Current status of Animal Experimentation in India

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Animals have played a very important role in the life of human beings. Experimentation in animals has given us enormous information and knowledge that made it possible to understand several diseases. Animal experimentation in biomedical research continue to remain crucial to a high proportion to find better ways to understand the course of human diseases further for prevention and treatment as there are no other alternatives to substitute biological system so far. Therefore, even today animals are indispensable for research for improving the health of humans and animals.

Currently, animals are used in the areas of biological studies of a fundamental nature, research & development, quality control of products and devices for human medicine, dentistry and for veterinary medicine, preclinical toxicological evaluation and other safety evaluations of vaccines and antibodies. They are used as part of development mandatory requirement for testing drugs and medicines in pharma industry as per current regulations throughout the world. Animals are also required for disease diagnosis, teaching and training. In the recent times, use of animals in academic institutions and universities has been banned especially for dissections & demonstrations for under graduates.

It is imperative that we respect the rights of animals and consider using them in the research most judiciously and in humane way. Currently in India, experimentation on animals is covered under the provisions of **Prevention of Cruelty to Animals Act, (PCA Act) 1960** and the Rules under the amended Act of 1998 and 2001. This is implemented through a committee called "Committee for the Purpose of Control & Supervision of Experiments on Animals (CPCSEA)". It is a statutory body which was established in 1964 under Section 15(1) of Chapter 4, of the PCA Act under the Ministry of Environment Forest & Climate Change. This Committee ensures registration of establishments and overviews housing, feeding conduct of experimental procedures in animals in the institution through its appointed members and nominees in the Institutional Animal Ethics Committee.

The main objective of the Committee is to ensure judicious use of animals in research. The committee emphasizes on implementation of 4R principles Replacement, Reduction, Refinement and Rehabilitation. Accordingly, committee critically reviews and suggests alternative methods and appropriate models wherever possible. It helps in reducing the numbers of animals and refine it by promoting sophisticated methods to alleviate pain and distress during experimentation. It suggests rehabilitation of large animals (above rabbits) following experimentation with defined norms already published in the website.

At present, in India, there are more than 2300 animal facilities registered with CPCSEA for conducting experiments using animals. In Andhra Pradesh there are about 67 registered facilities and in Telangana state there are 123 facilities. Among them, 96 are in and around Hyderabad.

At the time when users required quality animals free from any disease condition and when there were no facilities in the country that provide quality laboratory animals and demand for genetically defined animals came up with Council of International Organizations of Medical Sciences (CIOMS) International Union of Biological Sciences (IUBS) and UNESCO have met in Paris on 3-4th November 1956 with the aim to raise the standards in the use of laboratory animals on a global basis and took a decision was taken to establish independent centres in various countries.

A centre was created in India too exclusively for Laboratory Animal Science for the first time way back in 1957 in Mumbai before even the PCA Act came into existence. This centre was called Laboratory Animal Information Service (LAISC) with the funding support from UNESCO. Subsequently it was taken over by ICMR in 1959. The unit had undertaken survey for more than 2 years to understand the problems that existed within those scientific fields in which live animals were used for experimental procedures. The centre continues to be under ICMR and shifted to Hyderabad in 1976 and is now known as National Centre for Laboratory Animals Sciences.

Unfortunately, the problems related to experimentation remain the same, in terms of attitude of the users towards experimentation treatment and use of animals and in the thinking of administrators in terms of providing the infrastructure facilities for the welfare of animals.

Stricter requirements of controlled physical environment conditions and the quality of the feed & water come in the way of obtaining reliable results as per the guidelines given by CPCSEA. Many institutions failed to reach the expectations of CPCSEA in terms of providing the required environmental, social and food enrichment to the animals as per guidelines. Most important is reduction of unnecessary pain, suffering and wasteful use of animals. These organisations are registered and permitted to perform animal experiments following inspections at least a minimum of 2 times by a team of experts nominated by Central committee.

Committee spelt out in Chapter 4 of the PCA Act 1960 Rule 17 (d) which states that 'experiments on animals are avoided wherever it is possible to do so; as for example; in medical schools, hospitals, colleges and the like, if other teaching devices such as books, models, films and the like, may equally suffice." The Committee is empowered to take all measures to ensure that animals are not subjected to unnecessary pain or suffering during and after the performance of experiments. They are directed to use effective alternatives in the form of CD's, computer simulations, mannequin models, in- vitro methods, etc. these are found to be effective pedagogic models for teaching anatomy physiology Pharmacy sciences etc.

In view of the above Rule 17 (d) of the PCA Act, which is binding on all academic institutions using animals in dissection and experimentation many organisations have come out with stricter guidelines and recommendations.

University Grants Commission directed the establishments, colleges, institutions registered under UGC to use alternatives in the teaching of anatomy, physiology, zoology etc and completely ban the use of animals for dissection and experimentation in the teaching of Pharmacy, Life sciences at the undergraduate level and post graduate levels.

UGC recommendations were; 1. to strictly adhere to the Wild Life Protection Act, 1972 and the Prevention of Cruelty to Animals Act, 1960; 2. to constitute a Dissection Monitoring Committees (DMC) to look into the use of animals; 3. for both UG and PG programs, there shall be reduction in the number of animals for dissection and experimentation as well as in the number of species with all ethical considerations. Preference shall be given to laboratory bred animal models; 4. for under graduates only one species is allowed for demonstration by the faculty; students should not do any dissection; 5. PG Students have the option to perform dissection of selected species as per the curriculum or to have a project related to biodiversity/biosystematics etc.

The recommendations were approved by the UGC and Ministry of Human Resource Development. The issued guidelines will apply to all departments in universities and colleges dealing with animals in teaching and research under UGC.

Medical Council of India (MCI) in its gazette 19th March, 2014 notified that "For teaching Physiology and Pharmacology in UG curriculum, the required knowledge, skills training should be given by using Computer Assisted modules. Only an animal holding area, as per CPCSEA Guidelines, is required. According to these recommendations, MCI is not asking for central animal house and saying that department of pharmacology can maintain an animal house", which implies that the central animal facility is not required. There was some amount of confusion and contradiction in the regulations of the MCI with regard to the undergraduate teaching of pharmacology. On one hand, it has included applied or clinical aspects in teaching and on the other hand, however, many assessors of the MCI insisted for a central as well as the departmental animal house. MCI members in its meeting insisted Experimental Pharmacology laboratory and recommended equipment that included all requirements for the animal work. With this confusion, all colleges have established animal houses and obtained the CPCSEA license, and are trying to keep them functional at least on the days of inspection. There is a need for transparency and clarity in the MCI guidelines. Lack of clarity in the guidelines lead to confusion and this requires to be corrected.

Pharmacy Council of India had also issued a circular to all institutions under PCI to register with CPCSEA and implement the guidelines of CPCSEA for experimentation on animals. Institutions have been informed to stop dissection at the graduation level. They have even announced ban on usage of animals for any purpose. Many are under the impression that there is a total ban for conducting experiments on animals. However, it was later clarified by MoEF & CC that, under the existing rules all registered institutions can perform experiments on animals with the approval of IAEC after a thorough evaluation in its meeting with a full quorum of members' participation.

On many occasions, members and representatives of inspection teams from CPCSEA while inspecting and while recommending for registration or renewal of the college facilities insists that, they should fulfil all specifications mentioned in the guidelines. They forget the fact that, the guidelines are broad based to cover various institutions involved in breeding and supply, performing testing of final products, conducting experimentation as part of R&D and institutions performing Contract Research. As such there are no specific and separate guidelines for all these institutions having different activities. Similarly, no specific guidelines have been laid down for pharmacy colleges, medical colleges and university colleges where in very few experiments are performed in a year.

CPCSEA has already categorized organisations in to government, private, conventional, barrier, CRO etc while issuing their license during registration. There is a need for CPCSEA also to re-examine their guidelines and frame separate guidelines based on the extent of activity of the organisations especially for pharma and medical colleges. In other words a pharma college and pharma drug company should have separate guidelines. Similarly biotech, biopharama and biomedical institution should have separate guidelines from that of a medical college. CPCSEA should give some mandatory specifications taking into consideration all aspects of welfare and psychological wellbeing of animals, specifications mentioned for environmental conditions both micro and macro under animal husbandry & physical facilities related chapters of guidelines.

Simultaneously, there is a need for thinking and everyone has a responsibility to bring up more and more acceptable terms and modify if possible the institutional policies to strengthen the requirements for existing 4Rs' Replacement, Reduction, Refinement and Rehabilitation.

Currently the needs of health research are growing and medical developments will continue to depend on animals in future also. There are several diseases / conditions which require immediate answers. Stem-cells, gene therapy are now in initial stages. Hunt for development of vaccine and therapies for AIDS and Malaria are not over yet. Diseases like Alzheimer's, Parkinson's, are at the forefront Still, there is a lot to be done with regard to the development of more efficient prophylactic vaccines and curative drugs.

In the recent times there has been increasing threat from emerging historical diseases like TB, Leprosy and new diseases such as SARS Hantan, Dengue, Chikungunya etc. For combating the challenges posed from these diseases and many others, a number of new drugs and new generation vaccines have been developed by recombinant technology and many are in pipeline. Mapping of the human genome also put spurs to the discovery process. Drug targets got increased from 500 to 3,000 candidates in this decade generating more works in the preclinical area. Pharmaceutical companies are spending to the tune of about $12.5 billion every year.

We turn on to sophisticated genetic tests to identify basic causes of disease at the gene level. Typing of proteins and cell components to emerge more personalised "targets" that the potential new drugs might be able to affect. They need to be validated for safety and efficacy.

Indian pharmaceutical industry is growing at about 8 to 9 percent annually. There are approximately 250 large units and about 8000 Small Scale Units, which form the core of the pharmaceutical industry in India. Today, India ranked 3rd globally in terms of volume among the top 15 drug manufacturing countries with market US$ 14 billion, USA with US$ 200 billion and China with US$ 23 billion. It is predicted to grow to US$ 55 billion in 2015 and if aggressive growth strategies are implemented, it has further potential to reach US$ 70 billion by 2020.

In Pharmaceutical Market it is ranked 14th in terms of value in the world. By 2015, it is expected to reach top 10 in the world beating Brazil, Mexico, South Korea and Turkey. Indian pharmaceutical market is growing at 15 – 18 % per year. Indian bulk drug industry is expanding at an annual growth rate of 21 % to reach $16.91 billion by 2015.

Since all modern biotechnology derived pharmaceuticals exert highly human specific pharmaco dynamic properties, there is a need to study the safety in a species closely related to humans for legislative marketing authorisation and hence animals play an important role. As per statutory requirements also, these products will have to be evaluated for safety, efficacy and toxicity in rodents and non-rodents prior to phase I and phase II clinical trials.

Companies are spending almost US $ 800 -1000 millions for any new drug development. Out of which, US $ 200- 300 millions are being spent only for pre-clinical animal testing. It takes almost 10 years of research and efforts to develop one new molecule. It takes evaluation of at least one thousand compounds before a new drug is released in to the market.

It is becoming even more difficult now to come up with new drugs as the cost of R&D is expected to be even higher than in the last decade. Possible ways to reduce the cost [300-400 millions] is by out sourcing. M N C's are looking at the contract research options with early discovery research in low cost destinations. With the available expertise /manpower, the cost of pre-clinical trials could be brought down to 60% in India.

There are several enquiries from all over the world for pre-clinical studies in the established Indian institutions. One of the studies says that companies indicated preference for India, for its mature progress in drug development. However, Indian institutions are unable to take up for want of space and lack of infrastructural facilities.

Currently there are no facilities in the country that provide specific pathogen free (SPF) quality laboratory animals especially large animals and specialized strains of small animals such as transgenic and knock out strains. Established institutions are unable to meet even 20 percent of the demand. Concerns have been expressed in various meetings, symposia of INSA, AIBA and other science academies and associations. Government of India is keen on establishing the facilities to meet the demand.

Currently, proposals have been sent for the establishment of resource facilities at Hyderabad and Mumbai with estimated budgetary requirements of more than Rs. 350 Crores each. They are under active consideration in the PMO. However, medium size facilities at IIIM Jammu (J&K), NDRI Karnal (Haryana), RMRC Dibrugarh (Assam), HBL Chengalpattu (Tamil Nadu), RMRC Jabalpur (M.P), NII Faridabad (U.P) ranging from Rs 45-150 Crores have been approved and are under construction.

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