Animals in Science Committee
and
Animal Welfare and Ethical Review Bodies
Workshop

13th November 2014

Workshop Report

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This report is not intended to be, and should not be interpreted as, a policy statement or a work plan. The Workshop was established and held under the aegis of the ASC's AWERB-liaison Sub-group to promote discussion. Additionally, the statements reproduced here are statements that were made on the day, and do not necessarily represent the views of the ASC or of the majority of the Workshop's participants.

1. Executive Summary

1.1 Remit of the Animals in Science Committee

1.1.1 The Animals in Science Committee (ASC) is a non-executive, non-departmental public body set up under Sections 19 and 20 of the Animals (Scientific Procedures) Act 1986, as amended by EU Directive 2010/63/EU (ASPA). It is responsible for providing independent, expert advice to the Home Secretary on matters relating to the acquisition, breeding, accommodation, care and use of protected animals, as defined by the 1986 Act[1]. This especially relates to any experimental or scientific procedures applied to a protected animal that may have the effect of causing that animal pain, suffering, distress, or lasting harm.

1.1.2 In addition to the work commissioned by Ministers, it is within the ASC's remit to determine its own work streams and offer advice on such issues as it believes appropriate.

1.2 The relationship between the ASC and AWERBS

1.2.1 ASCs core functions and responsibilities under ASPA include:

- sharing and promoting best practice with, and between, Animal Welfare and Ethical Review Bodies (AWERBs) on matters relating to the acquisition, breeding, accommodation, care, and use of protected animals; and
- exchanging information and exploring possibilities for collaboration with national committees for the protection of animals used for scientific purposes in other European Union (EU) member states.

1.3 Aim and format of the workshop

1.3.1 A first tranche, information gathering, workshop was held on 13th November 2014 bringing together members of the ASC AWERB Subgroup and the chairs of a number [2] of AWERBs from across the UK.

1.3.2 The aim of the workshop was to:

  a. provide an initial forum to discuss the associated roles of the ASC and AWERBs, to ask questions and share experiences,
  b. identify and discuss challenges and opportunities,
  c. discuss and identify best practice and its most effective indicators;
  d. generate ideas of how 'best practice' can be shared;
  e. develop synergistic, and realistic, expectations between the ASC and AWERBS; and
  f. produce, from the discussions, a workshop report embodying the main points arising from the day's deliberations.

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[1] Sections 19 and 20 of the Animals (Scientific Procedures) Act 1986, as amended refer to the ASC

[2] A list of the establishments can be found on Page 14.

1.3.3 The report should provide a sound basis and potential work strands for the ongoing work of the ASC AWERB Sub-group.

1.3.4 The workshop comprised two presentations (copies of the presentations can be found at Appendices B and C), and four facilitated discussion sessions in which four themed questions were discussed.

1.3.5 Discussion questions were:

Session 1: *How should AWERBs be expected to contribute to the work of the ASC?*
Session 2*: What do AWERBs expect and want the ASC to do for them?*
Session 3: *How is best practice defined?*
Session 4: *What are the indicators of best practice, and how can they be assured?*

2. <u>Purpose and Structure of the Report</u>

2.1 This report summarises the discussions that took place on the day, and is intended to represent the diversity of views expressed. It is not a statement of the ASC's position and does not constitute an endorsement of the views expressed therein.

2.1.1 The four questions posed stimulated much discussion from which key themes emerged. For ease of reading and summation, discussion, considerations, comments and statements have been captured under emerging themes, rather than under the questions from which the themes emerged.

3.   Summary of Discussions

3.1   Building the influence of AWERBs

3.1.1   The ASC can act as a champion for AWERBs in communications at strategic level. The ASC could also have a role as "critical friend" and provide constructive challenge where necessary.

3.1.2   An AWERB can be an important repository and source of best practice, particularly now that many AWERBs carry out mid-term and retrospective reviews. The ASC could 'tap' into this resource and use the information to further educational outreach (perhaps to inform Ministers) and feed into the development of policy and ASPA guidance.

3.1.3   The ASC should help define 'best practice' and embed the role of AWERBs in organisational culture, and encourage AWERBs to adopt a joined up approach towards addressing ethical concerns. Effective training needs can also be identified from good practice; this would help empower AWERBs.

3.1.4   The ASC could act as an independent facilitator in the sharing of good practice across AWERBs. Information about good practice circulated by the ASC would have greater authority, spread more rapidly, and prove more influential than an AWERB alone.

3.1.5   Additionally, the ASC could encourage the promotion of best practice through establishing a network of AWERB Chairs, including holding regular meetings with them.

3.2   Beyond AWERBS

3.2.1   The ASC could facilitate dialogue between International animal welfare and scientific bodies, and act as a central point in circulating information to AWERBs on such meetings. It could also have a central role in organising meetings with other EU National Committees to encourage the sharing of best practice amongst AWERB counterparts across EU member.

3.2.2   A suggestion was made that the ASC should have a lobbying role with regulatory bodies in relation to regulations that implicitly or explicitly required animal tests (such as some toxicology testing), where it could be argued that humane alternatives were available or avoidable suffering would be caused.

3.2.3   Participants were aware that there are a number of organisations (such as LASA[3], RSPCA[4], LAVA[5], NC3Rs[6] IAT[7] etc) that have established communication links with stakeholders. These organisations are specialist in their remit and so principally inform associated (specialist) individuals/bodies such as scientists, animal technologists, veterinarians, Home Office Liaison Officers or lay members. At present, there is no framework for direct

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[3] Laboratory Animal Science Association
[4] Royal Society for the Prevention of Cruelty to Animals
[5] The Laboratory Animals Veterinary Association
[6] National Centre for the Replacement Refinement & Reduction of Animals in Research
[7] Institute of Animal Technology

dissemination of information to (or between) all AWERBs, to share best practice, discuss new ways of working, or compare experiences.

3.3   Information flow and sources

3.3.1   To fulfil its remit to share best practice and experience the ASC needs to receive the right information from AWERBs; establishing (or acting as) a 'conduit' between AWERBs is one way towards achieving that goal.

3.3.2   Participants felt it essential that an effective two-way communications process be established as a means of the ASC receiving and disseminating information.

3.3.3   Improved flow of information would strengthen an AWERB's ability to ensure that, for example, project licence applicants effectively reflect latest best practice, advances in 3Rs and appropriate attitudes and approaches to animal use.

3.3.4   The ASC could provide on its website:
- electronic links to organisations, forums or sites with useful resources for AWERBs
- a regularly updated list of frequently asked questions and answers across a range of relative AWERB subjects; and
- a procedure for communicating with the ASC, to include guidance concerning confidentiality when communicating with the ASC.

3.4   Internal communication

3.4.1   It is vital that animal technologists, care staff and researchers at all levels have the opportunity to regularly share with senior management their thoughts on establishment practices - often they have the most experience of how things are working (or not) in practice, and where procedures (management and scientific) can be further developed. Therefore, enhancement of communication laterally and hierarchically is pivotal. Clear leadership with an effective governance structure is essential.

3.5   Governance

3.5.1   There should be processes enabling AWERBs to have a strong voice on the good governance arrangements within the governance structures of their establishment, in respect of all matters affecting laboratory animals and their welfare. These must afford all of the establishment's AWERB members and staff the opportunity to contribute to the development of the 'big picture', or shared vision, beyond their immediate 'everyday' role.

3.5.2   Supported by the ASC, it is good practice for AWERBs to have protocols in place that effectively monitor the quality assurance of all systems within their establishment. Such protocols must go beyond monitoring and auditing, and provide options (with senior management support) for remedial actions where a system is found to be failing. The ASC could help to develop such protocols.

3.5.3   This would allow review of procedures and provide a measure of the effectiveness of an AWERBs governance, and communications, with staff within their establishment, and also with stakeholders beyond the establishment.

3.6   Promoting engagement

3.6.1   The ASC should (in a non-prescriptive manner) encourage, promote and host specific events to help with standardisation of operating procedures, assist in identifying training needs for members (including lay) and the bringing together (or facilitation) of an AWERB network forum.

3.7   AWERB Code of Practice

3.7.1   The potential for the ASC to produce codes of practice (CoP) for some areas of AWERB work was discussed. It was agreed that producing CoPs was perhaps not a practical route, but the ASC might produce guidance sheets on particular areas, with respect to scientific procedures how AWERBS operate, outlining solutions that have been found helpful in specific areas.

3.8   Raising profile and support of AWERBs

3.8.1   The ASC can help highlight the importance of the AWERB role, assisting AWERBs in raising their status and profile within establishments, e.g.

   a.   where the chairs of AWERBs and members were finding it difficult to gain support of establishment senior management;

   b.   at a strategic level, to promote communication (lateral and hierarchical) between researchers and animal technologists and care staff; and

   c.   recognising that there will be variation across AWERBs, to consider what might be the minimum level of support and resources that an establishment should provide to allow an AWERB to effectively, and sustainably, fulfil its tasks.

3.9   AWERB training and roles

3.9.1   Compared to Establishment Licence Holders, AWERB members often have little, if any, formal training to help them meet the requirements of their role on the committee. Similarly, AWERBs are established on a local basis with little national guidance and it is unlikely that a one-size fits all approach to the development of guidance would be appropriate. There will be, however, a number of common operational aspects of AWERBs where generic guidance could be provided, such as the *LASA/RSPCA Guiding Principles on Good Practice*, currently under revision.

3.9.2   Given the variations in size of establishments, and the nature of the work carried out, there will be differences in AWERB structure and composition. Given this, there

are likely to be some situations where certain configurations prove more effective than others. Gathering high-level information might provide insights as to which arrangements work best and identify potential models for improvement or enhancement to current governance structures.

3.9.3   As there is no designated formal training for AWERB chairs, it was suggested that thought should be given to introducing training akin to that of NHS Ethical Review Committees. This need not be a catch-all training programme, but perhaps a suite of training modules.

3.9.4   The ASC should have a pro-active role in endorsing and promoting the significant role that chairs and members of AWERBs commit to in terms of the dedicated time and energy required in their role, often against the heavily competing demands of their 'day jobs'. This should be recognised in their annual and professional development reviews.

3.10   Membership of the AWERB

3.10.1 Some participants felt that there should be members on the AWERB who could provide robust scientific debate and ethical challenge when considering project licence applications.

3.10.2 Unlike public advisory bodies, there is no statutory limit to the length of 'term' for AWERB chairs or members (although individual establishments may have a policy on this).   There was discussion as to whether appointments to AWERBs should be time-limited, including the chair (given anecdotal evidence that appointment of 'new' chairs can instigate a review and update of practices and procedures).

3.11   Lay membership

3.11.1 Participants considered whether the position of lay-member might best be undertaken by an expert in a relevant field, e.g. law or ethics, or by an individual with a role within the organisation that is not directly related to animal use. There was a view that it would be useful to gauge this approach across AWERBs.

3.11.2 A number of participants questioned how long a lay-member might, in actuality, remain 'lay'. There was discussion on the potential merits of schemes to rotate or alternate lay representatives, to help prevent lay members from 'turning native'.

3.12   What is best practice?

3.12.1 The following was proposed as an operational definition: 'The best currently observed practice or a readily implementable improvement to the currently available best practice if there was one.'

3.12.2 Many participants felt that best practice had to be defined contextually, and that there will never be a one size fits all. Different establishments, with different configurations and work, may set about the same task in different ways according to their circumstances.

3.12.3 Best practice must be attainable in practice and reproducible, bearing in mind the resources and constraints pertaining to a particular situation, with measurable and tangible outcomes - rather than the hypothetical outcome of a paper exercise.

3.12.4 Best practice should be an ideal to aspire to, and this ethos should be actively encouraged and embedded in the working culture across <u>all</u> levels of staff within an establishment.

3.12.5 In considering best practice, participants felt that (in the context of the question) best practice should be at two equally necessary levels, i.e. best practice in terms of organisational (operational) processes/practices and, then, best practice in terms of how actual scientific, and management, procedures are undertaken.

3.12.6 Proportionality must be borne in mind when considering best practice. It would not be best practice to strive to achieve perfection if the cost of doing so were widely disproportionate to the benefits obtained.

3.12.7 Alternatively, it was suggested that 'best practice' could be defined in terms of the approach taken by AWERBs to fulfil their tasks. With respect to refining procedures, housing, husbandry and care, best practice could take the form of:

- not assuming that current practices are the most refined;
- ensuring that new information to help improve practice is regularly researched and reviewed, and that potential refinements are applied and evaluated;
- having clear outcome criteria to determine whether refinements are successful;
- providing adequate resource and support to encourage and allow the implementation of refinements, and;
- ensuring the dissemination of experiences of implementing refinement, both within the establishment and externally.

3.12.8 For other areas such as acquisition, breeding, and transport, best practice could entail having a review system in place to ensure that all potential sources of discomfort, pain, stress or distress are identified and ameliorated or avoided.

3.13   How can best practice be measured?

3.13.1 Processes should be put in place for researching, evaluating and improving approaches to the practice. They should involve promoting a critical appraisal of what the organisation is currently doing. They should challenge perceived understanding and accepted practice, and should be about testing assumptions and considering all relevant criteria.

3.13.2 Best practice should take account of all aspects of the use of animals, and of their life experience, including due diligence on suppliers. It could be measured in terms

of training, standard operating procedures and organisational aspects such as dissemination of germane information to AWERBs.

3.13.3 There was discussion about what best practice might mean and whether the term 'good' practice might be more appropriate. There was general consensus that best practice had a more aspirational tone, and so was more appropriate.

3.14 Who should define best practice?

3.14.1 Some delegates expressed the view that AWERBs must be able to define best practice within their establishment, with assistance from the Inspectorate, by drawing from the wider knowledge of practice within other establishments. It is hoped that the refinements or amendments currently in the pipeline with respect to section 24 (of ASPA) will make this transfer of information straight forward.

3.14.2 AWERBs must establish SMART[8] objectives to measure "best practice" and how effectively it operates. As one example, there should be robust project licence review/retrospective tracking procedures.

3.14.3 All improvements to best practice must be evidence based, with the encouragement of an establishment culture that accepts new ideas from outside the organisation on ways of working, while still allowing for questions and fine-tuning proposals.

3.15 Best Practice Indicators

3.15.1 Participants were cautious in the consideration of quantitative indicators, as their use risks encouraging a 'tick box' approach.

3.15.2 Potential (measurable) indicators could include, but not be limited to:
- a good scientific approach;
- improvements in animal welfare;
- the use of both qualitative and quantitative measures; this is about assessing the quality of life of the animals rather than simply the number of animals used;
- how well an AWERB and its establishment meet their objectives; and
- whether concerns related to adverse effects become increasingly minor, this may reflect improved practice (providing, also, that there is a fall in adverse incidents).

3.15.3 Project licence applications that meet with positive assessment at all stages (by AWERBs and the Inspectorate) might be considered an indicator of best practice; as would reductions in non-compliance and infringements. AWERBs should proactively encourage that licences (demonstrably) include a strategy to drive the Three Rs – to reduce, replace, refine – throughout the duration of the licence for the project.

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[8] SMART (Specific, Measurable, Achievable, Realistic, and Timed) objectives.

3.16 Role of penalties and incentives

3.16.1 Some felt that 'sticks' have a role in enforcing minimal standards but not as an incentive to improve standards. Excessive use of penalties runs the risk of developing a 'blame culture' in which people become reluctant to report problems.

3.16.2 The use of external 'sticks', with respect to the establishment, combined with internal 'carrots' for those working within it may provide the best solution. If there is a serious risk that the establishment will be sanctioned this enables its management to improve standards internally by the use of inducements.

3.16.3 Incentives including rewarding individuals were discussed. For example, a form of internal award to staff who suggest examples of best practice and identify opportunities to share these throughout the organisation. Such awards could even be developed on a national basis, with the ASC assistance.

3.16.4 AWERBs must be able (with senior management support) to review any compliance problems and infringements on site, and share lessons internally on what is learned that benefits good practice. Any internal investigation should aim to promote a process of 'learning lessons'.

4   Conclusions and Next Steps

4.1   The workshop provided the first opportunity for a number of AWERB chairs to meet the Home Office's independent body responsible for advising on the care and use of animals under experimental or scientific procedures.

4.2   Feedback from the workshop participants has been extremely positive. Many stated that, whilst they had belonged to an AWERB (or previously an ERP) for a number of years, this was the first occasion on which they had had the opportunity to meet, exchange experiences and network with colleagues from other AWERBs – with many stating how rewarding it was to find out that they are 'not alone'.

4.3   The Chair of the ASC, Dr John Landers emphasised that the care, welfare and continual development of the principles of the 3Rs was not simply a matter for the UK. It was important that - working closely with committed and dynamic AWERBs - the ASC should be well placed to play a key role in disseminating evidence-based best practice more broadly across EU member states.

4.4   With particular reference to the emerging themes of communications networks, and training and support mechanisms, Dr Landers advised that the workshop's outputs will feed into the ASCs programme of work. It will be used to inform the means by which ASC engages with all AWERBs, on a national basis, and supports them in maintaining the highest standards.

Finally, thanks are given to the participants for their enthusiastic support and valuable contributions to this novel workshop.

Animals in Science Committee and
Animal Welfare and Ethical Review Bodies Workshop
Programme

10:30 – 10:45 Welcome: Aims of the day

Mark Greenhorn, Head of Home Office Science Secretariat and Services

10:45 – 11:00 AWERBs and the ASC

Presentation: "*How can the ASC assist AWERBs?*" Dr Penny Hawkins (ASC)

11:00 – 11:25 Round table discussion

'*How should AWERBs be expected to contribute to the work of the ASC?*'

11:25 – 11:45 Feedback by group rapporteurs and open discussion

11:45 – 12:10 Round table discussion

'*What do AWERBs expect and want the ASC to do for them?*'

12:10 – 12:30 Feedback by group rapporteurs and open discussion

12:30 – 13:30 Lunch

13:30 – 13:55 Round table discussion

'*How is best practice defined?*'

13:55 – 14:15 Feedback by group rapporteurs and open discussion

14:15 – 14:40 Round table discussion

'*What are the indicators of best practice and how can they be assessed?*'

14:40 – 15:00 Feedback by group rapporteurs and open discussion

15:00 – 15:30 Concluding remarks, emerging themes and next steps

<u>Organisations* represented at the workshop</u>

Astra Zeneca

Cambridge University

Cancer Research UK

Charles Rivers UK

Convance

Edinburgh University

Glasgow University

Glaxo Smith Kline

Huntingdon Life Sciences

Lilly UK

Manchester University

National Institution of Medical Research

Pfizer

Sanger Institute

* These organisations have given their permission for their name to appear in the report.

The A S C
Animals in Science Committee

Animals in Science Committee (ASC)
and
Animal Welfare and Ethical Review
Bodies (AWERBS)

Workshop: 13 November 2014

Slide 1

-Slide 2

About the ASC

- An advisory non-departmental, independent public body of the Home Office
- Established on 1 January 2013
- Replaced the Animal Procedures Committee

The Committee is convened to:
- provide advice to Ministers, Animal Welfare and Ethical Review Bodies;
- share best practice on matters relating to the acquisition, breeding, accommodation, care and use of protected animals;
- share information with national committees in other EU Member States on:
  - evaluation of project licences
  - operation of Animal Welfare and Ethical Review Bodies.

Slide 3

Members of the ASC

- Chair: Dr **John Landers**, Hertford College, Oxford
- **Ken Applebee,** Director of Biological Services, Kings College London
- Prof **Gail Davies**, Professor in Human Geography, University of Exeter
- Dr **Sophie Dix**, Senior Research Scientist, Eli Lilly
- Prof **Simon Glendinning**, Reader in European Philosophy, European Institute, LSE
- Dr **Huw Golledge**, Senior Research Associate at the Institute of Neuroscience, Newcastle University
- Dr **Penny Hawkins**, Deputy Head, Research Animals Department, RSPCA
- Prof **Malcolm Macleod**, Professor of Neurology and Translational Neuroscience, University of Edinburgh
- Dr **Matthew Parker**, School of Biological and Chemical Sciences, Queen Mary University of London
- **Anna Rowland**, Assistant Director of Policy for Fitness to Practice at the General Medical Council
- Dr **Gerlinda Stoddart**, Science Adviser, People for the Ethical Treatment of Animals
- Prof **Sarah Wolfensohn**, Professor of Animal Welfare, University of Surrey
- Dr **Gavin Woodhall**, Reader in Neuropharmacology, School of Life and Health Sciences, Aston University

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ASC AWERB Liaison Sub-committee

- Members are:
  - Dr John Landers (Chair)
  - Ken Applebee
  - Dr Sophie Dix
  - Prof. Simon Glendinning
  - Dr Penny Hawkins
  - Dr Gilly Stoddart
  - Prof. Sarah Wolfensohn

Slide 5

PRESENTATION 2

How can the Animals in Science Committee assist AWERBs?

Penny Hawkins, ASC

Slide 1

AWERB Sub-committee work to date ...

• ToR drafted for the AWERB Sub-committee
• Objectives encompass a proposed work plan, including:
  1. This meeting, for a sample of AWERB chairs to discuss how 'best practice' might be defined and how best to effect knowledge sharing

Slide 2

Future work

2. Writing to all AWERB chairs inviting them to identify
   • Current best practice mechanisms for information sharing
   • Needs for defining and sharing further examples of good practice
   • Potential themes and topics for one or more national AWERB workshop(s), to include expected outputs, resources required and the potential for collaborative knowledge transfer networks across AWERBs

Slide 3

Future work

3. Pro-actively promoting the establishment of an AWERB chairs' network
   • Considerations will include engaging with AWERBs to see whether there is a demand for a network, determining ownership and identifying long-term objectives

Slide 4

LASA ETES & HOLTIF Sections, LAVA and IAT Workshop (June 2014)
'Developing Guiding Principles on Good Practice - from ERP to AWERB'

Note: The Guiding Principles document is currently being updated to reflect the revised UK legislation. Publication is expected in spring 2015 – check http://www.lasa.co.uk/publications.html

Guiding principles on good practice for Ethical Review Processes
1st Edition - May 2010

Slide 5

Delegates were asked:

• How should AWERBs be expected to contribute to the work of the ASC?

• What do AWERBs expect the ASC to do for them?

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16

1. Advise and inform

- Set up a system of direct communication with establishment heads to reinforce importance of AWERBs
- Be clear about the ASC's role and expectations of its interactions with AWERBs
- Circulate new information on good/best practice in an easily accessible format
- Promote consistent implementation of changes to guidance and legislation
- Provide guidance, e.g. on difficult issues such as retrospective review of severe PPLs

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2. Encourage connections between AWERBs within the UK and AWBs and NCs in the EU

- Be a dynamic leader for NCs in Europe
- Feed back to AWERBs on best practice by EU NCs and AWBs
- Act as a hub for comms between bodies such as EU-NETVAL, national 3Rs centres, PARERE, training providers and national LASAs
- Encourage communication between AWERBs – a discussion forum (online)?

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3. Practical support

- Get ETHICS into the AWERB and promote its roles and importance
- Encourage a more challenging approach to ethical issues
- Stimulate constructive debate on 'difficult' issues, e.g. overseas collaborations
- Facilitate AWERB members sitting in on, or being seconded to, other AWERBs
- Set up a list of lay person candidates

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4. General

- Be <u>strategic</u> rather then dealing with details
- Maintain clear independence from the AWERBs
- Draw on any or all expertise needed to progress AWERB issues – regardless of the expert's affiliations

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Over to you …

Slide 11