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Veterinary Ethics Conference 2023

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Empirical evidence of inherent impossibilities within the ethical evaluation of animal research

Animal research within the EU

This year, *Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes* (henceforth The Directive) has been implemented across EU member states for a decade. It emphasises respect for the intrinsic value of animals and sets the ultimate goal of fully replacing their use in research. Until then, any use of animals must comply with the 3Rs: Replacing animals whenever a reliable animal-free method is available; Reducing the number of individuals used; and Refining the methods. Ensuring that these criteria are met, and performing a Harm-Benefit Analysis (HBA) whereby the total harm inflicted on the animals is weighed against the predicted benefit of the project, are the two main tasks of the appointed competent authority and must be carried out in a transparent manner. If, and only if, the 3Rs are considered adequately fulfilled and the benefit as outweighing the harm, a project may be granted ethical approval.

Due to its nature as a so called 'implementing directive', the manner in which it has been adopted by member states into national regulations varies, something which has not been without critique (Olsson *et al.* 2022). The European Commission Working Group has remarked that 'significant differences' between its implementations across nations are 'risking the main objectives of the Directive to deliver improved science and welfare and give a level playing field for the scientific community across the EU' (European Commission 2017). Furthermore, studies have questioned the ethical review process itself and the overall lack of *ethical* knowledge and dialogue amongst applying researchers and competent authorities (e.g. Ideland 2009). Some have even proposed that the HBA is an inadequate tool for ethical decision-making and that the review process as a whole needs reinventing (Grimm *et al.* 2015, Grimm *et al.* 2017).

Our study

Stemming from the awareness of said issues and congruous results from a recent pilot study by our research group (Jörgensen *et al.* 2021), we have conducted a larger empirical study of the Swedish ethical review process from which selected parts will be presented at the conference.

By analysing 44 sets of written documents from 2020 (corresponding to 10% of the number of processed ethical applications and decisions from the year in question) we have found that information provided by applicants pertaining to both harm and benefit vary greatly in quality and may in some cases even be severely lacking or completely left out. For example, humane end-points were only sufficiently described in five of the analysed applications and amongst the non-technical project summaries, only one out of 44 contained a complete account of the planned harm to the animals. Hence, Sweden's competent authority, the Swedish regional Animal Ethics Committees (AECs), often do not receive the necessary information on which to base their HBAs. Despite this, ethical approval is granted in 99% of all cases.

Furthermore, ambiguities within the regulatory demands concerning the ethical approval process together with a lack of guidance documents may further impede the role of the AECs as it is not entirely clear what is expected of applying researchers or AECs for them to simultaneously live up to the demands of the Directive and national regulations.

Additionally, despite the Directive requiring the ethical review to be transparent, it is difficult to assess the depth of the ethical deliberations on which the AECs have based their decisions. The vast majority of analysed decisions do not include any mention of the specific harm or benefit associated with the reviewed project in question. Instead, a brief template statement 'The committee considers the importance of the project to outweigh the suffering of the animals' (our translation) is commonly (in 39 out of 44 decisions) all that is said on the matter. As such, it is not only unclear *to what extent* the ethical committees have performed an ethical weighing of the projects they have been tasked with reviewing, but often *if* any ethical weighing has taken place at all.

We have reason to believe that the main causes of these shortcomings, other than limited ethical training of committee members, are: the lack of guidance documents detailing how to interpret and abide by the legal framework; a hard to use digital application form; coupled with the HBA itself being difficult to achieve (and assess) in practice. Regulations are unclear as to what information should be divulged by the applying researcher and to what extent decisions by AECs need motivating in order to fulfil transparency requirements. Further, we argue that the HBA is ill-suited to be used as a one-size-fits-all model for ethical deliberation and decision-making in relation to animal research. Hence, the reasons behind why thorough ethical deliberations are not always carried out as expected may be both complex and synergistic.

Veterinarians and ethical decision-making

Human-animal interactions unavoidably birth ethical dilemmas and those related to the veterinary profession are no exception. Should an elderly dog be put down or subjected to invasive surgery allowing it to live for perhaps just the short time it has left regardless? May we kill millions of healthy animals to prevent a potential disease outbreak amongst humans? How many mice can be subjected to severe pain in order to spare other mice from suffering altogether? In these cases, a HBA-approach is commonly used to make an ethical decision, and veterinarians may take direct part in the discussions or, at the very least, must act in accordance with the verdict thereof. Common for all scenarios is that multiple interests often conflict and stakes are high. A veterinarians' role is to shed light on the situation of the animals, whereas the legislator's role is to ensure that the process as a whole and the decision-making tool in particular is realistically applicable and fitting for its intended purpose. By continuing our research beyond the status quo, we hope to highlight challenges on both sides and to take part in improving the ethical review of animal research.

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