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Education and Training in the 3Rs

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Summary

To discuss education and training of persons involved in the design of animal experiments, a workshop was organised during the 7th World Congress on Alternatives & Animal Use. Speakers from Canada, Australia, Japan, United States and Europe gave an overview of education and training requirements and courses in their parts of the world.

During the subsequent discussion with the audience it was concluded that for every study involving animals there should be at least one person who is finally responsible. This person should have been educated in one of the biomedical areas and have completed a laboratory animal science course (LAS). Attitude training was regarded as the most important part of such a course. Furthermore, the content, length, skills training and harmonisation of LAS courses were discussed.

The final conclusion was that education on LAS and the 3Rs not only contributes to reducing animal numbers and animal suffering, but also to better science.

Keywords: education, 3Rs, laboratory animal science, training, guidelines

1 Introduction

When the use of animals in research is inevitable, it is of utmost importance that no more animals are used than strictly needed and that every possible measure to reduce suffering (refinement) is applied. Ideally, all persons involved in the use and care of laboratory animals must be specifically educated and trained. The quality of research and the welfare of the laboratory animal greatly depend on their competence. Implementation of the 3Rs not only depends on knowledge and skills but also on an attitude that is based on respect for animals.

In countries with legislation on the protection of animals used for scientific purposes the law often includes a section on competence of the institutes and persons dealing with experimental animals. But also in countries without such legislative requirements, initiatives have been taken to promote the education of these persons. However, at present there are still major differences between countries (and within countries between institutes) with regard to the programmes that must be taken in order to comply with the requirements. This is mainly due to the fact that only few of the existing regulations and guidelines are specific on length and/or depth of the courses for each of the categories of persons involved in animal experiments and care.

Here we will report on the results of a workshop, held during the 7th World Congress on Alternatives & Animals in the Life Sciences, on the topic of education and training of the category of persons who are responsible for the design of animal experiments (the scientist). The report presents an overview of the presentations of invited speakers, mainly dealing with initiatives that have been taken in several parts of the world (first part) and a summary of the discussion between the panel members and with the audience (second part).

2 Canada (Clément Gauthier)

The Canadian Council on Animal Care (CCAC) is the peerbased organisation overseeing the ethical care and use of animals in research, teaching and testing throughout Canada since 1968. Institutional Animal Care Committees (ACCs) pioneered by the CCAC are the keystone of the Canadian oversight system. ACCs act as local quality control structures responsible for informed decision-making based on science and societal values, while the CCAC provides quality assurance at the national level as quasi-regulatory body.

Adequate training for all personnel is an essential component of any institutional animal care and use program to ensure that animals are used in the most humane and ethical manner. The CCAC guidelines on: institutional animal user training was published in 1999 to present theoretical and practical training requirements for animal users including investigators, study directors, post-doctoral fellows, research team members (including veterinarians if involved in research) and graduate students. An accompanying Recommended Syllabus indicates the core topics to be covered. Twelve web-based modules on the Core Topics of the Recommended Syllabus were posted on the CCAC website (www.ccac.ca) with other resources prior to the mandatory implementation of the CCAC guidelines on: institutional animal user training through the CCAC Assessment Program, beginning in 2003. The requirements covered in the Recommended Syllabus and the related training modules are similar to those included in FELASA Categories C and B. The theoretical part covered in the twelve CCAC training modules can be taken in about 20 hours. However, the hands-on part is as extensive as the specialised research mandate of the institution and the content of the protocol itself require.

Through its overarching CCAC policy statement on: ethics of animal investigation (1989), the CCAC has incorporated adherence to the Three Rs principles of Russell and Burch (1959) as the fundamental basis for the ethical oversight of animal care and use in Canada. This ethical tenet is the third core topic required to be covered in any institutional animal care and use program. In addition to the current CCAC training module on the Three Rs, further training material has been developed under the new Three Rs Program initiated by the CCAC in 2008, namely a microsite on the Three Rs which includes information on Replacement, Reduction, Refinement alternatives and a Three Rs search strategy for investigators.

While the *CCAC guidelines on: institutional animal user training* (1999) covered primarily conventional laboratory animals, additional training material on wildlife and fish has been subsequently posted on the CCAC website, and training material on the use of farm animals is in preparation for posting in 2010.

The CCAC assesses institutional training programs as part of its certification of complete institutional animal care and use programs. However, the training and examination of individuals' competencies is the responsibility of the institution and its ACC as per the *CCAC guidelines on: institutional animal user training* (1999). Accordingly, while there can be agreement on general training principles and course contents through initiatives such as the one undertaken recently by the International Council for Laboratory Animal Science (ICLAS), reciprocal agreements regarding specialised competencies of individuals have to be achieved at the level of institutions.

3 Australia (Margaret Rose)

The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (NHMRC, 2004) governs any use of animals for research, teaching or product testing in the fields of medicine, biology, agriculture, veterinary, environmental or animal sciences. The Code details an ethical framework for deciding if and how animals can be used in these circumstances and provides principles to guide such decisions notably with regard to justification and the critical application of the 3Rs.

A fundamental principle of the Code is that scientists (researchers and teachers) have direct and ultimate responsibility for all aspects of the welfare of those animals they use, emphasising that this responsibility is embedded in the notion of a duty of care. The framework for ethical review and the arrangements for responsible use of animals are intricately linked such that ethical practice is integral to day to day decisions and activities.

An education program that promotes awareness of the issues informs the critical application of principles of the Code and provides the skills and knowledge to support the engagement of scientists that is essential to achieve its goals. Thus, through various educational activities, the Code requires institutions to ensure that scientists are aware of their responsibilities and have the knowledge and skills to undertake specific projects. In the case of students undertaking research training, there is a specific requirement that they receive instruction in their ethical and legal responsibilities as well as in the appropriate methods for animal care and use.

In most institutions it is mandatory that staff attend a course prior to working with animals but, given the diversity of scientific activities, institutions have developed programs customised to their particular needs. Courses range from intensive 2-3 day programs as a general introduction to the ethical and scientific issues to specific programs for wildlife researchers. Course content covers the scope of responsibilities of scientists, the role of the animal ethics committee (AEC) and the relationship between the scientist and the AEC, planning experiments emphasising the 3Rs, monitoring animal wellbeing, the management of pain and distress, animal models, research procedures and record keeping. The relationship between animal welfare and scientific outcomes is a core element of the Code and is highlighted in the course content. Key learning outcomes sought include an awareness of the range of ethical views and an understanding of the responsibilities of a scientist, the process for ethical review, the importance of animal welfare, the scientific basis for the application of the 3Rs and strategies to identify and manage pain and distress. Practical sessions to enable staff to develop confidence in handling animals as well as undertaking specific procedures are offered regularly. These sessions may involve the use of electronic materials that demonstrate appropriate handling

techniques, research methods and species-specific behaviours, including pain-related behaviours, as well as manikins to develop manual skills such as venipuncture or suturing methods.

To date we have not developed a national curriculum for the education of scientists, although this is currently under discussion and would draw on the experiences of extant courses. One consideration is the method of delivery for such courses, noting the need to consider teaching strategies to support adult learning (Dobrovolny et al., 2007). The availability of online course material is seen as being of potential value not only to enhance access to information but also as a way of sharing resources and expertise. But face-to-face discussion also is seen to be important to promote reflective practice and thus underpin the goals of the Code. Further, the publication of evidence-based guidelines, such as those recently published to promote the wellbeing of animals (NHMRC, 2008), provide important resources to support the delivery of courses emphasising the link between animal welfare and scientific outcomes.

In these educational activities, the Replacement of animals is emphasised and informed in a number of ways. Foremost, a heightened awareness of his or her responsibilities on the part of the scientist will support reflective practice and so inform consideration of opportunities to implement the 3Rs (Lloyd, 2009). Another important strategy is to highlight Replacement as the default position when planning a project, critically evaluating the need to use animals to achieve all or part of the scientific aims. Evidence of this approach is seen in the wellbeing guidelines mentioned above, in guidelines concerning specific procedures, such as the production of monoclonal antibodies and in the development of case studies such as those published as part of an on-line course. Further, the use of "local" examples of how animals have been replaced in certain studies provides a tangible context within which to discuss potential opportunities; this being reinforced by the recent establishment of a national prize for alternatives. Knowledge of and access to resources such as websites that provide information about alternatives are also important. Such information is highlighted on the website Animal Ethics Infolink (www.animalethics.org.au) that has been developed as an information resource for scientists and AEC members in Australia.

4 Japan (Tsutomu Miki Kurosawa)

All investigators involved in animal experiments, including undergraduate and postgraduate students, are required to have completed education and training as regulated by the notice of Ministry of Education and the Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain in Japan. The training course is established by the IACUC (Institutional Animal Care and Use Committee), and in most institutions a two hour course is presented. In Osaka University Medical School 1,600 participants take part in this course every year. During the course the 3Rs are specifically emphasised, as stated in the Law for the Humane Treatment and Management of Animals (Scientific use of animals). Apart from the formal course, practical training is provided in many institutions. In the practical training of the Graduate School of Medicine at Osaka University, supporting video programmes are used. Anaesthesia is considered most important for refinement and a 30 minute video on this subject is screened. Training includes proper animal handling and minor and major surgery with aseptic techniques. Also, post-surgical care and analgesia are emphasised. So far, the mouse is shown as a model.

Accreditation systems for laboratory animal research institutions are established by three different national organisations, namely Center for Accreditation of Laboratory Animal Care (HS foundation) for the institutions governed by the Ministry of Health, the Japanese Association of Laboratory Animal Facilities of National University Corporations for universities and animal breeding facilities and AAALAC International (Association for Assessment and Accreditation of Laboratory Animal Care). Six institutions are now accredited by AAALAC International.

The personal qualification system for junior and senior laboratory animal technicians and educators is established by the Japanese Society for Laboratory Animal Resources. The Japanese College of Laboratory Animal Medicine, which is a member of the International Association of Colleges of Laboratory Animal Medicine (IACLAM), has certified more than 70 diplomats. IACLAM is planning the international harmonisation of diplomats and their certification system. In practice, these professionals are already mutually recognised. Also in other Asian countries, accreditation by AAALAC International is becoming popular. Through the accreditation process of AAALAC International, the importance of education and training is receiving more attention, and the quality and harmonisation of the contents of education will be more realistic in the future. Also the OIE (World Organisation of Animal Health) Animal Welfare Code will soon be introduced, and this international standard will prove to be effective in improving laboratory animal welfare in Asian countries.

In Japan, international harmonisation of education and training is still rarely discussed.

The Working Group for laboratory animal welfare in OIE is currently discussing the training of veterinarians in laboratory animal medicine as one of the three priority areas. Other topics are laboratory animal transport, regulatory testing and the adoption of alternatives.

5 Europe (Bryan Howard)

European Directive 86/609 (European Council, 1986) recognises that the skills required of a competent researcher extend beyond the core scientific needs of the relevant academic discipline. There is a perceived increasing concern for wider implementation of the 3Rs within the European community, and the current proposal for revision of the Directive (European Parliament, 2009) urges an extension of the definition of competence to include better matching of scientific need with the impact of science on animals. For example, Article 7 of the Directive 86/609 stipulates that "Experiments shall be performed solely by competent authorised persons, or under the direct responsibility of such a person". Competence involves a combination of knowledge, skills, understanding and attitudes. Knowledge is the easiest of these to acquire – attending lectures, reading books, internet sources, etc. The development of understanding usually involves interaction with situations or other people and is best achieved in simulated or real practical situations. Skills and attitudes are something else, and are often acquired by working alongside a suitable role model, although a basic respect for animals and awareness of the theoretical basis of practical skills should be acquired beforehand. Although delivery of rounded competence within structured training programmes may be problematic, key elements can be developed alongside a commitment to lifelong learning.

European Member States have traditionally adopted national approaches to delivering training, but the Federation of Laboratory Animal Science Associations (FELASA) set out to recommend a formal structure for developing such competencies and established a series of working groups, one of which (FELASA, 1995) proposed a uniform educational approach to providing a foundation for the responsible use of animals. FELASA category C training is intended for those designing and directing animal experiments. Prior experience in laboratory animal science can provide a springboard for learning, and hence FELA-SA's stipulation of a Bachelor or MSc degree in an appropriate biological discipline as a prerequisite. The proposal comprised a course lasting approximately 80 h, involving both theoretical and practical instruction, with provision for alternative modes of study. It included the following topics:

- Biology and husbandry of laboratory animals
- Microbiology and disease
- Health hazards and safe practices in the animal house
- Design and conduct of animal experiments
- Anaesthesia, analgesia and experimental procedures
- Alternatives to animal use
- Ethical aspects and legislation
- Analysis of scientific literature

The Category C syllabus emphasises the importance of the 3Rs in the planning, design and conduct of scientific experiments – courses usually include practical guidance on searching for alternatives, reducing the numbers of animals used by appropriate experimental design and refinement by advising on how to conduct experimental procedures including anaesthesia so as to have minimal impact on the animals' well-being.

FELASA subsequently introduced an accreditation scheme which assures the quality of education and training, promotes responsible and high quality science, facilitates free movement of personnel between countries and assists with further harmonisation (FELASA 2002). This scheme further promotes refinement by insistence on low ratios of students to tutor in practical classes, scrutiny of the content and effectiveness of training and assessment, and reduction by promoting the use of replacement strategies in training and avoiding unnecessary use of animals because of a need to repeat training. Category C training has proven to be very popular, and many establishments in Europe have adopted it as the standard for training laboratory animal scientists.

6 United States (Marilyn Brown)

Laboratory animal use in the United States is primarily governed by two regulations, the Animal Welfare Regulations (AWRs, enforced by the US Department of Agriculture – USDA, CRR, 1985) and the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS) Policy (PHS, 1996), which is overseen by the Office of Laboratory Animal Welfare (OLAW) of the PHS. In addition, most major users of laboratory animals are involved in the voluntary accreditation program of the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC, Intl.). Both AAALAC and the PHS require compliance with the Guide for the Care and Use of the Laboratory Animals – the Guide (ILAR, 1996).

The AWRs address the training of individuals involved in animal research. The AWRs require that "Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures." Section 2.32 of the AWRs specifically addresses personnel qualifications. It is the institution's responsibility to ensure training, and this responsibility is "fulfilled in part through the provision of training and instruction ... " The AWRs go further and describe the general areas that must be included: humane methods of animal maintenance and experimentation including: basic needs of each species; proper handling and care; proper pre and post procedural care; aseptic surgical methods; the concept of the 3Rs; proper use of anaesthetics and analgesics; methods to report deficiencies in animal care and use; and how to provide information on alternatives. Training is one of the areas that are evaluated as part of unannounced USDA inspections which occur at least annually.

As previously mentioned, both the PHS and AAALAC expectations are based on the Guide, which also has a section on personnel qualifications and training. However, details of researcher training are not provided, except to indicate that they must comply with regulations. Several areas in the Program Description, which is the self assessment document serving as the basis for the AAALAC site visit, ask for details of training at the accredited institution. When conducting site visits, AAALAC site visitors will often review training records and, through observation of activities and questioning research personnel, make an assessment of the adequacy of training at the institution. AAALAC categories site visit findings as either a mandatory item (one that must be corrected to obtain or maintain accreditation) or a suggestion for improvement (something that the Council on Accreditation believes would further improve a satisfactory program). Of approximately 1000 site visits reviewed, 2.8% of sites had mandatory findings related to training. A majority of these (1.9%) were related to occupational health and safety. Suggestions for improvement of training occurred at 4.9% of the institutions with, again, the majority (3.9%) related to occupational health and safety. A review of these data indicates that 97.5% of accredited institutions had NO deficiencies in their training programs which would impact on animal welfare in their training programs. All of the top 100 funded academic institutions and virtually all of the major pharmaceutical and contract research organisations in the U.S. are AAALAC accredited. These institutions would represent a sizable majority of all vertebrate animals used in research.

Further directions are given in "Education and Training in the Care and Use of Laboratory Animals: A Guide for Developing Institutional Programs" (ILAR, 1991), which is a manual on training that provides additional specific guidance on development of training programs. It is published by the Institute of Laboratory Animal Resources (ILAR) of the National Academy of Science and provides additional specific guidance on development of training programs. The basis for such programs includes a list of subjects that should be included in core material and additional modules that are generally provided on an "as needed" basis. In addition, a full issue of the ILAR Journal was devoted to Training and Adult Learning Strategies for the Care and Use of Laboratory Animals (ILAR, 2007).

In the US, researcher training is not formalised at a national level as it is in some other regions. Using more of a performance based approach, researcher training is individualised at both the institutional level and the individual researcher level, based upon what species and procedures are involved. While this may seem to be a weakness by those who use other systems, the success of training (competency) is regularly assessed externally by regulators and site visitors and internally through biannual thorough review of institutional programs by the Institutional Animal Care and Use Committees. Reports of these reviews must be sent to the Institutional Official, who has legal responsibility to assure compliance and be available for review by external regulators and site visitors. The success of this system can be seen by looking at results of AAALAC accreditation site visit findings.

An additional measure of the status of researcher training was determined by a survey of US Board Certified Laboratory Animal Veterinarians. It was found that 87% of the respondents felt that, at their institution, research training was good to excellent. The most commonly identified strengths of programs included: comprehensive; standardised; tailored to meet needs of scientist; ease of access; training tied to research privileges; and face to face building of trustful relationships. However, areas for improvement were also noted and included such items as: the need for more hands on practical training; the need for more refresher courses and continuing education, and post training assessment and monitoring.

7 Summary of the Panel Discussion

During the workshop, the short presentations of the invited speakers were followed by a general discussion with the speakers and other participants on some key elements of the education and training of the scientist.

The first part of the discussion focused on identification of the persons that are actually responsible for the animal experiments and need education in laboratory animal science (LAS) and the 3Rs. Generally it is the principal investigator (PI) who designed the study, received the grant and who is often also legally responsible. This person generally does not perform the experimental procedures him- or herself, but, nevertheless, needs to be

educated in animal use and care (laboratory animal science) in order to have insight into all aspects of animal experimentation. It was concluded that the PI should at least have an academic background in one of the biomedical disciplines and have completed a course in LAS. In some countries, animal ethics committees (AECs, IACUCs, ACCs, etc.) assess the required skills of the persons involved in the animal experimentation and may conclude that the complete team, rather than one individual, has the necessary knowledge and experience for a particular study involving animals. It was, however, generally agreed that also in this situation there should be one person who is finally responsible for the experiments, and this person should have been educated in one of the biomedical areas and, in addition, must have taken some form of LAS education.

It was acknowledged that there are great differences between countries and even between institutions within countries with respect to the length (from 2 hours up to 120 hours) and depth of courses. In Europe, scientists are considered qualified (but not yet competent) to design animal experiments after having graduated in one of the biomedical disciplines and having completed the 80-hour FELASA C course on laboratory animal science. In the USA, IACUC's usually decide on what aspects the scientist should be trained in. This effectively means that there is a great variation in the requirements between institutes. Often, several modules must be taken in order to be approved to do animal research. Which modules must be completed depends on the nature of the research. A minimum duration of the course is regarded acceptable as long as the students are aware of the fact that education and training never stops and is a continuous process. It is very important that through continuing education scientists are kept up-to-date with new developments, even when they become more distantly involved in the practical aspects of animal experiments.

Attitude training was identified as the most important aspect of the course, which, at the same time, is the most difficult aspect to assess. Persons need to be trained in reflective practice. Ideally, attitude training should not be restricted to the LAS course but be part of the basic training of MSc students. As part of the attitude formation towards animals it should become natural that the default starting point is research without animals. The question that scientists should ask themselves is whether an experimental animal is really needed to obtain the necessary results of a study. Attitude training should include discussions on the ethics of animal experiments, which can be stimulated by inviting representatives from animal welfare organisations. Although ethics is seen as a recurring thread throughout the course, it was mentioned that it is also advisable to have an ethicist discussing bio-ethics during the course who could present the students with case-studies and ethical questions for group discussions. Education on all aspects of the 3Rs is seen as an essential and intrinsic part of the basic course. The scientists should be aware of the 3Rs principles and should not only be able to perform effective literature searches for alternatives, but should also understand why they are performing those searches.

Furthermore, the need for hands-on training of experimental procedures was discussed. It was generally acknowledged that some practical training in handling and basic procedures should be an essential part of the course. This training could also contribute to the attitude of the scientist, making him/her aware of the impact of procedures on the welfare of the animals and the results of the experiments. As some courses focus on the most commonly used laboratory animals, rats and mice, the question was raised whether it is ethical to use mice to train scientists that work only with fish, for example. On the other hand, not every technique with every animal can be covered during the course. For example, when persons perform wildlife studies, some of the courses will have no opportunities or knowledge available for such specific training. It was suggested that in these situations the scientists should be allowed to train "on the job" and have the team leader sign off and be responsible for the competence of the team members. Therefore it was concluded that specific skills for the performance of procedures should not be part of the general course but should be taught on an individual basis, depending on the requirements of the research. For that reason it was suggested that the ideal course should contain a basic theoretical component for every scientist involved in animal experiments. The practical training should then be given in separate modules or on the job, specifically focused on the animals and procedures the scientist is going to work with and apply.

To facilitate access to LAS courses, some modules could be supplied through the Internet (Web-based learning). On the other hand, it was also generally agreed that group discussions, student to student and student to teacher contact and discussions have a great impact on the students and their attitude development and are often appreciated by them. But the modern opportunity of group discussions through the Internet allows flexibility and may also stimulate interactions among students and between students and teachers. As was stated during the discussion, young students are used to the new media and to communicate by these modern means. What education method is preferred also depends on resources and teacher's availability. This is particularly crucial in Asian countries, where training in laboratory animal science is not yet common. Furthermore, it is not only the cost of the course that should be taken into account, but also the cost of the scientist who is not available for work when attending such a course. On the other hand, it was stated that it should be realised that education on laboratory animal science and the 3Rs not only helps to reduce animal numbers and their suffering, but will also contribute to better research.

To harmonise course content and length and facilitate exchange of scientists several organisations (FELASA, ILAR, CCAC and ICLAS) have developed guidelines documents and guiding principles. Future activities could possibly lead to harmonisation of the different guidelines documents.

8 Conclusion

The need for the education and training of scientists in the principles of laboratory animal science and the 3Rs is generally acknowledged. It was agreed that a major objective of education and training is the development of a proper attitude, based on respect for animals and consideration of 3Rs alternatives. In addition, some form of hands-on training is essential. Live contact between the scientist and laboratory animals in the form of animal handling and observations was mentioned as the minimum that courses should provide.

There are, however, major differences between countries on how competence can be achieved. Harmonisation of course content and the goals to achieve is important for the international exchange of scientists. The workshop revealed a fundamental difference between countries that require a general course for all types of experiments (with emphasis on attitude) and countries that tend to follow a system with modules designed to meet the specified needs of the scientist (with some emphasis on technical aspects). This discrepancy needs to be further discussed before recommendations on international harmonisation of requirements can be made. This workshop may provide a basis for further discussions on this process. Guidelines as proposed by ICLAS, ILAR, CCAC and FELASA can be used to develop generally accepted criteria for such courses.

The final goal will be to minimise the use and suffering of laboratory animals by raising awareness of the opportunities that 3Rs methods offer. This will not only benefit the animals but also improve the quality of science.

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