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How our approaches to assessing benefits and harms can be improved

ES Sena* and GL Currie

Centre for Clinical Brain Sciences, University of Edinburgh, Chancellor's Building, 49 Little France Crescent, Edinburgh EH16 4SB, UK
* Contact for correspondence and requests for reprints: emily.sena@ed.ac.uk

Abstract

Harm-benefit analysis (HBA) underpins the ethical framework of the regulation of animal experiments. This process involves a qualitative, and generally subjective, assessment of the potential benefits weighed against likely harms to be caused to animals. However, there is scope to prospectively quantify this process. A systematic and empirical assessment of historical data can give insights into why benefits are not realised and the magnitude of harm that animals experience. There is substantial scholarly evidence that risks to the 3Vs, the three core aspects of experimental validity in animal experiments (internal, external and construct validity) and low statistical power are limiting the reliability and reproducibility of research. Assessment of the 3Rs (reduction, refinement and replacement) is embedded in HBA and specifically seeks to minimise harm to the animals. However, no formal structure is in place to assess the likelihood of benefit, and we champion the 3Vs as a scale with which this may be achieved. Ethical approval procedures that consider the 3Vs and 3Rs using meta-research may be an approach to facilitate HBA. In ethical considerations related to animal research, there are value judgements that are integral to HBA, which cannot be measured directly. However, a quantitative and systematic approach is likely to be of added value. The perspective and examples described in this paper relate to laboratory animal research, but the approaches may lend themselves to different settings involving animals to ensure that decision-making and changes introduced, for example, to improve animal welfare, are evidence-based.

Keywords: *animal welfare, benefit, experimental validity, harm, laboratory research, meta-research*