Protection of Animals and Animal Experimentation: A Survey of Scientific Experts

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thanized by returning more of these dogs to their owners.

- It holds irresponsible pet owners proportionately accountable for the added financial burden placed on the community.

4. Ratio of Animals Altered to Population

One major factor affecting the success of a spay/neuter clinic or program is the number of animals altered per year in proportion to the population. Although the ratio refers to the human population and the number of animal surgeries, this formula was used as a basis for comparison purposes only. There is approximately one dog for every six persons. This is, therefore, a fairly constant factor that can be used for determining the number of spay/neuter surgeries that need to be performed to reduce the animal population growth rate.

Since no program or clinic has been in operation long enough or performed enough surgeries per year to report zero growth in the animal population, it is difficult to identify the minimum number of surgeries that should be performed per year to make a program maximally cost-effective and manageable.

5. Restrictions on Income and Financial Need

Six survey respondents reported that their program included low-income or financial need qualifications. Only one program, in Annapolis, Maryland, performed enough surgeries to be an effective program. The program in Annapolis also included mandatory spay/neuter of all animals adopted from the shelter. Based on the survey responses concerning the problem and lack of success with low-income restrictions, the program in Annapolis, Maryland, appears to be successful in spite of the restriction on income, rather than because of it. In general, limiting clients based on income criteria is a factor that would handicap a program or clinic.

Conclusion

Stray and unwanted animals create a costly control problem that continues to escalate at an enormous rate. Yet, of all the elements that contribute to the cost of animal control activities, the stray and unwanted animals problem is the one that can be most effectively reduced. The answer is the increased sterilization of the animals that are capable of breeding and creating the overpopulation, resulting in stray and unwanted animals. Although sterilization is available today, not enough pet owners choose to have their animals spayed or neutered because of the cost of the surgery and the lack of education regarding the results of animal overpopulation. Information obtained from a survey of cities that have spay/neuter clinics or programs indicates that a municipality run spay/neuter clinic is an effective means of reducing the growth of the animal population, because it provides low-cost surgery, combined with education programs and legislation, that encourages pet owners to have their animals sterilized.

A municipally run clinic would reduce future operating costs, based on its reduction in the growth of the animal population, and would also provide other indirect benefits. Animal Control personnel would have more time to enforce the Animal Ordinance, which would result in an increase in the percentage of the animal population being licensed. This would also produce additional revenue and reduce the number of violations of lease and licensing ordinances. Such a clinic must provide low-cost spay/neuter surgery to all residents and must also support the veterinary needs of the City Animal Shelter.

In some cities, development of a municipally run spay/neuter clinic has been opposed by local veterinarians, who consider it to be an infringement on the rights of the public sector of their profession. Although education programs sponsored by the Animal Control Division to promote responsible pet ownership would indirectly increase the demand for veterinary services, it is not known to what extent this would offset income lost from those pet owners who would choose to obtain low-cost spay/neuter surgery from a veterinary clinic.

The need for reduction in growth of the animal population and the escalating costs of animal control activities warrant the involvement of local government.

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Norbert Lagoni and Hans-Joachim Wormuth are with the Institute for Veterinary Medicine (Robert von Oertzen Institute) and the Federal Health Office, 100 Berlin 33. This paper is an edited version of a report published by the Federal Health Office in 1983, entitled Tierschutz und Tierexperiment-Durchführung, Bewertung und Aussage von Tierversuchen und alternativen Verfahren, Bga-Bericht/81, Dieterich Reimer Verlag, Berlin, 1981.

This article summarizes information from a survey of biomedical scientists, specifically pharmacologists and toxicologists, on the use of laboratory animals and the potential for replacing their use with alternative methods for the development and evaluation of pharmaceutical substances. The majority of those surveyed felt that the alternatives could supplement or complement animal tests, but not replace the tests altogether. However, most favored the use of nonsentient material in safety tests.

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Zusammenfassung


Introduction

To an increasing extent, animal experiments have become a subject of public discussion. There are some social groups who assert again and again that animal experiments are dispensable in many biomedical fields because they can now be replaced by alternative methods. We report how, for the first time in the German-speaking area, scientists of various disciplines, who hold different attitudes toward the problems involved, were surveyed by questionnaire on the subject of toxicological evaluation of pharmaceutical substances using animal tests. Information was sought on the value of animal experiments for safety evaluation in acute, subacute, chronic, mutagenicity, carcinogenicity, and embryotoxicity studies. The questionnaire also asked for the scientists' assessment of alternative methods and their reliability.

Method

Information was collected by means of a written questionnaire between the end of June to mid-August of 1980. The addresses of the persons to be interviewed had been taken from lists of university lecturers, participants at various conferences, and the membership list of the German Pharmacological Society. Additionally, the questionnaire was sent to all medical societies and associations. Questionnaires were sent to a total of 1,526 scientists from the fields of pharmacology and toxicology, veterinary medicine, pharmaceutics, biology, genetics, biochemistry, and physiology. These scientists were affiliated with universities, industry, and governmental and private research institutions. There was a 60 percent (916 questionnaires) response, but only 682 questionnaires were evaluated; the rest arrived too late for analysis or were incomplete.

Disciplines, Experience in Animal Experimentation, and Fields of Activity

The majority of responses came from pharmacologists and toxicologists (53.6 percent), while scientists in pharmaceutics and biochemistry accounted for approximately 10 percent each. Veterinarians accounted for a further 3 percent, with the remainder (about 24 percent) coming from biology or other disciplines. Two-thirds of those responding used animals in experiments. The "typical" period of experience in animal research was found to be between 15 and 20 years, and the majority of those investigators came from the disciplines of pharmacology, toxicology, and veterinary medicine. Of the pharmacologists and toxicologists interviewed, approximately 48 percent of the respondents were affiliated with universities, and only 37 percent were affiliated with industrial establishments.

Results and Conclusions

An analysis of the disciplines and place of employment of the 682 respondents showed that approximately 40 percent were employed by industry and 40 percent by universities. Approximately 9 percent were employed by other research institutions (e.g., Max Planck Institutes), 6 percent in hospitals, and some 2 percent in governmental regulatory bodies. Of the pharmacologists and toxicologists surveyed, approximately 48 percent were employed by industrial establishments and approximately 40 percent by universities, whereas approximately 61 percent of the pharmacists worked in industry, while only 26 percent were affiliated with university institutions. In contrast, most of the biochemists, veterinarians, and biologists surveyed were affiliated with universities and research institutions.

It is important to note that those whose answers indicated insufficient knowledge were not included in the final calculations of percentages. Of those that remained, it was found that these respondents did not consider that animal experiments could be replaced by alternatives in testing for toxicity at present. They felt that alternative methods, if applicable, could be used as supplements or complements, but not replacements. Also, the majority of those who were surveyed predicted that only small gains could be made in reducing the number of animal experiments. In fact, they argued for a need for more animal experiments and for longer periods of testing, which would result in a reduction of more experimental animals and an extension of pain and suffering. However, the majority of the respondents were in favor of using material incapable of feeling pain in special (short-term) toxicological studies. There were some noteworthy differences of opinion on a number of issues. Scientists from industry and from universities differed, in some cases, over the length of time necessary for chronic studies. University scientists advocated more extended periods of animal testing. The LD50 statistic was considered to be of great importance by 48 percent of the respondents and of little or no importance by 35 percent of the respondents. A mere 34 percent of the respondents proposed that medical and scientific reasons be considered as the most important criteria in choosing appropriate animal models. Another 34 percent identified economic and regulatory requirements as being more important. Concerning the issue of the number of species required for testing, "two mammal species" was chosen as preferable by 67 percent of those who indicated some knowledge of the issues. However, 21 percent felt that three or more mammals should be used in testing. For acute toxicity testing, 42 percent felt that the follow-up period should be 2 weeks, while 31 percent felt it should be 1 week (or less), and 27 percent chose more than 2 weeks.

On the question of alternatives, the respondents were asked to comment on the application of clinical data and the utility of mutagenicity tests. A small proportion (7.7 percent) felt that data from chronic animal toxicity studies could be completely substituted by clinical data from human studies. Partial substitution was considered possible by 41.4 percent, and 25 percent considered that substitution of animal data was impossible. Concerning the issue of short-term tests for mutagenicity evaluation, 13.1 percent of the respondents expressed their opposition to these tests. Those who accepted short-term mutagenicity tests disagreed when such tests should be conducted. Some (20.1 percent) felt that short-term tests should always be done, while others favored them only in cases of suspected mutagenic effects (24.0 percent) or in cases when it was anticipated that there would be long-term administration of a drug (17.5 percent).
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It is important to note that those whose answers indicated insufficient knowledge were not included in the final calculations of percentages. Of those that remained, it was found that these respondents did not consider that animal experiments could be replaced by alternatives in testing for toxicity at present. They felt that alternative methods, if applicable, could be used as supplements or complements, but not replacements. Also, the majority of those who were surveyed predicted that only small gains could be made in reducing the number of animal experiments. In fact, they argued for a need for more animal experiments and for longer periods of testing, which would result in the use of more experimental animals and an extension of pain and suffering. However, the majority of the respondents were in favor of using material incapable of feeling pain in special (short-term) toxicological studies.

There were some noteworthy differences of opinion on a number of issues. Scientists from industry and from universities expressed more extended periods of animal testing. The LD50 statistic was considered to be of great importance by 48 percent of the respondents and of little or no importance by 35 percent of the respondents. A mere 34 percent of the respondents favored that medical and scientific reasons be considered as the most important criteria in choosing appropriate animal models. Another 34 percent identified economic and regulatory requirements as being more important. Concerning the issue of the number of species required for testing, "two mammal species" was chosen as preferable by 67 percent of those who indicated some knowledge of the issues. However, 21 percent felt that three or more mammals should be used in testing. For acute toxicity testing, 42 percent felt that the follow-up period should be 2 weeks, while 31 percent felt it should be 1 week (or less), and 27 percent chose more than 2 weeks.

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Discussion

These examples indicate that there is considerable divergence of opinion among experts about the use of laboratory animals. This may be due to the lack of any real scientific basis for the design and selection of animal tests for toxicology testing. For various reasons, including concern about the ethical issues regarding use of experimental animals and the performance of animal experiments, there seems to be an urgent need to create a rational basis for animal experimentation in the field of drug safety. Therefore, it is recommended that appropriate committees to address this issue be formed within scientific societies. The present inquiry might provide a basis for such action.

These panels should explore the various kinds of approaches that might be taken to limit or partially omit animal experiments in toxicology in the future. It is important that the inquiry be conducted under carefully defined conditions for each individual field of application (e.g., acute toxicity or mutagenicity). The LD50 test can serve as an example. Experimental animals are undoubtedly needed to determine an LD50. Nevertheless, the general importance of this parameter for risk evaluation is a matter of great controversy, especially in relation to drug testing.

Industrial drug research is already extensively using short-term tests, involving material incapable of experiencing pain, in the screening process of new drugs. Such tests contribute to a reduction in the consumption of experimental animals and to a limitation in the total number of animal experiments. Short-term tests may also be used to study the actions or toxicological profile of an active substance, and they are generally cheaper and quicker.

It is recommended that the importance of, and the conditions for, a more extensive use of alternatives be studied more extensively. This would include coordination of research activities and dissemination of experimental data, as well as the provision of funds to finance specific research projects. At the same time, efforts should be initiated to have the concept of alternative methods included in any new national and supranational legislation that deals with toxicology testing and research.