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### **Educational Forum**

# Restriction on animal experimentation for medical education and research: pros and cons

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#### **ABSTRACT**

Recently, a lot have been written and discussed about animal experiments and ethics. Still there is too much confusion among academicians and researchers about the future of use of animals in biomedical research and up to what extent their use in laboratory, research institutions, and medical colleges. This article highlighted and discussed about various aspects of this burning issue along with several pros and cons.

**Keywords:** Animal experiments, Ethics, Biomedical research, Drug discovery, Medical education

#### INTRODUCTION

Today, medical students, teachers, and researchers are in deep dilemma regarding the use of animals in education, training and research purposes. This state of uncertainty aroused due to lack of proper guidelines regarding animal experimentation and over enthusiasm shown by animal activists.

In present context, one needs to setup balance among the actions, responses, and their applications for the society. Medical profession is meant for the betterment of not only human population but also helps in maintaining a proper balance of the ecological system. One should not have an impression that the deeds of medical professionals benefit only human beings and neglect the other species. Use of one species can be utilized for exploring the knowledge and preparing better medicines and techniques to be used in other species. The present article discusses and highlights

the different positive and negative aspects involved in animal experimentation in medical education and research.

Since ages, animals have been recognized, valuated, and given a very important place in maintaining ecological balance. The different mythologies always respected animals either by preserving or giving them the place of god. When such importance has already been given to animals then how a medical professional can be so cruel to use them indiscriminately. The medical researchers know their boundaries and do their best for the betterment of society. Usually, they are bound by rules and ethics not to jump for experiments directly in the most advanced species, i.e. the human being without having proper prior knowledge. To get the primary knowledge in a proper form, one is bound to expose and do the new in congeners who are very close to human beings. To achieve this, the medical researchers use animals (small and large) depending upon feasibility and suitability for a particular study. The knowledge, techniques, and medicines acquired by these experiments are used for the betterment of whole world, <sup>1,2</sup> as in the case of cardiopulmonary bypass surgery technique countless animals experiments were done which resulted in the success of open heart surgery.<sup>3</sup>

### HOW A NEW DRUG MOLECULE REACHES TO THE BEDSIDE

A new drug is either a new chemical entity (NCE) or new formulation or extract obtained from different biological sources. When any new entity is encountered, no one can predict its beneficial or harmful potentials. When prediction is uncertain, the use is not justifiable directly in the human being. The animal research is used to fill the gap between the unknown to the known about the new drug molecules. First of all, a new entity (potential drug) is exposed to animals for their toxicity profile and therapeutic values. If the compound is found suitable, i.e. less harmful and more beneficial for a particular indication then researchers think further otherwise the compound is discarded at very beginning. Thus, basic animal research is needed to obtain safety data and helps in selecting the proper dose, route and indication for human use. This process of drug development is called preclinical phase. Thus, animal experimentations must develop an NCE into a drug.

The drugs which pass through preclinical phase with the safety and efficacy profile are ready to be administered in human beings. At this juncture, the uncertainty is reduced but not completely vanishes. To overcome this uncertainty, new drug candidate is used in limited number of healthy volunteers only after approval of drug controller authority, as in Phase I clinical trial the number of subjects is around 10-100. If the drug is found safe then, further research continues in the form of Phase II clinical trial (50-500 patients) for proper evaluation of drug against proper indication. If it is found beneficial, then large number of patients (Phase III clinical trial - few hundred to few thousand) are exposed to the drug for the therapeutic potential evaluation and confirmation in population of different areas. The data gathered during all preclinical and clinical trial phases are submitted to the appropriate agencies/authorities for approval of the drug to enter the market. However, the research and development process do not end here, and Phase IV clinical trial is designed to have continuous scrutiny over the period of time after the drug launched into the market.4

All these clinical trial phases are only possible when the safety and efficacy data of animal experimentations are available. The role of animal experimentation is justifiable, provided it has followed under proper guidelines.

## CONTROVERSIES REGARDING USE OF ANIMALS FOR EDUCATION AND RESEARCH PURPOSE

Several issues have been raised time to time regarding ban on the use of animals for education and research. Though, at first look, it seems reasonable but it needs deep thinking before getting into the concluding remarks.

The use of animals for higher secondary and intermediate classes for demonstrating different organ systems cannot be justified because of following reasons:

- a. Students are not sure to opt the biomedical science stream
- b. At this level, the basic knowledge and skills can be acquired by using computer models rather than at the expense of animal life
- c. There is no animal keeping facility in schools
- d. No facility for disposal of animal carcasses which further endangers environment
- e. This type of teaching encourages the black marketing of innocent animal species.

In nutshell, it can be concluded that animals should not be sacrificed for students of intermediate level and lower classes.

In teaching and learning process of graduates other than medical stream, the whole or part of various animals are being used for different experiments. The students doing graduation and post-graduation (PG) in zoology and related subjects need to know in-depth knowledge. As it has been said, practical teaching gives the best form of learning. Even then it is better to avoid animal experimentation when they are performed to just demonstrate old methods and techniques which can be learned by computer software/ simulations. The limited use of animals can be justified for research at this level, provided the use is ethically and socially acceptable. While designing the curriculum of these courses, the administrators must focus about this issue. The uses of animals can only be done in those institutes which have proper animal keeping and disposing facilities.

Traditionally, the knowledge is given to medical and dental students by lectures, tutorials, and practical. Practical may involve the use of cadavers and animals as whole or its parts. The aim of under-graduate (UG) medical and dental teaching is to familiarize the students with physiological, pathological and pharmacological facts without any intention to explore the new ones. Only for this purpose, use of any animal cannot be justified. Someone may say that students can learn better if they do experiment on animals themselves or observe the responses. But their plea may be rejected at the present scenario due to availability of many computer aided simulations which are designed in such a way that students can observe the responses as if they are in the animal itself. So in our opinion, the use of animal experiment for medical and dental graduate teaching is not justifiable, and it is rightly banned.

PG and research scholars pursuing in different subjects require a different type of knowledge and skills. These students need perfection in their subjects, for which computer-aided simulations along with the use of animals

may be required. These students are fencing in one particular field for which they may need the exploration of new knowledge. For getting this new knowledge, the use of animal experimentation might be the necessity. These students may be allowed for animal experimentation, provided the animal use is strictly under ethical guidelines. They may utilize this animal experimentation knowledge into exploring and discovering the new modalities of diagnosis/ treatment. Skills in conducting animal experiments (*in-vivo* skills) can be imparted only during PG training, for not just as a part of the curriculum but also for capacity building.<sup>5</sup> Those PG students and medical faculty who are supposed to work in research field should be provided facilities like "compulsory practical training research workshop" to enhance their skills on animal experiments as they have not done this in UG curriculum.6

### SCENARIO OF ANIMAL EXPERIMENTATION IN PHARMACEUTICAL INDUSTRY

There is always a need for new drugs for which a continuous medical research is required. Drug discovery programs are run mainly by the pharmaceutical industries themselves or by the research organizations. Those industries involved in medical research must be permitted to use animals provided all criteria have been fulfilled. Some of the experiments may be carried out by the researcher on the human or animal cell lines for understanding the molecular mechanisms involved in signal transduction and their regulation by a particular drug molecule.

### CURRENT GUIDELINES ON ANIMAL EXPERIMENTATION IN INDIA

Before independence, there were no restrictions and guidelines related to animal use. The first law in the name of prevention of cruelty on animals was framed in sixties and has undergone many amendments and revisions. The constitution of the committee in the name of Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) has regularized the animal uses. CPCSEA takes care of legal and ethical issues of animal breeding, keeping, and disposal. At present, the CPCSEA is working throughout India by appointing their nominees and inspecting the sites physically. The adherence to CPCSEA guidelines is mandatory, and no one can think of violation. Any research project which involves the use of animals has to be screened critically and passed by the Animal Ethics Committee.<sup>7</sup>

To conclude, the animal activists protesting against the use of animals are not always wrong but the other aspects should also not be ignored. The killing of animals at school and UG level may not be ethically justified when computer software for the same are available. But the use of animal experiments to explore the new knowledge/techniques/ modalities for betterment of human and ecosystem can be justified. The most important challenge is to identify the differences between justifiable and non-justifiable uses of animals on the scientific, moral, and ethical basis. For the new drug discovery and development, animal experiments are essential to understand the molecular mechanisms of a particular potential drug molecule for the cure of noncurable animal or human diseases. Before permitting animal experimentation, the authorities must ensure ecological and human benefit. Ban on animal experimentation should be categorized rather than absolute.

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