


ANIMAL PROCEDURES COMMITTEE

August 2009

Report of the Suffering and Severity working group on
the strengths and weaknesses of the current system of
severity limits as a way of prospectively assessing
suffering and severity



REPORT OF THE SUFFERING AND SEVERITY WORKING GROUP ON THE STRENGTHS AND WEAKNESSES OF THE CURRENT SYSTEM OF SEVERITY LIMITS AS A WAY OF PROSPECTIVELY ASSESSING SUFFERING AND SEVERITY

Background

A number of expert bodies have made recommendations that the current system for assessing and reporting severity be reviewed:

1. The House of Lords Select Committee on Animals in Scientific Procedures(2002) report paragraph 9.34¹ stated:

“From the licences we have seen, we consider that the current system of assessing pain and suffering is already highly misleading. Licences are allocated into one of three severity bands, based on the experience of suffering of the "average" animal. We consider that if a procedure involves 20% of animals in mild severity, 70% in moderate severity and 10% in substantial severity, then this should be recorded”

2. A Boyd/RSPCA report of discussions on categorising severity (2004)² and the APC review of Cost-Benefit assessment in the use of animals in research (2003)³ also called for a similar review.

3. First, we note that at the time this and similar recommendations were made there was (and currently there still is) no system for the retrospective reporting of the actual levels of suffering of animals under procedures.

4. In July 2004 following, a request from the Minister to the Animal Procedures Committee for practical recommendations with a view to a new system for severity limits and bands, the Suffering and Severity working group was established to evaluate the following:

¹ <http://www.publications.parliament.uk/pa/ld200102/ldselect/ldanimal/150/150.pdf>

² http://www.boyd-group.demon.co.uk/severity_report.pdf

³ <http://www.apc.gov.uk/reference/costbenefit.pdf>

- The strengths and weaknesses of the current system of severity limits and bands as a way of prospectively assessing suffering and severity. If significant weaknesses are perceived, what alternative system could be proposed.
- How suffering and severity might be assessed retrospectively.

In October 2008 the APC/LASA Working Group⁴ published their final report on retrospective reporting of severity which addressed the second topic.

This report addresses the first topic and evaluates the current system of using severity limits and bands.

Our approach

5. The Suffering and Severity working group consider that:

- (i) the expected and actual levels of animal suffering in procedures should not be hidden and where possible greater detail should be provided;
and
- (ii) the Home Office should be accountable for the level of suffering that it authorises when granting licences and for its oversight of animal procedures.

Severity classification

6. The current system of severity classification is as follows.

(i) Within project licenses, protocols are currently given mild, moderate, substantial or unclassified⁵ *limits* based on the maximum suffering that is expected that any animal will be permitted to experience. Licencees are required to keep animal suffering below the severity limit. These limits are used as a licensing tool to control the maximum permissible suffering that might be experienced by any animal in a given protocol.

(ii) The licences themselves are allocated into mild, moderate, substantial or unclassified *bands*. Allocation into these bands is based on the overall suffering likely to be experienced by all animals

⁴ Final report of a LASA/APC Working Group to examine the feasibility of reporting data on the severity of scientific procedures on animals October 2008.
http://www.apc.gov.uk/reference/lasa_apc_final_report.pdf

⁵ Paragraph 5.42 of the Guidance on the Operation of the Act defines severity classifications. "Unclassified" is defined as performed entirely under general anaesthesia, from which the animal does not recover consciousness.

undergoing regulated procedures within the authorised programme of work. It incorporates both the total numbers of animals that might experience mild, moderate, substantial suffering or unclassified suffering and the likely duration of the suffering in the allocated band at each level of suffering. The numbers of projects falling into each band are reported in the annual statistics⁶ and currently are the only indicator available to the public of the degree of animal suffering that may be experienced by animals under the Act.

The banding system: subdivision of the “moderate” category

7. A number of stakeholders have criticised the classification system stating that the moderate limit appears to be a “catch-all” grouping and have called for a subdividing of the moderate limit to differentiate further the extent of suffering predicted. The Suffering and Severity working group have considered this proposal and decided that it would be premature to reach a conclusion on this for the following reasons:

- i. According to the LASA/APC Working Group report of 2008 on retrospective reporting, which the working group commissioned and which the APC has forwarded to the Minister; “subdivision of the moderate category was viewed as an improvement of the descriptive power of the current classification system that could assist in tracking progress in refining procedures. The consensus of opinion was that refinement often takes place in small steps, and follow-on reductions in severity might not necessarily cross severity category boundaries (e.g. from moderate to mild), but might occur within categories (e.g. from the upper to the lower end of moderate).
- ii To increase the number of severity categories would however increase the bureaucratic burdens of reporting, particularly if it is difficult to clearly delineate the boundary between upper and lower moderate.
- iii Any proposal to alter current severity classifications should be revisited once there is experience of retrospective reporting using the current three category classification.”

It is desirable that the prospective and retrospective systems should be compatible with one another. Changes are already being considered because of

⁶For published Statistics on the use of animals in scientific procedures in Great Britain 2007, <http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/statistics/>

the proposed revisions to EC Directive 86/609⁷ and so additional changes to severity classification at this stage would be inappropriate.

The House of Lords Committee recommendation

8. With respect to the House of Lords Committee's proposal that licenses should provide a breakdown of suffering and severity, giving numbers of animals in each category, the Sub Committee conclude that this is not practical. At the times that a licence is being drafted by the applicant and then granted by the Home Office it will commonly not be possible to identify which animals, and how many animals, will undergo each predicted level of suffering under the procedures. Decisions as to this may only become possible after the procedures in question have commenced.

Conclusions on the Home Office ability to protect animals via severity limits

9. We consider that the present system of severity limits allows the Home Office to control permissible suffering imposed on animals during the course of experiments. We are satisfied that this system protects animals effectively.

Predictions of suffering

10., The assessment of suffering made in licences is purely predictive; it does not provide or purport to prove any information about the actual levels of suffering of particular animals or groups or numbers of animals on procedures. It provides information as to what licensees expect and what the Home Office licences. As the House of Lords committee stated, this information may in fact mislead, since many readers will assume that the predictive 'assessment' provides a picture of the actual suffering of animals when this is not in fact the case.

11. A better approach would be to establish a system for the retrospective reporting of actual suffering which would, if implemented, provide all the necessary information in a way that is not misleading. As noted above the APC has recently forwarded proposals for such a system to the Home Office.

Accountability of the Home Office

12. As to the accountability of the Home Office for the limits that it sets, this will be greatly enhanced once a system for retrospective reporting is introduced. Then it will be possible for the actual suffering experienced by animals to be compared with the limits set at the onset that were approved by the Home Office and to hold the Home Office accountable for those decisions.

⁷<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0543:FIN:EN:PDF>

Dissemination of information

13. We do, however believe that there would be merit in requiring the licensees to predict the degree of suffering that might be experienced by animals in their projects and the number of animals within each limit. Such information would avoid the potential for misleading readers that the current banding system involves.

APC recommendation

The APC recommends that the Home Office should consider the abolition of the banding system

14. Currently banding is used by the Home Office Inspectorate to help in the cost benefit analysis and to identify projects which must be submitted to the APC for its consideration. Both of these functions can be achieved by the proposals in the next paragraphs (Criteria as defined on the APC web site⁸). The actual banding process is not essential to them.

15. The provision by licensees of information predicting the degree of suffering and the numbers involved would assist licensees, Ethical Review Processes/Committees and the Inspectorate in assessing the likely harms to animals. Moreover if retrospective reporting is adopted, the predicted suffering could be matched against the actual suffering experienced by animals at the end of the project, thus providing an indication of the accuracy of predictions of suffering. **This proposal differs from the House of Lords Committee's proposal in that these figures would be estimates only, and would not form part of the conditions of the licence.**

16. This could be achieved for instance by modifying table 19a. There is currently a column in this table for the Severity limit. This could be replaced with a table in which applicants describe what they visualise as the estimated prospective suffering [ie for each protocol, the numbers of animals expected to experience each limit of suffering].

17. Since the House of Lords report was issued, licensees can, under the present legislation, be requested on a voluntary basis only to provide project licence abstracts which are prospective narratives and provide much "prospective" information. Furthermore Revisions to EC 86/609⁷ Article 40 also recommends the publishing of non-technical summaries, suitably redacted to preserve appropriate confidentialities. Though the Directive does not specify

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details of severity the Sub-Committee believe that the publication of such an 'abstract' would provide information that would underpin accountability

18. The information in the proposed table 19a would be reported in the abstracts which licensees currently produce and which are on the Home Office website.

19. Such a system would be more transparent than the present system, as licensees and the Inspectorate could account for the costs and benefits of procedures while the existing limits would remain as a control system.

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