OPINION

Animal Ethics Training for Postgraduates in Medical Schools in India: Catch Them Young!

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Adequate training in ethics for young scientists will serve as an important means of improving animal-based research in India

In India, students specialise in pharmacology after their graduation from medical or other health-related courses. Animal experiments form an integral part of the postgraduate curriculum in pharmacology, and equip the aspirants with the technical know-how and skills for future research. Therefore, these young researchers have an obligation to fulfil the course requirements before their final assessments. The conduct of these experiments demands a considerable knowledge of animal ethics with respect to humane treatment, gentle handling and proper utilisation of laboratory animals, based on the Three Rs concept, in order to provide high-quality information.1

Though ethics is a highly individualised concept, its application in research has been defined and refined from time immemorial, highlighting the safety, rights and well-being of the animals during the course of the study. The constant challenge is the justification by the scientific community of the costs to animals used in research, weighed against the expected benefits to the human race.

The use of animals in research has often been questioned ethically, due to the poor predictive power of the results, owing to differences between animals and humans in terms of their physiology and pathology, as well as the influence of human genetic variation. The action and expression of a novel test agent vary from species to species, and the observations are extrapolated to anticipate the effects in humans. What is revealed is often far from that observed in human beings.2,3

On the other hand, progress in pharmacology owes a great deal to animal studies, which provide the early biological information on any new drug, and form the basis for designing clinical studies. Animal research has led to the development of many new forms of treatment, due to the increased understanding of the disease process at the cellular and molecular levels. A number of alternatives to animal experiments have been suggested and adopted, such as the use of cell cultures, stem cells, nanotechnology, micro-dosing, etc., which serve to supplement and complement the information generated from whole animal studies. Since animals cannot yet be completely replaced in research, because of our inability to mimic the complex physiological systems of whole living organisms, it is important that researchers focus on maximising the principles of reduction and refinement in animal experiments.4

Currently, in India, all animal research undergoes a screening process by an Animal Ethics Committee, to ensure that it is conducted ethically in accordance with the international guidelines. However, the lack of adequate reporting of ethical aspects in relation to animal experiments in the published literature in Indian journals, suggests that there is a need to bring in the concept of animal ethics at an early stage of research training.5,6 Moreover, unlike most of the European countries where courses based on the FELASA guidelines are mandatory for biomedical scientists, there is no such requirement for Indian researchers.7

A structured Laboratory Animal Science (LAS) course on the handling and care of laboratory animals, for all postgraduate programmes involving animals, has been suggested in India.8 This course will impart knowledge about the various animal species, their anatomical and physiological differences, their healthcare needs, overt behaviour, and their appropriateness as disease models, and about the available alternatives. This should exert a significant impact on ethical issues that concern animal experiments, and is likely to leave a positive impact on the postgraduates, inculcating a greater sense of responsibility while conducting animal experiments. Moreover, awareness about Indian regulatory laws dealing with ethical considerations, will provide young researchers with socially-acceptable guidelines and ensure a more humane approach and the generation of high-quality results. The prerequisite LAS course, with
animal ethics as an integral component, will cover the essential aspects, based on standards and guidelines laid down by the international agencies. It will also encourage the participants to be sensitive to these issues.

The animal ethics component of the LAS course

In accordance with the principles of the Three Rs and the ARRIVE guidelines, the main desiderata of the curriculum for this course should orient the trainees to assess their animal studies from different angles which have a direct or indirect bearing on ethical considerations. The course curriculum concerning animal ethics could include the following areas:

1. **Therapeutic need**: The need for the proposed study in therapeutics should be clearly defined. The researcher should be able to justify the contribution to existing medical knowledge for health benefits (harm-benefit assessment).

2. **Literature search**: A systematic review and meta-analysis of the published literature related to the study should be carried out. This will help to avoid duplication of study and permit a more-precise estimation of the number of animals that need to be used in the proposed study. Moreover, it helps to provide scientific evidence of procedure refinement and its impact on the study outcome.

3. **Logistics**: The researcher should verify the availability and accessibility of the laboratory facilities, chemicals, instruments and trained technicians required for the execution of the proposed study. A pilot study can also provide evidence on the estimated number of animals needed and refinements to the experimental procedure, which will help in reducing the dependence on animals. The research study should be planned, so that multiple organs can be used, once the animal has been humanely killed.

4. **Methodology**: A description of the precise objectives, experimental procedures to be used, and knowledge about estimating the right sample size, research design, and analysis of the results by employing appropriate statistical tests, will help to minimise the number of animals required for the study.

5. **Humane aspect**: Socially-acceptable techniques and procedures for anaesthesia, analgesia and euthanasia must be considered thoroughly, in order to reduce pain and suffering to the animals. Rehabilitation and humane methods of disposal should also be considered.

6. **Regulatory aspect**: The constitution, role and responsibilities of the ethics committee and the method of critical review for rationality, procedures, sample size and available alternatives, should be explained in detail, so as to generate scientifically-relevant and statistically-valid results. Moreover, due consideration should be given to the maintenance and care of animals according to the current guidelines.

Attendees should also be familiarised with national regulations with regard to animal ethics issued by the Indian National Science Academy (INSA), the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), and the Indian Council of Medical Research (ICMR).

Conclusions

Animal-based biomedical research should keep up with good ethical practices, not least in order to improve the scientific validity of results. The ethical considerations in a study should continue from its conception through to its completion and the review of the results. An adequate training in ethics through a LAS course for young Indian scientists will serve as an important means of improving animal-based research.

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4. An appropriate proportion of the inspections shall be carried out without prior warning.

5. Records of all inspections shall be kept for at least 5 years.

**Article 35: Controls of Member State Inspections**

1. The Commission shall, when there is due reason for concern, taking into account, inter alia, the proportion of inspections carried out without prior warning, undertake controls of the infrastructure and operation of national inspections in Member States.

2. The Member State in the territory of which the control referred to in paragraph 1 is being carried out shall give all necessary assistance to the experts of the Commission in carrying out their duties. The Commission shall inform the competent authority of the Member State concerned of the results of the control.

3. The competent authority of the Member State concerned shall take measures to take account of the results of the control referred to in paragraph 1.

This is a welcome development, as experience in the UK over many years has clearly shown that the ASRU Inspectorate has not only played a vital role in preserving the balance between the legitimate interests of science and the welfare of laboratory animals — which is a key aim of the governing legislation — but has also provided invaluable advice on best-practice and on the application of new procedures developed in other establishments.

In the last two years, the ASRU Inspectorate has focused its inspection activity in a risk-based manner, by using objective as well as subjective evidence. Hence, each of the 180 establishments in the UK where research on animals may be done has been formally risk-assessed. Both the frequency and the nature of inspections are affected by that risk assessment. Factors taken into consideration in assessing risk include the numbers of procedures being undertaken, the severity of those procedures, the species being used (non-human primates, cats, dogs and horses are considered to be ‘special species’) and the compliance history of the establishment. Places which have infringed in the recent past are considered to be of higher risk.

These are objective measures which are used as evidence for the risk assessments. But equally important is the subjective evidence provided by inspectors who are normally assigned to about ten places and hence become quite familiar with them. The effectiveness of the Animal Welfare and Ethical Review Body (AWERB) and the named persons (Vets and Animal Care & Welfare Officers, as well as the new Training & Competence Officers and Information Officers) is assessed — as also is the focus given to good standards of housing and care, including environmental enrichment and the maintenance planned by the facilities. Commitment to training and supervision are also important indicators.

All of these factors offer opportunities to Establishment Licence Holders to actively manage the perceived risks carried at their establishments, and also enable inspectors to offer advice and encouragement. It is gratifying that the European Directive appears to model itself on the UK approach to inspection, albeit requiring a minimum level of inspection significantly lower than that practised in the UK. The UK government has committed itself to maintaining a strong and properly resourced inspectorate. The implementation of well-informed risk analysis ensures that the allocation of valuable resources (i.e. professional inspectors) is used to the greatest effect.