Lessons learned: challenges in applying current constraints on research on chimpanzees to other animals

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Abstract The Institute of Medicine (IOM) Committee on the Necessity of the Use of Chimpanzees in Biomedical and Behavioral Research made a series of recommendations that, as of an announcement on June 26, 2013, the National Institutes of Health (NIH) is turning into implemented guidelines. Many advocates, including some researchers and scholars, have suggested that the Committee's recommendations could be applied successfully to other animal species. This article examines, from my perspective as the IOM Committee's chair, some of the most important features of the Committee's work, addresses whether chimpanzees represent a special or unique case for the purpose of research policy, and suggests an approach for evaluating the applicability of the Committee's recommendations for other animal species used in research. I first present my perspective on the features of the Committee's work that influenced its approach and conclusions. I then argue that despite the fact that chimpanzees represent a somewhat unique case for restricted research use, their case still offers important lessons for policy regarding the use of other species. Finally, I offer some observations regarding the recommendations and implications of the report from the NIH Working Group charged with crafting guidelines for implementing the IOM Committee's recommendations.

Keywords Animal research · Public policy · Chimpanzees · Institute of Medicine · NIH policy

Background on the IOM Committee

The impetus for the formation of the Institute of Medicine (IOM) Committee and its work was the proposed move in 2010 of 176 chimpanzees owned by the National

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Institutes of Health (NIH) from semi-retirement in a research colony housed at Holloman Air Force Base in Alamogordo, New Mexico, to a larger and active nonhuman primate research facility in Texas. The proposal met with strong objections from a wide array of constituent communities, ranging from animal welfare and animal rights advocates to Governor Bill Richardson and the two US Senators from New Mexico, Jeff Bingaman and Tom Udall. The concerns of stakeholders included everything from the loss of jobs to the ethics of research involving nonhuman primates.

The concerns expressed by these groups differed, but they shared a common interest in addressing questions about the future of chimpanzee use in research in the US. Because the majority of chimpanzees in research colonies in the US are either owned or financially supported by the NIH (just over 600 of the approximately 950 total animals), NIH policy effectively dictates practices around the use of about twothirds of the chimpanzees involved in research in the country. Senators Bingaman and Udall, along with Senator Tom Harkin of Iowa, authored a letter to the director of NIH requesting an in-depth analysis by the National Academies of the current and future need for chimpanzee use in biomedical research. In order to allow time for the analysis before taking any action, the NIH suspended the transfer of the animals in the Alamogordo colony in early 2011 and tasked the Institute of Medicine to undertake a study of the need for the use of chimpanzees in biomedical and behavioral research. The first meeting of the IOM Committee on the Necessity of the Use of Chimpanzees in Biomedical and Behavioral Research occurred in April 2011, and it subsequently held two additional meetings, including a public workshop. It released its report in December 2011 [1].

Notable features of the IOM Committee's work

The IOM Committee's work was influenced by a number of factors, most notably its composition and its charge. These two aspects are not unique to this particular Committee's work, but they are critical to a proper understanding of the context, constraints, and limits under which the Committee worked. Their influence on the scope and potential impact of the Committee's work and its products reached far beyond what a reader of the final report is positioned to understand or appreciate.

The Committee was a mix of basic and applied scientists (most with expertise in infectious disease), veterinarians, a primatologist, an anthropologist, a representative of the disease advocacy community, and me as chair and the only member with advanced training in ethics. This composition made for a diverse set of perspectives, but also with limited ability to address issues of ethics. That fact was reinforced by the charge to the Committee, which did not include consideration of the ethics of the use of chimpanzees in research [1, p. 13]. In spite of the composition of the Committee and limitations of the charge given to it, the Committee expressed its collective consensus view in both the public session of its first meeting and in its report that ethics must be and would be at the core of its considerations: Neither the cost of using chimpanzees in research nor the ethical implications of that use were specifically in the committee's charge. Rather, the committee was asked for its advice on the scientific necessity of the chimpanzee as a human model for biomedical and behavioral research. The committee agrees that cost should not be a consideration. However, it recognizes that any assessment of necessity for using chimpanzees as an animal model in research raises ethical issues, and any analysis must take these ethical issues into account.... For the committee, this ethical context is reflected in its assessment of when, if ever, the use of chimpanzees in biomedical research is necessary. [1, pp. 14–15]

While the recommendations of the Committee did not, and by its remit could not, focus primarily on the ethical issues raised by research on chimpanzees, ethics informed five central aspects of the recommendations made by the Committee.

First, presuming that it is acceptable to use chimpanzees in research at all—a controversial but required premise for the Committee to be able to undertake its task—the term "necessity" can and should be understood (among its many uses) as a required condition of the ethically acceptable use of chimpanzees as research subjects. In this usage it is a morally necessary, though not sufficient, condition of morally justified scientific research involving chimpanzees. The Committee was not asked to opine on what the morally sufficient conditions would be. Therefore, the principles articulated by the Committee to satisfy the conditions of necessity for the use of chimpanzees themselves advance an *ethical* and not merely a scientific requirement.

Second, the Committee recommended that animals acquiesce to their participation in particular research projects. Acquiescence is the concept by which the Committee articulated its sense that chimpanzees have the capacity to express their willingness to submit to research procedures (or their unwillingness) and thereby represents a form of voluntariness of action, without the Committee needing to take a position on whether chimpanzees have the capacity for either voluntary *assent* or voluntary *consent*—which would indicate and require more advanced cognitive capacities than does submission. Such advanced cognitive capacities are more than can be expected of chimpanzees and are required for an understanding of the concepts of assent, consent, and refusal as well as an understanding of what it is to give permission. That said, a requirement of acquiescence is an acknowledgement of at least basic decision-making capacity, voluntary action, and significant moral status, which can be realized in practice by respecting chimpanzees' abilities to make decisions and their willingness or refusal to participate in a particular research procedure.

Third, the Committee recommended that research chimpanzees be maintained in ethologically appropriate environments. The Committee was not charged with specifying the conditions of animal care and housing, which is an area of policy analysis and recommendation addressed by a standing committee of the National Research Council (NRC). However, the Committee did feel strongly that for research on chimpanzees to satisfy conditions of necessity, in addition to adhering to the recommended principles, research also needed to be performed on animals under as little stress as possible to assure that the highest quality data and the best science is performed. That meant a clear statement about suitable environments for the animals, most easily articulated as "ethologically appropriate" environments, which the Committee took to mean environments that would share the features of environments in which the animals would live under natural conditions. The Committee left the articulation of the specific details of what such conditions should include to the NIH implementation effort.

Fourth, a few aspects of the charge given to the Committee limited the scope of its analysis and recommendations. These included a focus on necessity of research related to *human* health alone and not to research that might inform or advance the health of chimpanzees or other animals. This limitation in scope was a function of the fact that the impetus of the Committee was research funded by the NIH on NIH-owned or -supported chimpanzees. Similarly, the Committee was required to restrict its recommendations to chimpanzees and no other great apes or other nonhuman primate species.

Finally, the Committee was charged with examining necessity and making recommendations regarding "contemporary and anticipated... research questions to determine if chimpanzees are or will be necessary for research discoveries" [1, p. 13]. This charge had two effects on the Committee's deliberations. First, it restricted the possibility of a finding that all use of chimpanzees in research should be prohibited because of the impossibility of predicting the near and distant future and definitively foreclosing any future uses that could meet the principles established. Second, the requirement to consider future uses necessarily limited the Committee's recommendations to high-level principles and criteria, with the expectation that implementation guidelines would be undertaken by a future body to be determined by NIH leadership. This expectation was met with recommendations for implementation released by the NIH Working Group in January 2013 [2] and acted on by the NIH director in June of the same year [3].

The case of chimpanzees and limitations on research use

The Committee made recommendations focusing on its charge to address necessity that resulted in a set of principles and related criteria that severely limit the cases in which use of chimpanzees can be justified [1, pp. 26–35]. Many interested stakeholders and scholars have since questioned whether the recommendations ought to apply more widely than to chimpanzees. One important question is: does the chimpanzee represent a unique case for creating restrictions on research use? I argue that the answer is a qualified yes (where the qualifications themselves are important moral considerations) for reasons that fall into two categories: considerations that are unique to chimpanzees in research captivity and particular aspects of the practices of using chimpanzees as a research model.

Among the reasons chimpanzees have been consistently used in research are (1) features unique to them as a species, and (2) unique aspects of US research practice and policy. Chimpanzees are nearly as long-lived as humans, with lifespans reaching 70 years in captivity. This longevity, combined with a federal ban on

euthanasia of research chimpanzees except "as in the best interests of the chimpanzee involved" [4], has meant that a large population of research chimpanzees is housed at taxpayer expense and treated as an available research resource. Unlike the case in any other research animal species, this ready availability and commitment to long-term care and housing has made for persistent ongoing use of chimpanzees in research over many years. Second, the IOM Committee found that in practice, chimpanzees are used in research largely when no other suitable animal models are available or appropriate, or when the closest approximation to humans is desirable, making chimpanzees the animal model of last resort and among the most difficult and expensive animals to use in research.

Finally, a recommendation of the IOM Committee regarding the use of chimpanzees that is unlikely to apply to the use of many other species is the following: "There must be no other research model by which the knowledge could be obtained, and the research cannot be ethically performed on human subjects" [1, p. 4]. This recommendation was justified by a feature particular to chimpanzee research, in that biomedical research protocols involving chimpanzees consist almost exclusively of studies related to human health that could also be justifiably performed on humans, such as studies of treatment of infectious disease requiring infected subjects. The Committee's view was both that justifiable studies of human health yield more useful results when performed on humans and that past practice and ready availability of chimpanzees has made them a sometimes too easily used resource as a replacement for human subjects. In contrast, the use of human rather than animal subjects is more difficult to justify in much earlier-stage basic science research meant to assess biological mechanisms or early toxicology studies rather than research that is meant to be the final step before human trials.

These particularities of chimpanzee research make it difficult to justify the direct application to other species of the principles articulated by the IOM Committee. That is not to say that the principles will not be important in consideration of research on other species, but that additional conceptual and justificatory work will be required both to modify the principles appropriately and to defend their appropriateness and applicability.

The further applicability of the Committee's recommendations

The basic necessity framework presented by the Committee is among the features that should have wider applicability, as should some general lessons from the Committee's analysis of chimpanzee research. Applying a necessity framework to animal research beyond chimpanzees and even great apes is attractive for the work it could do to explicitly acknowledge the importance of necessity for scientifically robust and ethically defensible uses of nonhuman animals in research. This will require additional conceptual work to articulate the concept of "necessity" beyond the rather primitive conceptions in currently available literature. This work of specification for categories of animal species used in research can begin with and be advanced by the Committee's framework. In the sections that follow, I enumerate what I take to be a few key lessons that are to be learned from the IOM Committee's work and report.

Past value is not a predictor of future necessity

When researchers were asked in the past to justify their claims that continued use of chimpanzees should be endorsed, they unfailingly pointed to examples of research performed in chimpanzees that led to clear and seemingly unmistakable advances in human health. In every case, however, the Committee found that while those past examples did lead to important gains in human health, either alternative research models exist today or the same research could be performed safely with human subjects using current-day research methods. From this perspective, there was no valid claim of scientific necessity for the current or future use of chimpanzees. Similar analysis should prove to be a useful exercise for assessing the continuing use of other animal species.

An available resource is a used resource

As noted above, captive research chimpanzees occupy a unique category as research animals—they are long-lived, they cannot be euthanized as a rule, and the majority of the population is owned or supported by federal research dollars. This unique combination of features has given research using chimpanzees its own inertia, and, while no other research animal species shares the combination of features unique to that of chimpanzees in research, it is worth considering whether parallel thinking or behaviors may be responsible for the use of other animal species.

Criteria based on necessity force justification

Among the changes that the IOM Committee's framework introduced is the requirement to justify, based on necessity, use of chimpanzees in research. This may be the most important and lasting contribution of the Committee's work, in that it introduces a requirement that stringent criteria must be met, with fact-based justifications in support of claims that the criteria are satisfied. Implementation will depend on the creation and implementation of a review process by which proposals for research on chimpanzees can be evaluated. The steps necessary for establishing such a process are described below.

Observations from the NIH Working Group report

Just over a year after the release of the Committee's report, in January 2013, an NIH Working Group appointed by NIH Director Francis Collins issued a report on guidance implementing the Committee's recommendations [2]. The intervening year between the end of 2011 and the end of 2012 was not one of inactivity, however. Not long after the release of the Committee's report, New Iberia Research Center (NIRC), the facility that holds the largest group of privately owned

chimpanzees, announced that it would apply the IOM Committee's guidelines to research on *both* the NIH-owned and privately owned chimpanzees in its facility; and in late 2012, the NIH announced that all the chimpanzees it owned at NIRC would be retired to a sanctuary within 12–15 months, with the first 125 making the move to sanctuary as soon as additions could be constructed at existing facilities.

The Working Group report, issued on January 23, 2013 [2], represented the second phase in the recommended changes to research policies related to chimpanzees. That report provided guidance to the NIH Director through the NIH Council of Councils. The Working Group was created "to advise the NIH on the implementation of the recommendations of the Institute of Medicine's (IOM's) Committee on the Use of Chimpanzees in Biomedical and Behavioral Research regarding the use of chimpanzees in NIH-sponsored research" [2, p. 2], and on June 26, 2013, NIH Director Francis Collins announced the agency's decisions regarding implementation. In what remains of this commentary, I will provide an evaluation of the guidance contained in the Working Group's report and NIH implementation announcement, in terms of how well they meet the recommendations and intentions of the IOM Committee's report.

Overall, the NIH Working Group's guidelines and the subsequent NIH decision represent a faithful implementation of the IOM Committee's recommendations, and both documents offer compelling arguments supporting the IOM principles and criteria [2, 3]. This fact alone is a heartening conclusion because of its strong endorsement of the analysis, principles, criteria, and recommendations of the IOM Committee and indicates a clear path towards implementation in the form of NIH policy. The explicit endorsement of the Committee's overall approach indicates an unstated but important implicit agreement with the ethical positions embedded in the Committee's positions. Like the Committee, the Working Group indicated that the trajectory in the necessity for the use of chimpanzees is trending rapidly towards zero and went somewhat further than the IOM Committee in suggesting that it had difficulty envisioning any need whatever for research on emerging diseases.

Because it could not absolutely rule out the possibility of future necessity for research on new, emerging, or re-emerging diseases, the Working Group recommended retaining a small standby population of 50 animals, sufficiently diverse in age and gender and between research-experienced and research-naïve animals [2]. One wonders how this objective will be maintained given the Working Group's recommendation of a breeding ban. The limited support offered for the need for a reserve research population coupled with a breeding ban seems to indicate a view that even this smaller research population may be unnecessary and soon will diminish to zero. Further evidence of skepticism over a true ongoing need is the Working Group's recommendation of frequent ongoing assessment of the need, size, and composition of any maintained research colony. The NIH announcement endorsed this view in establishing a research population of no greater than 50, with re-evaluation after 5 years [3].

Finally, the evident trajectory towards far fewer chimpanzees maintained for biomedical research will have implications on where and how behavioral research can and will be performed going forward. The implication of the Working Group's recommendation regarding future colony size and its recommendations to "re-examine programmatic priorities in these [behavioral] areas of research" [2, p. 32] is that behavioral research on chimpanzees will look very different in the future than it has in the past, including moving from traditional research settings to "nontraditional research settings, such as accredited sanctuaries and zoos, as long as such settings provide ethologically appropriate physical and social environments" [2, p. 32].

The NIH announcement marks the culmination of a two-plus-years process, with the agency fully implementing the IOM Committee's principles and criteria as recommended. The only aspect of the Working Group's recommendations that was not adopted are the specifics it crafted regarding the enclosure size necessary to meet the IOM Committee's criterion regarding "ethologically appropriate" housing, on the grounds that greater research is needed [3]. Such research will be important for determining how best to implement this remaining recommendation from the Committee.

Conclusion

Among the most important features of the IOM Committee's recommendations was that arguments from necessity should be rendered coherent with arguments and perceptions about ethics. This alignment made for well-grounded conclusions that met with support from a diverse range of stakeholders, despite their potentially divergent perspectives, and contributed to the significant policy impact of the Committee's work. This observation raises questions about how successful the process would have been had a different set of perspectives led to more divergent conclusions. Fortunately the path from facts to recommendations was clear, and the policy environment for research on chimpanzees has changed dramatically as a result. While it remains to be seen whether the changes will have more generalizable impact on policies related to other nonhuman animal species used in research, it is now beyond reasonable doubt that the IOM Committee's efforts and experience, augmented by the subsequent recommendations of the Working Group and implementation by the NIH, offer vital lessons and precedents for the future of animal research policy generally.

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