'Culture of Care pledges'.

- Consider a scheme to recognise good practice and introduce a small reward system for staff.

- In one establishment, animal technicians had led an event, with invited scientists, in order to promote animal technicians' roles.

- Promote a Speak Up Culture.

- To promote two-way dialogue and to hear the voice of staff who carry the burden of care, AWERBs can ensure that they invite representation from the animal care team to be a member of the AWERB. This should be a distinct role from the NACWO role.

- Have Culture of Care as a regular item on AWERB agendas.

- Encourage AWERB members to join AWERB Knowledge Hub as a means of accessing information about, and sharing good practice on, culture of care issues.

3. Harm-Benefit Analysis

3.1. In 2017, the ASC published the report: 'Review of harm-benefit analysis in the use of animals in research'. Attendees were given a presentation on those aspects of the report's recommendations where delivery could be supported by AWERBs.

3.2. Attendees were invited to discuss which of the recommendations relating to assessing and reducing harms they had been able to action and how they have done this. Additionally, where recommendations had not yet been actioned, attendees were asked what might assist them in taking these forward.

Role of Hubs sharing information on:
Common reporting standards for data on animal welfare, including cumulative suffering (as taken from recommendation 1)

- Standardising recorded data from across species or within species would have value. For instance, biobank data collecting end of life blood samples and telomeres could be used to assess cumulative severity and provide vast datasets of information.

Data and evidence regarding factors that cause animals harm (as taken from recommendation 3)

- Cumulative severity can be difficult to record. Making data available on harms for animals via a credible platform could be helpful. The recordable outcomes might be quite simple i.e. weight loss, pain response; a neutral assessment of these outcomes would be necessary.

Tools for recognising and recording cumulative severity (for project review and ethical discussion functions) (as taken from recommendation 8)

- In complex protocols it was often difficult to map out the experimental paths representing all possible severity options for an individual animal, flow diagrams/mapping can help visualise these. These might not pick up on contingent harms, however the approach could be expanded to capture these.

- Timeframe was important in recording cumulative suffering i.e. would three immunisations at three-weekly intervals be a mild or moderate procedure?

- Hubs might offer help on how to visualise severity pathways and how to address calculating suffering, possibly drawing case studies from within the Hub.

Challenge the necessity and justification for severe procedures (as taken from recommendation 9)

and

Ways of refining severe procedures (as taken from recommendation 11)

- Attendees felt both these recommendations could be implemented but noted the possibility of definitions for severity becoming skewed if some researchers, not wishing to be associated with severe severity procedures, understate interventions to achieve a moderate severity classification.

Role of Hubs in Assessing and Weighing Benefits

3.3. Attendees discussed their role in assessing and enhancing benefits through the processes of harm-benefit analysis, with particular reference to:

- Use of the ASRU advice note;

- Consideration of how to enhance benefits;

- Discussion of benefits from basic and regulatory research, or research with societal concerns; and,

- The role of AWERB Hubs to support discussions about assessing and enhancing benefits.

3.4. Key findings included:

- Generally, potential benefits were not assessed well; more focus should be given to benefits being assessed throughout the project and beyond.

- It was acknowledged that institutional/organisational decisions on the types of research that will be conducted are often agreed at much higher levels than the AWERB and that often by the time a project reaches the AWERB this is too late in the day to discuss some of the wider ethical issues.

- It was difficult to assess the benefits of basic research. Greater clarity around the purpose of the work and the anticipated benefit was needed i.e. what questions were being asked by the programme of work?

- Often, while the research project objectives were clear no associate benefits had been identified. These need to be clarified and matched up in the project proposal.

- Benefits can be speculative. However, strong groundwork, clear objectives, defined milestones, and good experimental design along with clear mapping of relevant markers for translation provide a firm basis to make achieving the benefits more likely.

- The example of regulatory licences was mentioned where a vaccine might be tested on animals with very few having adverse reactions. In these cases, the number of animals required was set by the medicines regulator and it would be difficult for the AWERB to find additional benefits.

- Attendees also noted that though alternative testing methods are used in the UK, these might not be recognised in another country with whom the establishment might be collaborating or for whom they might be carrying out the testing.

4. Practical ethics – starting the discussion

4.1. Attendees received a presentation on the AWERB's responsibilities in delivering the ethics role, along with the potential problems that might be encountered. Following discussion attendees noted:

- Confusion remained over what constitutes 'ethics', with the focus tending to be on assessing harms and application of 3Rs. While these are part of an ethical framework, they do not constitute it all.

- Ethics can also be regarded by some as a bit of an 'add-on' to be carried out by someone trained e.g. a philosopher;

- Ethics covers many disciplines, and AWERBs may already 'do' ethics but they need a better awareness and understanding of this;

- A good AWERB Chair should actively encourage ethical conversation while ensuring discussion is kept within the appropriate ethics boundaries;

- Hubs could encourage AWERBs to identify where they do engage in ethical considerations, while challenging them to identify where establishment structures or 'custom and practice' might push ethical assessment to the margins;

- There is a tendency for institutions to conflate ethical issues with reputational risk issues and these are different. It should be noted that the mandate given by ASPA to AWERBs does not include reputational risk to the institutions.

5. Open AWERB meetings

5.1. Attendees discussed the concept of open AWERBs, what constitutes an open AWERB meeting – crucially that it is not generally open to external attendees – and how open meetings had the potential to benefit the establishment.

5.2. The following key points were identified:

- An AWERB which held open meetings reported that these were mainly attended by the in-vivo community, with occasional attendance by others such as HR or finance.

- Observing open AWERBs would be particularly useful for students who would later present their own projects to the AWERB committee and may also may help mitigate some of the anxiety reported by project applicants.

- They can also provide opportunities to disseminate information to all staff as it gives individuals a chance to air views.

- On a practical level, room size was a limiting factor in the scope for open meetings, however including a teleconference line might help address this.

- Following discussion, some AWERBs agreed to consider moving to open meetings. With that in mind, ASC members will update the Support Note to include details on holding open meetings.

- It was also noted that a lot could be achieved in terms of sharing and disseminating information by having a good quality internal resource area such as webpages.

- Where open AWERBs exist, it is reported that a small part of the meeting (at the end) is closed and for AWERB members only. This allows for the AWERB to reflect on discussions and if necessary take a vote on the advice to be given or the approach to be taken.

6. Dealing with late PPL applications

6.1. Attendees were invited to discuss what actions they take to encourage timely submission of PPL applications, how effective these have been and what action they take if it becomes apparent a new application is unlikely to be approved before the existing one expires.

- Applicants are given reminders at – 1year, 6 months and 3months. One establishment shared that if these reminders were sent by the AWERB chair this was often very effective.

- One establishment reported that if, despite providing sufficient support, an application is late it is allowed to lapse, with all project work required to stop, although the animals are protected. Initially, this approach had been painful for both the establishment and applicants, however applications are now submitted on time.

- Another establishment charges the applicant for extra work involved in late applications (for instance transferring animals to another licence). All additional work is now costed and can make late applications expensive for the applicant.

- Attendees considered what additional steps could be taken to discourage habitually late PPL applications and to what extent AWERBs should be

involved in monitoring and/or solving this problem: Late applications put considerable pressure on AWERB members and ASRU.

- Attendees enquired 'who did the Home Office reminder letters go to?' Can this be checked to ensure it is working efficiently? A reminder from the AWERB chair may be more effective (see 6.1)

- It was suggested it would be a good idea if applicants had a named alternative scientific contact, even if on an informal basis, as this can help, for example, if the applicant is ill. In cases such as these the AWERB can work with the named contact.

- One suggestion was if PPL holders have not submitted their applications within 6 months of the deadline, stop ordering animals for them.

- AWERBs could discuss the suitability of applicants? Tardy PPL submission do not fit with good 'culture of care', and the ELH can be advised along these lines?

7. Concluding remarks, emerging themes and next steps

7.1. Common themes that had arisen during the day:

- Benefits of open AWERBs to share information more broadly with staff, help familiarisation, and promote the role of the AWERB;

- Maintaining momentum of the Knowledge Hub to continue to share information and ideas on good practice;

- The ASC could support Hubs and AWERBs on assessing harm benefit by providing focused recommendations for AWERBs;

- Hubs as a mechanism to provide greater clarity in the AWERB role of how to start an ethics conversation other than in the area of 3Rs;

8. Next Steps

- A note summarising the workshop discussion would be forwarded to Hubs and the presentations would be added to the Knowledge Hub library.

- The ASC AWERB Subgroup would produce a short set of good practice recommendations against each of the tasks of an AWERB (see para 2.3).

- More generally, the ASC AWERB Subgroup would reflect on the issues raised during the meeting and how to address these, updating the AWERB support note as appropriate.

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Annex A

**5th Animals in Science Committee and
Animal Welfare and Ethical Review Bodies Hub Workshop
13 March 2019, 10.00 – 16.15**

Welcome	**Sally Robinson (ASC)**
Update on the work of the ASC **Current workstreams, Hub Restructure,** **AWERB Knowledge Hub Groups**	Sally Robinson (ASC)
The role and operation of and AWERB **Presentation/Workshop/Feedback**	Sally Robinson (ASC)
The harm-benefit analysis **Presentation/Group Discussion**	Gail Davies (ASC) & Penny Hawkins (RSPCA)
Practical ethics – starting the conversation **Presentation/feedback**	Maggy Jennings
An open AWERB? **Presentation/Group Discussion/Feedback**	Wendy Jarrett (ASC)
Dealing with late PPL applications **Group Discussion**	Clare Stanford (ASC)
Concluding remarks, emerging themes, and **next steps**	Sally Robinson (ASC)