Pound, P., & Blaug, R. (2016). Transparency and Public Involvement in Animal Research. Alternatives to Laboratory Animals, 44(2), 167-173.

Comment

Transparency and Public Involvement in Animal Research

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Summary — To be legitimate, research needs to be ethical, methodologically sound, of sufficient value to justify public expenditure and be transparent. Animal research has always been contested on ethical grounds, but there is now mounting evidence of poor scientific method, and growing doubts about its clinical value. So what of transparency? Here we examine the increasing focus on openness within animal research in the UK, analysing recent developments within the Home Office and within the main group representing the interests of the sector, Understanding Animal Research. We argue that, while important steps are being taken toward greater transparency, the legitimacy of animal research continues to be undermined by selective openness. We propose that openness could be increased through public involvement, and that this would bring about much needed improvements in animal research, as it has done in clinical research.

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Key words: *animal research, openness, public involvement, transparency.*

Introduction

It is generally agreed that scientific research should be conducted in accordance with widely shared ethical norms, be methodologically sound, provide sufficient value to justify public expenditure and be transparent (1). Research involving animals has long been contested on ethical grounds (2), but new to this debate are mounting evidence of poor scientific method (3–7) and growing doubts about its clinical value (8–11). In terms of transparency, there is increasing acknowledgement among scientists of the need for researchers to be more explicit when reporting animal research in scientific publications (12–14), and to make that research accessible and reproducible (15). There is also a growing discourse about the need for institutions and organisations conducting animal research to be more open about their activities, and for greater transparency in the regulatory processes. Nevertheless, the most common public perception of organisations that use animals in research is that they are secretive (16), and this has long been the perception in the UK (17).

McLeod and Hobson-West (17) recently identified three key discourses relating to openness within animal research. They suggest that: a) animal protection groups advocate greater transparency as a means of countering a secretive system; b) the animal research community advocates it as a means of countering misinformation and misunderstanding; while c) government and research funders argue that openness will counter mistrust in science and government. The authors propose that, while each of these three discourses hopes for a different outcome as a result of greater transparency, it is likely that together they will challenge the *status quo* and put organisations to the test. Here we consider the extent to which the transparency agenda does challenge the *status quo*, examining recent developments within the main group representing the interests of the sector, Understanding Animal Research (UAR), and within the Home Office, which regulates animal research in the UK. We propose that while greater openness is to be welcomed, there is a danger that this may remain too selective (18). We suggest that public involvement may guard against this possibility, and argue that traditional objections to public involvement can be overcome.

Legitimacy Requires Transparency

UAR

In 2014, UAR published its *Concordat on Openness in Animal Research* (19). The Concordat required its signatories (institutions undertaking, or

funding, animal research) to commit to enhancing communications with the media and the public about animal research, to be proactive in giving the public opportunities to find out about animal research, and to publicly acknowledge that they conduct or fund that research. During the development of the Concordat, the UAR commissioned Ipsos MORI to conduct a public consultation (part publicly-funded through the MRC), and participants were assured that their views would influence the final document (20). Consultation participants mainly wanted external scrutiny of the animal research sector and for the sector to communicate more openly about its activities. Ipsos MORI summarised the predominant view as follows: "A prerequisite for the animal research sector calling itself open and transparent is that it should subject itself to external scrutiny by those who have an interest in the animals' welfare, rather than by those who have a vested financial or scientific interest in the research being carried out" (21, p.37). The principle of public scrutiny, however, held by participants to be the best guarantee of openness, did not make it into the Concordat.

Commentators have asked why the sector, traditionally secretive about its work, has recently declared an interest in greater transparency (22). One explanation is that the Concordat represents an attempt to strengthen trust in scientists (23), following a decline in public support for animal research (24). However, the Nuffield Council on Bioethics (2) has noted that a context of greater openness also allows increased potential for a disproportionate focus on the benefits of animal research. Closer examination of the Concordat's commitment to 'encouraging communication with the media' is informative. It states: "Where animal research has played a significant role in a scientific advancement and/or product development, we will include information about that animal research in relevant communications, including media releases" (19, p.7). Clearly then, signatories commit to communicating positive or promising results to the media, but whether they are as willing to communicate negative or controversial findings in the interests of greater openness is less apparent. As such then, increased transparency within this context appears to provide greater opportunity for promoting the 'promissory discourse' (25), i.e. for broadcasting information about 'new breakthroughs' and medical advances that animal research will 'one day' bring about. Pollock and Williams (26) argue that while 'promissory organisations' have the mechanisms and networks for both communicating successful claims and managing more contentious claims, they not only reflect what is going on in a field, but actively contribute to shaping expectations about that field. Brown (27) suggests that the 'dynamics of expectation', or the 'talking up' of biotechnology also functions to secure resources and support for the research.

Finally, increased openness allows for the possibility of 'normalising' animal research, another of UAR's aims (28). This is achieved through increased 'incidental and normative' mention of the involvement of animals in media research reports (29), which over time may function to construct an appearance of consensus regarding the legitimacy of animal research. It can be seen then, that while UAR's stated aim was to strengthen public trust in scientists, additional benefits may be gained from advocating greater openness.

Home Office

The Home Office has similarly asserted a commitment to greater transparency within animal research. It is currently reviewing Section 24, a privacy clause within the *Animals (Scientific Procedures) Act 1986* (ASPA), which represents the main legal constraint against transparency in the UK. Section 24 functions to protect scientists from having to disclose information that they do not wish to disclose, and is now regarded as incompatible with Government policy on openness and transparency (30), which requires more information to be made publicly available.

In terms of routinely available information on UK animal research, the Home Office annual report on the number of procedures conducted on animals used to be all that was available. However, anonymised lay summaries of projects licensed by the Home Office have been publicly available since 2004 (31), and the Home Office's Animals in Science Regulation Unit (ASRU) has started publishing its Annual Report (32), as well as reports of non-compliance and selected investigations of animal facilities (33). In 2015, information on the actual (rather than predicted) severity of each procedure was published for the first time (34), to conform to European *Directive 2010/63/EU* (35). The ASPA itself was amended in 2013, when the European Directive, itself a driver for greater transparency, came into force. Together, these represent important steps toward greater openness, but unfortunately, they are undermined by a layer of secrecy at the very heart of the animal research process, namely, the harm–benefit assessment.

In addition to holding personal and establishment licences, UK animal researchers have to apply for a Home Office project licence, which requires them to outline the anticipated benefits of their proposed research, together with its predicted harms to animals. The Home Office then conducts a harm–benefit assessment to determine

whether the benefits are likely to outweigh the harms. Although the harm–benefit assessment is widely regarded as the cornerstone of the regulatory system, it is conducted behind closed doors, contrary to Article 38 (4) of *Directive 2010/63/EU*, that states "The project evaluation process shall be transparent" (35). Certainly, more information on the harm–benefit assessment is provided now than ever before (36), both in terms of how applicants should outline predicted harms and benefits, and in terms of how the Home Office should come to a judgement on them. Ultimately, however, an objective, systematic approach to weighing harms and benefits appears to be lacking, and it remains unclear to outsiders exactly how the assessment is conducted in practice. The Animal Procedures Committee (APC), which until recently advised the Home Office on animal research, concluded that it was primarily the project applicants who actually conducted the assessment, with *assistance* from the Home Office (37), but the Home Office asserts that the assessment is undertaken by their inspectors on the basis of information provided by applicants (36). Another impediment to transparency is the lack of clarity about whether licences are ever refused, or whether, after modification, they are all approved.

The Animals in Science Committee (ASC), which replaced the APC in 2012, was asked by Norman Baker to review the conduct of the harm–benefit assessment (38), but has yet to report. We suggest that the harm–benefit assessment must be made more transparent, not only because it represents one of the most contentious elements of animal research, but also because an obvious conflict of interest exists. Project applicants have a clear interest in their research being approved, so are unlikely to be able to give an objective account of its harms or benefits. Equally, it is doubtful whether Home Office inspectors are able to take a genuinely neutral stance, since, coming from biomedical research backgrounds themselves (36), they are likely to operate within the same scientific paradigm in which animal use is taken for granted. Furthermore, there is good evidence that the animal research sector routinely overestimates the significance (3, 4) and benefits (39) of animal research.

Conversely, the sector may downplay the harms experienced by research animals. The APC (37) notes that some procedures with the potential to cause substantial suffering are classified as moderate, and Lyons (40) provides evidence for this. He describes research involving the transplantation of either pig hearts, kidneys, pancreatic islets and/or bone into baboons or macaques, for which the researchers proposed a 'moderate severity' categorisation. This categorisation was accepted by the Home Office, but was at odds with the symptoms the animals displayed (documented in leaked reports), and the fact that several were found dead in their cages.

Transparency Requires Public Involvement

As noted above, lay summaries of research involving animals are publicly available after a project has been approved by the Home Office. However, because the lay summaries are anonymised, they cannot be linked with the outcome of the research in the form of publications; furthermore, because the severity category of the research is not included in the lay summaries and there is insufficient detail on the harms endured by animals (41), it is not possible to identify the costs of that research to the animals used. Consequently, although lay summaries of all approved research projects are available, the criteria needed to form an assessment of those projects — i.e. their harms and benefits — are lacking. It has been argued that it is desirable, from both a moral and a scientific standpoint, for the ethical information associated with approved experiments (i.e. ethical review documents, information on experimental procedures and their severity, and considerations of the Three Rs) to be linked with the outcomes of those experiments (42). This would allow members of the public to follow a research project through from ethical review, to Home Office licensing, publication and the outcomes and impact of that research, providing transparency and the possibility of scrutiny.

The *ex post* availability of lay summaries on the Home Office website in fact represents a compromise, since, in 2003, the APC recommended making project applications publicly available *prior* to Home Office approval (37). The APC argued that this would enable members of the public to have input into decision-making by giving animal protection organisations the chance to suggest possible alternatives to research on animals, and interested parties the opportunity to contribute suggestions regarding the Three Rs, i.e. the *reduction*, *replacement* and *refinement* of the use of animals in research (43). In general, it was felt that public involvement in the harm–benefit assessment would increase confidence that the licensing process was sufficiently rigorous (44). In thus recommending public involvement, the APC proposed a genuinely transparent process, as well as indirectly acknowledging the existence of a wealth of valuable untapped knowledge held by expert members of the general public, animal welfare and protection organisations, and animal replacement scientists.

This idea was also popular among some of UAR's consultation participants, who were keen for different groups, including animal welfare and

anti-vivisection groups, to scrutinise applications, "…to check whether the benefits were really likely or were simply a result of researchers 'talking up' their projects" (21, p.31). As the report states, "Without evidence of this external scrutiny, many participants felt that any other efforts made by the sector to be open would not be credible or convincing" (21, p.38). Such external input would not only make the assessment more transparent, but also, in obliging the Home Office to consider contributions from competing value systems and stakeholders, would provide the opportunity for the sort of robust public engagement that genuine openness surely demands. If project applications were to be made publicly available prior to Home Office approval, then some practical obstacles would need to be overcome, including how to deal with the sheer quantity of applications. Perhaps, to begin with, research categorised as 'mild' could be excluded. Applications could be anonymised, if necessary. However, public involvement might serve as an impetus to improve the application form, which, at present, lacks an explicit method for weighing the harms and benefits. In general, public scrutiny might encourage the Home Office to make the licensing process more rigorous, robust, explicit and objective, as it would need to be able to defend its decisions in public.

Within clinical research, it is increasingly recognised that public involvement can help ensure research integrity, minimise adverse effects on participants, enhance public accountability (45), increase relevance (46) and improve research tools, questions, processes, outcomes and implementation (47). It has been predicted that research without evidence of public involvement will, in the future, be considered flawed, because of the importance of transparency in maintaining public confidence in it (48). Much needed improvements would accrue from public involvement in animal research. As well as responding to the expressed wishes of the public, such involvement would help to ensure bias-free transparency, legitimacy, accountability and public trust. It would also help to guarantee that the moral judgements inherent in animal research reflect the values of the wider community (49, 50). Currently, the only opportunity for public involvement is as a mandatory lay-member on an Animal Welfare and Ethical Review Board (AWERB), to which researchers submit their proposals before applying to the Home Office. Such boards, however, are dominated by scientists and do not lend themselves to equal participation by lay-members, particularly if the latter hold differing views about animal research (49). Genuine opportunities for public involvement might also lessen the likelihood of direct action. While the latter is often cited as the reason why animal research institutions have been secretive (23), it could be, as Garner suggests, that "…this style of direct action is itself, at least partly, a product of a helplessness brought about by a feeling that conventional politics is a waste of time, because the odds are so stacked against animal advocates" (51).

Objections to public involvement include the limits of citizen capacity, the complexity of science and the need for professional autonomy (52). Such objections are common in jury trials, bioethical regulation, planning committees, mental health and healthcare provision (53), but advances in participatory evaluation and deliberative democracy provide a way forward (54). Deliberative forums (55), citizens' juries (56) and democratic governance innovations (57) facilitate open public debate informed by guided input from experts. Such deliberative methods have been shown to effectively engage and educate the public (58), to bring new solutions into existence and — seemingly paradoxically — generate informed support for professionals. As Dzur (53) argues, the very status and authority of experts depends upon lay involvement in some form; he proposes that knowledge professions that fail to work alongside citizens, seem to demand an unquestioning compliance to authority that is unhealthy in a democracy — this fuelling citizen disengagement and rendering professionals vulnerable to public scepticism about their authority, competence and elite bias.

Clearly there are many different 'publics' within this debate. Some support animal research, some oppose it, some have a scientific interest, and some prefer to 'blank out' those aspects of life that involve animal use. For many people, animal research is an issue that raises profound ethical dilemmas, but one they prefer not to dwell on. Nevertheless, many have the impression that it is secretive and suspect that such secrecy might be at the expense of the animals involved (59). Even participants with only limited knowledge and interest in the use of animals in research are capable of developing reasoned attitudes and conducting harm–benefit assessments when asked to do so (60, 61). This suggests that, given the opportunity, 'ordinary' citizens would be able to contribute to harm–benefit assessments if public involvement were a possibility. Some members of the public, for example, patients' groups, will have a particular interest in certain research areas and will be motivated to participate for that reason (62). Others may be inspired by concern for the welfare of research animals. Expert members of the public might wish to contribute to ideas on the Three Rs — for example, animal replacement scientists might want to offer information about relevant alternatives to the methodologies proposed. Whatever the impetus, members of the

public, who, after all, indirectly fund most animal research, can and should be able to scrutinise the practices and processes of that research and hold researchers accountable (63). Indeed, the contested nature of animal research, together with doubts about its clinical value and evidence of poor research conduct in this field, make the case for public scrutiny all the more urgent.

Received 20.08.15; received in final form 18.01.16; accepted for publication 04.02.16.

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