RSPCA response to the Bateson report

<u>'A Review of Research Using Non-Human Primates: Report of a panel chaired by Professor Sir Patrick Bateson'</u> (the 'Bateson report') was published in July 2011.

The Bateson panel examined research projects involving experiments on primates, carried out between 1997 and 2006 with financial support from the Medical Research Council (MRC), Biotechnology and Biological Sciences Research Council (BBSRC) and the Wellcome Trust.

The report identifies many deficiencies and questionable aspects of individual research projects with respect to the way these were planned, approved, carried out and exploited for scientific and medical benefit. It makes a series of recommendations to address these problems.

It is important that these issues have been raised and made public in such an authoritative forum and the RSPCA welcomes the recommendations which address them. *If implemented immediately and assiduously,* the recommendations should make a real contribution to reducing the numbers of primates used in research, and the level of suffering they experience. They should also help deliver a more acceptable level of accountability regarding the allocation and use of public and charitable funds.

The RSPCA supports the majority of the recommendations, and believes that they must be pursued and implemented without delay. The Society will be following this up with the research funders and other appropriate bodies.

Background

The RSPCA has always been deeply concerned about the use of non-human primates in scientific research and testing. In the public debate, the justification provided for the use of primates is usually given in very general terms e.g. that 'the use of primates is essential to the understanding and cure of serious medical conditions'. However, the Weatherall Committee in its 2006 report The use of non-human primates in research commented on the difficulty they experienced in finding evidence to support such statements, particularly data on the actual outcomes of individual research projects. To support a better informed debate on primate use, they recommended that the major organisations funding primate research should undertake a systematic review of the outcome of the research they had funded over the preceding decade. The MRC, BBSRC and Wellcome Trust agreed to do such a review.

The RSPCA welcomed the recommendation and the funding bodies' willingness to take it forward, but became extremely concerned when the promised review took over three years to get started. Eventually, a review panel was set up, chaired by Sir Patrick Bateson, and the panel's report ('the Bateson report') was published in July 2011. It was evident from this that carrying out the review was more difficult than expected because the MRC, BBSRC and Wellcome Trust had no information readily available on the outcomes of the research they had funded. This is in marked contrast to research funded by DEFRA where at the end of individual projects, a report, which clearly show the objectives and whether they were achieved, is made freely available on the internet. It seems disgraceful that public or charitable funds can be spent on research which is not followed up and

exploited, and the Society considered it truly astonishing that no such system was in place for primate research, particularly when this raises such serious ethical and animal welfare concerns, and when the scientific community are prepared to be so dogmatic about its absolute necessity. Fortunately, this point was recognised in the Bateson report and recommendations were made to try to rectify the situation.

Unfortunately, when the report was launched, the media chose to focus on the fact that for 9% of the research reviewed, the panel concluded that 'no scientific, medical or social benefit had emerged'. It was therefore assumed that the remaining 91% of research had a benefit and was justified, although the report does not actually say that. This inevitably resulted in a polarised media debate, which deflected attention away from the serious criticisms within the main body of the text and from the extremely important recommendations which occur throughout.

General comments on the report

The original objective of the review, defined by the Weatherall report, was to assess the *outcome* of primate research (its contribution to science and to medical progress) over the 10 years between 1997 and 2006, but the task given to Bateson was enlarged, and made more difficult, by also asking the working group to include assessment of the quality of the research and impact on the experimental subjects, and to 'identify strengths and weaknesses of the funded science'. The aim was to bring together three factors - scientific quality and importance, probability of medical and public benefit and the likelihood of animal suffering - into an overall assessment of whether each research project was 'acceptable and justifiable'.

The approach of the panel, and the process described in the report for carrying it out, is welcomed by the RSPCA because it directly addresses the question of scientific and ethical justification for the use of primates. Understandably, the report took a long time to produce, and the panel would no doubt have considered a great deal of information which could not be presented in a document such as this. The information provided is therefore all that is available, in the public domain, about the research that was reviewed, given that the projects (and hence the publications arising from them) are not identified in the report. This makes it impossible for the reader to be much wiser about what the primates were actually used for (other than the overall research field e.g. neuroscience, vision...), or to have an understanding of the specific criteria used to judge the justification for their use, or to understand what the outcomes had been. This is our major criticism - the report does not actually provide an answer to the central question about what ten years of primate research achieved. It lacks detail about the projects which were reviewed, and is not clear about the conclusions which the panel reached regarding scientific quality and importance, probability of medical and public benefit, and the likelihood of animal suffering in each case. An overall conclusion concerning the justification and acceptability of each project is rarely mentioned, despite the fact that such a conclusion was the stated endpoint of all project assessments (Report sections 1.6 and 6.1, and Appendix 3.1). There is also a puzzling inconsistency in that the full text is quite critical of the research, but this is not always reflected in the conclusions which in some cases seem quite anodyne in comparison. It thus leaves scope for misinterpretation (as described in the 'Background' section above). It is also a pity that the panel saw fit to add comments on harassment of researchers by extremists and aspects of the regulatory system in the UK, since these points were adequately covered in the Weatherall review and revisiting them again detracted from the central point of the review.

However, aside from these concerns, the RSPCA welcomes the report and believes it should provide a driving force for change *if it is taken seriously by the research community* - including all those who fund, regulate, carry out and publish research on primates. It identifies many

deficiencies and questionable aspects of individual research projects with respect to the way these were planned, approved, carried out and exploited for scientific and medical benefit, together with a number of general 'cross-cutting' issues that need attention, and makes recommendations to resolve these problems. It is important that these issues have been raised and made public in such an authoritative forum and the RSPCA welcomes the recommendations which address them.

Comments on specific recommendations

Recommendation 1 underlines the need for rigorous review of grant applications with regard to scientific value, probability of benefit, availability of alternative approaches and likely animal suffering. **Recommendation 2** calls on funders critically to examine the choice of primates as test species, and the possibility of using alternative methods. These are fundamental requirements which should have been addressed by the researchers, Home Office, local ethical review process, and the funders themselves before the projects started. Indeed, we have been repeatedly told over many years that such rigorous review is standard practice. It is therefore disturbing - and telling - that the Bateson Panel felt it necessary to restate these requirements. Future reviews of grant and project applications must be more rigorous.

Recommendation 3 addresses the need for greater scrutiny of the likelihood of the perceived benefits of a project being realised, taking into account the existence of structured plans for data dissemination and translation to the clinic where appropriate. This is important, because it is essential to ensure the exploitation of research and achievement of medical benefit that is so often cited as the justification for using animals, otherwise animal lives are completely wasted.

Recommendations 4 and 13 call for greater efforts to monitor research outcomes and to facilitate the identification of opportunities for further exploitation of results. The latter requires that 'a culture of routine output reporting should be embedded in all funded researchers and that provision of such data should be a condition of the grant. In particular, where grants were awarded on the promise of human health benefits, the grantholders should provide evidence of interest in and use by the medical and biopharmaceutical sectors. Failure to update funders regularly with relevant data should disqualify grant-holders from further funding'. Not only is evidence of the expected outcome required, but as pointed out in Recommendation 3, a strategy should be in place before any animal work starts that will facilitate the realisation of the benefits cited as justification for the infliction of animal suffering. These recommendations need to be implemented without delay.

The panel drew attention to the fact that increased understanding of biological or medical problems is fundamental to medical progress, but that it may not lead directly or quickly to medical solutions, so the 'potential' as well as actual medical benefit of primate projects was assessed. This is not easy to do, and the report makes it clear that they had to rely largely on their own assessment of the potential medical benefit of each project, stating in **Section 5.5.2** that: 'The Panel's assessments of medical and other benefits were made with difficulty and often could be no more than informed guesses.' This in itself indicates that a totally unacceptable situation has existed for many years in the public funding of research, particularly where such research has involved the use of primates: neither the necessity for the experiments, nor their value has been clearly established, despite claims to the contrary made by the research community, the funders and the Government. The panel concluded that researchers and funders 'should avoid overstating and generalising the medical benefit of NHP research since this cannot be substantiated in many cases' and argued that 'statements should reflect the actual basis for funding decisions...'(Recommendation 12). We agree.

The majority of the other recommendations also require immediate action. For example, ensuring that projects with particularly high welfare costs are only funded if they have a *high likelihood* of

delivering scientific, medical or social benefit, together with the need to use less invasive techniques (Recommendation 8) is important. Recommendation 6 refers to the need to publish results, whether regarded as positive or negative, to prevent unnecessary duplication and to ensure that the benefits of research are implemented. Recommendation 7 emphasises the need for funders to ensure that well-trained, competent personnel and adequate facilities are available before research is carried out. The need to extend the funders' responsibility to work they fund abroad (Recommendation 9) is increasingly important with global collaborations in science, although the Panel recognised that the funders have taken this seriously in recent years.

Conclusion

Any criticism of primate use is traditionally countered with assertions from within the research community that universal good practice both in terms of the rigour of review of research and its conduct is, and has always been, applied. If this were indeed the case, then the panel would not have needed to make the majority of its recommendations, since they clearly refer to measures which *should* have been standard practice for many years if legal, ethical and scientific requirements were indeed being properly considered. It is deeply worrying, and a serious indictment of certain sectors of the research community, that the panel clearly felt that there was much room for improvement.

The recommendations in the report are extremely important since, if implemented immediately and assiduously, they should make a real contribution to reducing the numbers of primates used in research and the level of suffering they experience. They should also help deliver a more acceptable level of accountability regarding the allocation and use of public and charitable funds. The RSPCA supports the majority of the recommendations and believes these must be pursued and implemented without delay. The Society will be following this up with the research funders and other appropriate bodies.

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