

Comment

Wider Recommendations for Institutions made in the Brown Report following the BUAV Investigation into the Use of Animals at Imperial College London

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Summary — In December 2013, a group of experts produced a report on the management of an animal unit at Imperial College London, following a BUAV investigation that found evidence of systematic failures in the care and monitoring of animals used in procedures there. The Brown report looked at four areas: the animal welfare and ethical review body (AWERB), the operation of the unit, training, and overall culture. The report made 33 recommendations to improve practices at Imperial College, many of which were relevant to other institutions. In this report, we identify the recommendations that are applicable to all animal facilities, and redraft them as a checklist with supporting information to assist those reviewing their animal care policies. We support the Brown Report's recommendation that institutions should have a vision statement and an action plan, as well as a 'champion' for the Three Rs. We encourage all institutions that use animals to, as a first step, review the performance of their animal units against this checklist.

Key words: *animal experimentation, BUAV, Imperial College London, Three Rs, undercover investigations.*

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Introduction

In April 2013, the BUAV released footage containing evidence of poor standards of care and surgical technique at a unit in Imperial College London, compiled during an undercover investigation (1). The unit was the Central Biomedical Services facility, which provides animal housing and testing services for researchers at the university. The BUAV found a variety of failures at the facility, including: the exceeding of severity limits; poor monitoring of animal welfare; substandard surgical practice and anaesthesia; failure to administer analgesics; and inappropriate methods for killing animals. The BUAV prepared a detailed, confidential report, which it sent to Imperial and the Home Office to assist them in investigating the allegations.

The Home Office instigated an investigation, but by September 2014, the results had not yet been made public. However, their conclusions were summarised recently by the Animals in Science Committee (ASC), which advises the Secretary of State on matters concerning the use of animals in scientific procedures (2). The ASC had been asked by the Home Office to review their report and

make general recommendations. It reported that the Home Office had concluded that "*non-compliances were of a persistent nature, including ongoing instances after April 2013, and all of these could broadly be traced back to failings in the management structures*". The ASC itself agreed that there had been "*a systematic pattern of infringements, of which the ASC notes that at least two involved tangible welfare costs...*" The ASC strongly recommended that "*the Minister should consider whether he can continue to have confidence in the current Establishment Licence Holder at Imperial College London retaining this role*". Soon after the publication of the ASC report, the Establishment Licence Holder did indeed 'step down' from his responsibilities (3).

In the meantime, Imperial College had set up its own inquiry, headed by Professor Steven Brown. Given that Brown was himself an animal researcher employed by the Medical Research Council, one of the key funding bodies of the work being performed at the unit, the inquiry could by no means be considered wholly impartial or independent. Brown gathered a small group of external experts, who interviewed staff, reviewed documents and visited the facility. Rather than exam-

ining the specific BUAV allegations of misconduct, the committee's remit was "to undertake a broad and detailed examination of all aspects of animal experimentation at the College facilities, including areas such as ethical review, operations, compliance, training and management" (4).

The Brown Report

The subsequent Brown Report was published in December 2013 (4), as reported in *ATLA* (5). It essentially agreed with the BUAV's assessment of the management and culture of care at the unit. The Brown Report found Imperial College to be seriously lacking in all the four key areas it looked at: operation of the body that oversees animal welfare and the ethical review of new projects involving animals; operation of the unit (particularly staff resources and communication) training; and overall culture. The report concluded that Imperial College "lacks adequate leadership, management, operational, training, supervisory and ethical review systems to support high standards in animal use and welfare". The report made 33 recommendations to Imperial College, which included increasing staffing resources and restructuring key positions to ensure there was proper oversight. Imperial College responded to the report by agreeing with its findings and promising to make the necessary changes (6).

Concern was raised at the time: if an institution of such high academic standing could have such poor management and standards of care, then what could be the situation in less high-ranking institutions? As if to answer this question, the Brown Report made the point that many of its recommendations were relevant to all institutions. The Brown Report acknowledged in the press release of the report that, "While our focus has been on Imperial College, the committee's recommendations should serve as a useful framework for other institutions to review their policies and practices" (7).

Unfortunately, the Brown Report did not actually highlight what these wider recommendations were. As a result, even if those from other institutions are aware of the report and have read it, they might not easily be able to identify lessons relevant to them. If the time and care taken to produce the report is to have any wider impact in the animal research community and on the subsequent use and care of animals, it is important that these recommendations are received and acted upon more widely.

Recommendations from the Brown Report that are relevant to all institutions

Here, we have sought to draw out those recommendations from the Brown Report that are appli-

able to other institutions. We summarise them and provide supporting information to elaborate on the points they raised, by using either the Brown Report itself or key literature sources. We felt that the best way to present the recommendations was in the form of a checklist of questions covering the four areas highlighted in the Brown Report: the animal welfare and ethical review body (AWERB); the operation of the unit; training; and overall culture. The questions relate to whether each area is currently 'fit-for-purpose', which is the question the Brown Report experts were asking themselves during the inquiry. We have necessarily had to change the text of many of the recommendations, in order to put them in the form of a question, but we have taken care not to distort or add to the recommendations made by the Brown committee. These are questions based on the recommendations of the Brown Report and they are not our own. We encourage all institutions that use animals to, as a first step, review the performance of their animal units against this checklist (see Table 1). The questions are, in most cases, independent of each other, and no hierarchy for them is implied. The Brown Report did not prioritise one area over another, nor it he give priority to elements within each area, and we do not so here. Suffice to say, the implication is that if an institution fails in relation to any one of the questions, it cannot consider itself truly fit-for-purpose.

It is important to note that the Brown Report focused on operational and strategic issues only. Their recommendations are clearly inspired by the findings at Imperial College, and therefore do not cover all the issues that institutions need to consider when they are conducting animal research. The Brown Report did not, for example, cover adherence to legislative requirements and other international guidelines, housing standards and conditions, husbandry, the standards of the procedures themselves, the quality and value of the scientific work, investment in alternative methods, or policies on publication. It also did not include recommendations that the BUAV would like to see addressed, such as increased transparency of the work being done at the institution, policies for ensuring the same standards are adhered to when using animals outside the facility in collaborative work, and, importantly, a strategy to move away from animal experimentation altogether.

Performance of the local Animal Welfare and Ethical Review Body

Under the new EU Directive on the protection of animals used in scientific procedures (*Directive 2010/63/EC*; 8), all institutions should have an Animal Welfare Body (Article 26). The role of this

Table 1: Questions for determining 'fit-for-purpose' for the operation of animal research institutions

1. Performance of the local Animal Welfare and Ethical Review Body	Y/N
Does the AWERB provide a forum for the robust review of projects and the cost/benefit assessment?	
Does the AWERB periodically review and determine strategy in terms of animal welfare improvements and the development of the Three Rs?	
Does the AWERB have frequent face to face meetings?	
Does the AWERB regularly conduct retrospective reviews of research at the institution?	
Are the activities of the AWERB transparent?	
Are meetings inclusive and informed?	
Does a senior official administrate/chair the AWERB? Do they have sufficient time resource to do so? Are they free from conflicts of interest?	
2. Operation of the animal units	Y/N
Has the use of barrier systems been reviewed to ensure they do not restrict the free flow of staff or direct veterinary oversight?	
Are staffing levels sufficient to enable husbandry and animal welfare monitoring duties to be performed without placing strain on members of staff?	
Is there sufficient staff resource available for out of hours and weekend working?	
Is there an unambiguous policy for action in the event of animal welfare concerns?	
Is there standardised documentation to monitor animals during experimental protocols (or if stock animals give cause for concern)?	
Are all project licences, including protocols, adverse effects and humane endpoints readily available at key working areas?	
Do technical staff formally monitor all theatre and procedure areas at least once daily (more frequently for complex procedures)?	
Are technical staff at all levels (including NACWOs and NVS) encouraged to attend research group and AWERB meetings?	
3. Training and competency	Y/N
Has there been a recent review of resources available for staff training and competency assessment and whether this is sufficient?	
Is there formal, systematic training, supervision and competency assessment in place for staff at all levels including licence holders?	
Are mechanisms in place within the institution (such as the AWERB, direct training, other fora) to ensure that staff are kept informed in developments in animal care and welfare?	
Has consideration been given to the need to appoint a senior Named Training and Competency Officer (NTCO)?	
4. Culture, leadership and management	Y/N
Does the institution have a vision statement and action plan for the Three Rs, aiming to set the highest standards, challenge complacency and promote change?	
Is a senior team or individual tasked with the responsibility for providing strategic leadership to ensure delivery of this action plan?	
Are there mechanisms in place to challenge complacency in animal welfare standards and to encourage the development of new ideas to implement the Three Rs?	
Has there been a review of animal research at the institution to identify management and operational structures that could be a risk factor for poor communication?	
Does the institution reward developments in the Three Rs with an annual prize or similar incentives?	
Is there an institution-wide mechanism for whistle-blowing that includes animal welfare concerns?	

body is quite fundamental: it has to advise the institution on the Three Rs, and establish operating procedures for monitoring animal welfare and follow up on projects (Article 27). In the UK, institutions combine the conduct of a preliminary ethical review of project applications with this role in the form of an Animal Welfare and Ethical Review Body (AWERB), which is mandatory under the revised *Animals (Scientific Procedures) Act*. Since the functioning of this body is vital to ensure that the use of animals is legal and conforms to best practice, whether it is doing its job is a fundamental question for any institution. The Brown Report identified some key questions to ask regarding the functioning of the AWERB.

One of the failings at Imperial College was the lack of direct face-to-face contact in a number of key parts of the animal research process, including that covered by the AWERB. In particular, ethical review of projects was often done electronically. The Brown Report said that “A local ethical review process conducted electronically fails to provide a forum for all staff to come together to review projects, consider the cost/benefit assessment and very importantly to deliver a dynamic process for the development and implementation of improvements in the 3Rs.” Serious consideration of projects and retrospective review of them should, in the opinion of the Brown Report, be done face-to-face.

Transparency in the AWERB’s activity is recommended by the new Home Office Guidance (9) and the ASC (2). The Brown Report recommended that meetings are publicised in advance, and that anonymised minutes of the meetings made available to all staff. This did not happen at Imperial College, and there was a low level of awareness of the AWERB’s activities. If the AWERB is to perform its role in promoting awareness of animal welfare and the Three Rs, there needs to be a “clear process for the dissemination to all staff of 3Rs information and welfare improvements that might emerge from NACWO discussions or the local and central process”.

The Brown Report also considered that AWERB meetings needed to be inclusive and informed. It was important that staff with specific skills or knowledge in the areas of discussion or assessment were encouraged to attend and to contribute. Equally, researchers proposing new projects or amendments should attend the meetings to discuss their proposals, and during discussion of retrospective reviews and other assessments of ongoing work. They further suggested that technical staff at all levels (including Named Animal Care and Welfare Officers [NACWOs] and Named Veterinary Surgeons [NVSs]) should be encouraged to attend research group and AWERB meetings, in order “to improve communication and understanding of particular research projects”.

The Brown Report considered it important that the person in charge of the AWERB was in a senior

position, but had time to perform the role effectively and without conflicts of interest. Often institutions combine roles, and, at Imperial College, the NVS performed the role of head of the AWERB, as well as being the Named Training and Competency Officer (NTCO). This, as the Brown Report noted, was “unsustainable”.

For further information on Animal Welfare Bodies and Ethical Review processes, see:

- Home Office (2014). Animal Welfare and Ethical Review bodies (AWERBs). In *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986*, Section 10, pp. 88–89. London, UK: Home Office (9);
- RSPCA & LASA (2010). *Guiding Principles on Good Practice for Ethical Review Processes. A Report by the RSPCA Research Animals Department and LASA Education, Training and Ethics Section* (ed. M. Jennings), 66pp. Horsham, Sussex, UK: RSPCA (10); and
- RSPCA (2009). *A Resource Book for Lay Members of Ethical Review Processes*, 2nd edition, 60pp. Horsham, Sussex, UK: RSPCA (11).

In addition, the European Commission is in the process of publishing guidance on the Animal Welfare Body, but has already published Guidance on the performance of project evaluation, including harm–benefit assessment and the retrospective assessment of projects. Both documents will be available from:

http://ec.europa.eu/environment/chemicals/lab_animals/interpretation_en.htm

Operation of the animal units

Some of the BUAV’s main concerns about the care of the animals at Imperial College, and indeed, all institutions that have been investigated over recent years, are the lack of appropriate out-of-hours care, insufficient monitoring of animals even during normal hours, and failure to rapidly deal with animal welfare issues should they arise. The new Directive requires that “each breeder, supplier and user has **sufficient** staff on site” (Article 23; 8). The analogy with patients in hospital is something that institutions should be fully aware of. Hospitals would not dream of leaving patients unattended at night, even if they were not considered at risk. We are routinely told that there is 24-hour veterinary care, but, if there is nobody there to call the vet or nobody is actually checking the animals regularly to assess their need for veterinary care, then the ‘24-hour veterinary care’ concept is rendered unacceptably meaningless. In some cases, we have found institutions leaving the animal units completely unstaffed — if there was a fire, break in or equipment failure the animals

would most definitely suffer. The recent fire at the Manchester dog's home puts this need into sharp perspective. We were pleased to see the Brown Report acknowledge the importance of out-of-hours care. Their requirement was that there must be “sufficient staff resource available for out of hours and weekend working that allows sufficient time for an independent overview of the welfare of animals housed in the facilities and the time required to deal fully with any welfare issues when problems arise”.

The Brown Report also agreed with our finding that barrier systems can prevent appropriate veterinary oversight. At Imperial College, the NVS was prevented from entering the unit if he/she had attended other units in the last 48 hours. They were therefore not able to physically enter the unit and directly inspect any animal that was of concern. There were ridiculous scenarios, where the NVS would look at videos of the animals or make a judgement based on a description of an animal's appearance, given by a technician by telephone. Clearly, sufficient veterinary capacity is required to ensure that an NVS can physically inspect the animals at any time. Without a thorough review of policies and honest discussions with staff, issues such as this may have continued unchallenged.

The Brown Report also identified the need for “an unambiguous policy for action in the event of animal welfare concerns”. In effect, this requires institutions to have protocols in place for recording animal health and welfare, complemented with clear lines of communication for passing on any concerns to those responsible for taking action. At Imperial College, project licence holders were sometimes e-mailed to come down to look at the animals. In other cases, the NACWO, and even the NVS, did not have confidence that they had authority to euthanise an animal in distress — they do — and this led to further delays in dealing with specific animals. The Brown Report recommended the use of observation sheets for animals, a mechanism for informing licence holders that does not rely on e-mails, and greater awareness of the responsibility of the NVS and NACWOs. In addition, they recommended a mechanism to bring animal welfare concerns to the attention of the AWERB and the establishment licence holder, including concerns that might be considered ‘whistle-blowing’.

Score sheets can also be used to record information on the severity of experiments, which would be relevant to retrospective review (and, therefore, relevant to the AWERB) and to the development of earlier humane endpoints. In fact, Brown recommended that protocols, adverse effects and humane endpoints for each licence should be readily available at the level of the holding room, and procedural and post-operative areas. Lack of

availability of project and personal licence documents “could lead to difficulties in acting upon licence requirements for safeguarding welfare and applying humane endpoints along with associated compliance issues when procedures are being conducted.” Indeed, poor knowledge of the severity limits for procedures, humane endpoints, and doubts over whether procedures were permitted under the relevant licence, were all witnessed and documented in our investigation and report.

Lack of supervision of often young and inexperienced licence holders who were conducting procedures, was a problem, not just in terms of academic experience, but also in terms of animal welfare. Young researchers were observed to be attempting procedures without supervision, and were clearly lacking in sufficient knowledge and confidence. Others were observed to be performing inappropriate procedures. Had an experienced technician with sufficient authority been present, these occurrences might have been avoided. The Brown Report recommended that technical staff should ensure they observe procedures and contribute to the supervision of licence holders. They suggested that formal procedures should be put in place to ensure technical staff feel empowered and resourced to monitor all theatre and procedure areas at least once daily (and more frequently, in the case of complex procedures). We would consider this an absolute minimum.

For further information on animal welfare monitoring, see:

- Hawkins, P. (2011). A guide to defining and implementing protocols for the welfare assessment of laboratory animals: Eleventh report of the BVAAWF/FRAME/RSPCA/UFAW Joint Working Group on Refinement. *Laboratory Animals* 45, 1–13 (12); and
- European Commission (2012). *Working Document on a Severity Assessment Framework*, 18pp. Brussels, | Belgium: European Commission (13).

Training and competency

Failure to keep up with training requirements can lead to serious problems. The new Directive now requires that “staff shall be adequately educated and trained before they perform any of the following functions; a) carrying out procedures on animals, b) designing procedures and projects, c) taking care of animals or d) killing animals” (Article 23). The Brown Report recommended that there is a formal, systematic training, supervision, and competency assessment in place, for staff at all levels, including licence holders. This should also include assessment of trainers to ensure continued delivery of best practice. The Report also noted that other mechanisms for sharing best practice should be in place, such as direct training, the

AWERB and other forums (e.g. research group meetings). These can help “ensure that staff are kept informed in developments in animal care and welfare, other 3Rs issues and resources and that there is sharing of best practice between staff and units”.

The implications of the Imperial College investigation to training and the Three Rs were discussed in more detail by Combes and Balls (14).

For further information on training and competency, see:

- Home Office (2014). Section 9: Training. In *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986*, pp. 80–87. London, UK: Home Office (9);
- European Commission (2014). *A Working Document on the Development of a Common Education and Training Framework to Fulfil the Requirements under the Directive*, 97pp. Brussels, Belgium: European Commission (15); and
- LASA (2013). *Guiding Principles for Supervision and Assessment of Competence as required under EU and UK Legislation*, 24pp. Hull, UK: Laboratory Animal Science Association (16).

The National Centre for the Three Rs (NC3Rs) also provides guidance on best practice for specific procedures, see:

<http://www.nc3rs.org.uk/our-resources>

Culture, leadership and management

Although leadership was the fourth area covered, it is the most important, as the Brown Report explained. Without strong leadership, necessary changes, and appropriate management of those changes, will not occur. The Brown Report identified the need to drive through positive changes and attitudes to animal welfare by the production of a vision statement and an action plan for the Three Rs. For Imperial, The Report assumed that Imperial College wished to set the highest standards and become a world leader in this area. It suggested that this vision statement should be created with input from staff at all levels, and should subsequently be widely disseminated.

Furthermore, the Report suggested that a senior team, or individual, should be given the responsibility for providing strategic leadership, to ensure delivery of this action plan. It was considered important that this team, or individual, should be free from conflicts of interest and resource issues, so that they could “act as a genuine champion of the 3Rs”. Clearly, some element of change-management was needed at Imperial College, and this might well be the case elsewhere. To this end, we fully support the statement in the report that there

need to be “mechanisms put in place to challenge complacency in animal welfare standards and to encourage the development of new ideas to implement the 3Rs”. A senior ‘champion’ with the drive to encourage the highest possible standards of animal welfare, and therefore of the science, would help any institution to continuously improve its practices. Such a champion would also be motivated to root out complacency and institutional structures that served, as they did at Imperial College, to stagnate progress and even create a ‘them and us’ attitude between researchers and technicians that can lead to poor communication, lack of trust and, ultimately, poor animal welfare. The Brown Report recommended an inclusive approach to the implementation of policies and forums that would help foster better communication, understanding and respect.

For further information on institutional processes, see:

- Home Office (2014). Section 3.13: Your responsibilities as an establishment licence holder. In *Guidance on the Operation of the Animals (Scientific Procedures) Act 1986*, pp. 22–31. London, UK: Home Office (9); and
- NC3Rs/BBSRC/Defra/MRC/NERC/Wellcome Trust (2013). *Responsibility in the Use of Animals in Bioscience Research: Expectations of the Major Research Councils and Charitable Funding Bodies*, 24pp. London, UK: NC3Rs (17).

In addition, the European Commission is in the process of publishing guidance on the Animal Welfare Body and National Committees, which includes how to foster a ‘culture of care’, and the NC3Rs has a briefing on creating an institutional framework for the Three Rs, see:

http://ec.europa.eu/environment/chemicals/lab_animals/interpretation_en.htm, and
<http://www.nc3rs.org.uk/institutional-framework-3rs>

Implementation of the Recommendations

Table 2 outlines the key elements of the recommendations of the Brown Report in the form of a flowchart, identifying the element that needs to be addressed first. The Brown Report was clear that each institution needs to start with a vision statement for its animal research, and in particular, how it sees itself in terms of promotion and implementation of the Three Rs. Only then can the institution review its performance against this vision statement. Clearly, every institution should strive to be a world leader and employ the highest standards of animal care, but, at the very least, must comply with the law, which includes adherence to

Table 2: Suggested order of processes for existing animal use establishments to review the operation of their animal units

1. Issue a vision statement	Agree on a vision statement and publish it and establish monitoring for compliance with it.
2. Appoint a ‘champion’	Appoint senior individual to work closely with AWERB to actively promote application of Three Rs, especially development of <i>replacement</i> methods.
3. Review operation of the units	Thoroughly review the operation of the unit and the welfare of the animals to identify where improvements can be made.
4. Produce an action plan	Develop an action plan based on information gathered from the review.
5. Regularly review the four key elements:	Task the ‘champion’ with regularly reviewing the performance of the unit against the vision statement and the action plan as well as four key operational areas.
<i>AWERB</i>	— Establish an AWERB that is fit-for-purpose.
<i>Training</i>	— Ensure all personnel have regular and appropriate training to their needs.
<i>Protocols</i>	— Develop and publish clear and unambiguous protocols to standardise and optimise best animal welfare and scientific practice.
<i>Resources</i>	— Ensure adequate resources are available to implement all of the above, including the action plan.

the Three Rs. Reviews need to be thorough and, ideally, impartial. Institutions could ask other institutions to help, as Imperial College did. The checklist provided in Table 1 can provide a basis for evaluation of the operation of the unit, but should not be considered exhaustive. As mentioned above, there are several other elements that need to be reviewed, including adherence to legislative requirements and guidelines, the welfare of the animals, the severity of procedures, the use of non-animal replacement methods, etc.

Following a review, the institution needs to implement an action plan, which might include new appointments, policies and protocols. The creation of a leadership role at this stage is necessary — an individual or a team to ensure that the action plan is followed through and the vision statement is adhered to. The Brown Report rightly identified this person or these persons as needing to ‘champion’ the Three Rs. The champion could be the establishment licence holder, but it certainly needs to be a senior figure.

Ensuring that elements such as the AWERB, resources (equipment, housing and staff), protocols, and training are sufficient to progress the vision statement and action plan, should then be the responsibility of the champion and should be regularly reviewed.

What is important, however, is that all these changes and resulting policies and practices are *communicated, transparent, inclusive* and, importantly, *monitored* by the institution. Whether the institution is ‘fit-for-purpose’ should be measured, not in terms of the presence of policies, staff and training (inputs), but on verifiable improvement to animal welfare (outputs).

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