Free Executive Summary

Strategies That Influence Cost Containment in Animal Research Facilities

Committee on Cost of and Payment for Animal Research, Institute for Laboratory Animal Research, National Research Council

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Executive Summary

The Committee on Cost of and Payment for Animal Research, in the National Research Council's Institute for Laboratory Animal Research (ILAR), was appointed to advise federal funding agencies and grant awardees on three matters:

1. Develop recommendations by which federal auditors and research institutions can establish what cost components of research animal facilities should be charged to institutions' indirect cost pool and what animal research facility cost components should be included in the per diem charges to investigators, and assess the financial and scientific ramifications that these criteria would have among federally funded institutions. The results of this phase of the study were released in an interim report within 6 months of receipt of funding.
2. Determine the cost components of laboratory animal care and use in biomedical research. This will be used to establish a cost baseline that all institutions that use animals in biomedical research, education, and testing can use as a measure of performance efficiency.
3. Assess and recommend methods of cost containment for institutions maintaining animals for biomedical research.

The second task was not done by the committee, because it was discovered that Yale University was well along in planning to conduct a survey of institutions to determine, among other items, cost components of laboratory animal care and use.

The Committee on Cost of and Payment for Animal Research used a variety of sources of information in writing this report: the conclusions, but not the underlying data, of a survey conducted by The Ohio State University Office of Research, for the Committee for Institutional Cooperation (CIC study, Appendix B); the 1999 *Animal Resources Survey* (1999 ARS), conducted by the Yale University School of Medicine's Section of Comparative Medicine; published data; and the collective experience of the committee members. The report covers cost of personnel, laboratory animal management, veterinary medical care, equipment and facility design, compliance with regulations, and future directions in research that uses animals.

Of 130 institutions surveyed, 63 responded to the 1999 ARS. To focus on traditional laboratory animal medicine programs, all institutions with an average daily mouse census of 1,000 or more were selected for further analysis. That resulted in 53 institutions that were then grouped by size of mouse holdings: group 1, 1,000-9,999; group 2, 10,000-29,999; and group 3, 30,000 or more.

Personnel represent the largest cost item in the total costs of an animal research facility (ARF), accounting for 50-65% of the total costs. Of the institutions responding to the 1999 ARS 54 had a veterinarian as a director of the animal care program. If institutions with an average daily mouse census of over 1,000 were focused on, there was no difference in mean director full-time equivalents (FTEs) by group size. Furthermore, the institutions in each of the three groups had an average of nearly 1 FTE associate or assistant director and roughly 0.9 FTE business manager. That indicates that directorship overhead was nearly the same regardless of size of institution. Thus, directorship costs per mouse are higher in smaller institutions. Total managerial staff ranged from a mean of 4.0 in group 1 to 5.4 in group 3, again resulting in higher costs per mouse in the smaller group. Total clerical FTEs doubled from group 1 to group 3, and total technical staff rose from 15 to 42 FTEs. In summary, smaller institutions have higher proportional personnel costs, reaffirming the old adage of economy of scale.

As a case study, the use of team management (or "total quality management") at the University of Michigan is described. Animal care has been strengthened and streamlined as a result of having managers, team leaders, and animal care staff work together collaboratively. A more customer-oriented focus has emerged from this process, improving the ability of the animal care program to meet the needs of researchers. Two years after implementation of the team concept, the University of Michigan was able to reduce per diem rates for rodents by 50% and customer complaints dropped to less than half their previous level. Team management improved working conditions, an important factor in staff retention

according to the 1999 ARS, although salary and opportunity for advancement were more important retention factors.

Containing costs of laboratory animal management depends on high-quality information yielded by carefully kept records and a comprehensive cost-accounting system. Such a system will permit determination of the costs and benefits of various services and identification of cost savings. It is false economy to purchase animals whose health status and genetic background are unknown; their use can lead to poor scientific data that are inaccurate or misleading because of undetected health problems in the animals. Breeding animals inhouse depends on research needs and on a careful comparison of purchase versus breeding costs. The use of core laboratories is a way to centralize services and thereby realize economies of scale, and it usually results in higher-quality data because core laboratory staff are experienced in the techniques of the laboratory. Such laboratories might produce transgenic or knockout animals, monoclonal antibodies, behavioral testing, and the like.

Costs of veterinary medical care are largely for personnel. The veterinarian director of an animal care program is usually trained in laboratory animal medicine and frequently is a diplomate of the American College of Laboratory Animal Medicine. The salaries of such specialized veterinarians are higher than those of veterinary support personnel, so institutions should make use of these veterinarians to take full advantage of their professional competences and delegate technical and administrative duties to lower-paid employees. Veterinary residents and certified laboratory animal and veterinary technicians can be used as an effective extension of the veterinary medical staff, as noted in the CIC study (Appendix B). Smaller institutions can choose to use part-time veterinary consultants or share positions with other institutions. The mix of species, the presence or absence of a surgery program, and the use of animal models that require intensive veterinary assistance because of experimental complications, invasive procedures, or spontaneous disease are determining factors in the amount of veterinary input required. In general, rodent-only programs require less clinical veterinary support than surgery-intensive programs and programs that use larger species extensively. Well-trained, experienced technicians working under the supervision of a veterinarian can deliver much of the veterinary care required by an institution, thereby lowering costs.

Diagnostic laboratory support is usually contracted for unless the institution is large and can fully support an inhouse laboratory. Health surveillance is expensive, and exact needs depend on several factors, such as species used, source of animals, facility design, and animal housing conditions. Frequency of sampling and method to be used for health

surveillance should be based on a risk assessment that incorporates those factors.

The committee considered principles that govern the design of new or renovated animal research facilities, and these principles are presented herein. There are tradeoffs among low maintenance, efficient animal care, investigator convenience, equipment costs, security, and initial cost of construction. Cost estimates are valuable in making choices. Increasing cen-tralization results in increased labor productivity and decreased cost of operation per square foot—a finding that should be considered when renovations or expansions of animal research facilities are contemplated. Decreasing the costs of animal husbandry involves consideration of type of caging (conventional, microisolator, or individually ventilated caging), automatic watering, robot arms for rodent-cage processing, choice of environmental enrichment, bulk purchase of material (depending on space costs), inhouse breeding versus purchase of animals, and medical supplies, including personal protective equipment.

Attention to facility design, equipment, and operating procedures should result in an animal facility that is efficient and easy to manage and maintain. Use of individually ventilated racks could increase intervals between cage changing from 3-4 days to as much as 14 days. Connecting the racks directly to building supply and exhaust can lower maintenance costs by ventilating the cages instead of the whole room. Automatic watering decreases labor costs, but its use can result in undesirable side effects, such as inoperative valves or cage flooding. Using larger water bottles and acidifying or chlorinating the water is an alternative. Careful sizing of animal rooms in the facility permits optimal placement of the racks so that cages can be accessed with a minimum of effort and mobile animal transfer stations can be used. In large facilities, use of robots can permit automation of many parts of the cage-changing process, such as moving cages to the cage-washing room, dumping cages, loading and unloading cages into the cage washer, putting bedding in the cages and filling water bottles, and transporting the clean cages and bottles back to the animal rooms. Experience with the use of robots is limited, and it may be several years before their ability to save costs is determined. Ensuring that the interstitial space (space above the room ceiling) is readily accessible and is laid out so that duct work and machinery are easily maintained reduces costs and exposure of maintenance workers and animals to each other. Walls in rodent rooms might not need to withstand the assault of large animals and can be constructed with material that is less expensive than traditional concrete masonry.

The institutional animal care and use committee (IACUC) is responsible for oversight of an institution's animal care and use program. The cost of that activity is often underestimated because the institution does

not account for faculty time spent on IACUC activities. In addition to the costs of faculty time on the IACUC, there are the known costs of administrative staff to support the IACUC functions and the unknown costs of faculty time spent in completing protocols. A National Institutes of Health study of regulatory burden (NIH 1999) cited six major categories of regulatory issues: redundancy of program and facility inspections; different annual reports required by the Office of Laboratory Animal Welfare (OLAW), the US Department of Agriculture (USDA), and the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC); USDA requirements that do not allow for professional judgment; significant differences between OLAW and USDA requirements; inconsistent interpretation of regulations and policies by oversight groups; and complexity of regulations governing the import and movement of nonhuman primates. NIH did not estimate the cost of those issues, but addressing them should result in savings of time and money.

Of institutions that replied to the 1999 ARS, 48 reported costs of supporting the IACUC of $0-$301,000. Larger institutions (group 3) spent more on IACUC support, had programs for monitoring use of animals in research in addition to semiannual inspections, and had more faculty and staff serving on IACUCs; but the cost of compliance as a percentage of research dollars received was generally higher for small programs. The proposal to require USDA to regulate use of rats, mice, and birds in research will probably increase the regulatory burden, particularly for smaller institutions.

Many factors will contribute to increased mouse use over the next few years: the genome project and functional genomics, interinstitutional transfer of various mouse lines, conditional and tissue-specific mutations, chemical and viral mutagenesis, creation of therapeutic models, and in vivo gene-transfer experiments. In light of those factors, many institutions are projecting at least a threefold increase over 5 years. Other species—such as rat, rabbit, pig, and nonhuman primate—might become models in gene transfer experiments. In addition, growth in the use of aquatic species—including *Xenopus* frogs, zebrafish, and other fishes—is likely. Such projected increases require construction or renovation of new space, a portion of which must be flexible to accommodate nonrodent species.

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Preface

Care and use of animals in research are expensive, prompting efforts to contain or reduce costs. Components of those costs are personnel, regulatory compliance, veterinary medical care, and laboratory animal management, equipment, and procedures. Many efforts have been made to control and reduce personnel costs, the largest contributing factor to cost, through better facility and equipment design, more efficient use of personnel, and automation of many routine operations. However, there has been no comprehensive, recent analysis of the various cost components or examination of the strategies that have been proven or are purported to decrease the cost of animal facility operation.

The National Research Council appointed the Committee on Cost of and Payment for Animal Research (Cost Committee) in January 1998 to examine the current interpretation of governmental policy (Office of Management and Budget Circular A–21) concerning institutional reimbursement for overhead costs of an animal research facility and to describe methods for economically operating an animal research facility. The study was conducted under the auspices of the Institute for Laboratory Animal Research (ILAR) of the Commission on Life Sciences. The committee produced its first report titled *Approaches to Cost Recovery for Animal Research: Implications for Science, Animals, Research Competitiveness, and Regulatory Compliance* in May 1998. The principal conclusion of that report was that animal research facilities are used extensively for the conduct of research and support an environment and animal health profile that are integral to the validity of the experimental animal model. Hence, the facilities and

administrative (F&A) costs should be eligible for inclusion in an institution's indirect cost category. The Office of Grants and Acquisition Management of the Department of Health and Human Services ultimately accepted most of this recommendation and extended its applicability to institutions governed by Circulars A–21 and A–122 (see Appendix A). This action also catalyzed an NIH committee's final revisions of the NIH *Cost Accounting and Rate Setting Manual for Laboratory Animal Facilities*. The Cost Committee then considered cost containment methods for animal research facilities and wrote the present report. This report is intended primarily for directors and managers of animal research facilities.

The literature available to the Cost Committee that specifically addresses cost containment methods was relatively sparse. However, two other sources of information were available: The Ohio State University Committee on Institutional Cooperation Study (CIC) of 12 institutions (see Appendix B) and the Yale University 1999 Animal Resources Survey (1999 ARS) of 63 institutions (see Appendix C). The present report is based upon the experience of the committee members, most of whom have been directors of laboratory animal facilities, researchers relying on animal models or professionals overseeing research resources for many years (see biographical sketches, Appendix D), information in the literature, and the two surveys.

This report has been reviewed by persons chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the National Research Council's Report Review Committee. The purposes of the independent review are to provide candid and critical comments that will assist the authors and the National Research Council in making the published report as sound as possible and to ensure that the report meets institutional standards of objectivity, evidence, and responsiveness to the study charge. The contents of the review comments and the manuscript draft remain confidential to protect the integrity of the deliberative process. We thank the following persons for their participation in the review of this report:

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William P. Yonushonis, DVM, Director, Laboratory Animal Resources, Ohio State University, Columbus.

The list shows the diversity and background of the reviewers, again attesting to the rigor of the process of producing this report. Although the persons listed have provided many constructive comments and suggestions, responsibility for the final content of this report rests solely with the authoring committee and the National Research Council.

I am very thankful to the committee members, reviewers, and ILAR staff. Members of the committee demonstrated their expertise, dedication, and perseverance and donated their precious time and energy to focus on this project throughout their tenure on the committee. The

reviewers provided invaluable insights that helped to make the final report more relevant, informative, and robust.

The committee wishes to thank Robert Jacoby of the Section of Comparative Medicine of Yale University School of Medicine, for making available the data from the 1999 ARS, and Rajasekhar Ramakrishnan and Steven Holleran of the Division of Biomathematics and Biostatistics, Department of Pediatrics, College of Physicians and Surgeons, Columbia University, for summarizing and analyzing the data. Ralph Dell was an extraordinary liaison with the groups on the Cost Committee's behalf, playing a pivotal role during our critique and refinement of the survey instrument and the analysis of survey data. The committee deeply appreciated his deft management of the review process and concluding efforts toward publication of the final report. The committee is further indebted to Kathleen Beil and Marsha Williams, of ILAR staff, for their cheerful support of committee functions, manuscript preparation, and producing all the tables (Appendix C) summarizing the 1999 ARS.

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