

Does Accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) Ensure Greater Compliance With Animal Welfare Laws?

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Accreditation of nonhuman animal research facilities by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) is widely considered the “gold standard” of commitment to the well being of nonhuman animals used in research. AAALAC-accredited facilities receive preferential treatment from funding agencies and are viewed favorably by the general public. Thus, it bears investigating how well these facilities comply with U.S. animal research regulations. In this study, the incidences of noncompliance with the Animal Welfare Act (AWA) at AAALAC-accredited facilities were evaluated and compared to those at nonaccredited institutions during a period of 2 years. The analysis revealed that AAALAC-accredited facilities were frequently cited for AWA noncompliance items (NCIs). Controlling for the number of animals at each facility, AAALAC-accredited sites had significantly more AWA NCIs on average compared with nonaccredited sites. AAALAC-accredited sites also had more NCIs related to improper veterinary care, personnel qualifications, and animal husbandry. These results demonstrate that AAALAC accreditation does not improve compliance with regulations governing the treatment of animals in laboratories.

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In the international scientific community, voluntary accreditation of nonhuman animal research facilities by the private Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) is widely considered by scientists, research institutions, and

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government agencies to be the “gold standard” (Boone & Holt, 2000; French, 2012; Wersinger & Martin, 2009) of laboratory oversight and commitment to the well being of nonhuman animals used in research.

To secure AAALAC-accreditation, a facility must first submit to AAALAC with an application fee and a detailed description of its animal care and use program (program description), including information on animal husbandry, veterinary care, professional, technical, and administrative support for the program, institutional policies pertaining to animal care and use, and the facilities where the animals are housed and used. Two or more AAALAC representatives tour the facility and prepare an evaluative report based on standards derived from the *Guide for the Care and Use of Laboratory Animals* (Institute of Laboratory Animal Research [ILAR], Committee for the Update of the Guide for the Care and Use of Laboratory Animals, National Research Council, 2011)—considered “a basic guide to the establishment of specific standards for accreditation” (AAALAC, 2013g)—along with additional standards “based on prevailing directives, conventions and guidelines in the country where the accreditable unit is located” (AAALAC, 2013g). In the United States, AAALAC (2010) explains that these standards include the Animal Welfare Act (AWA) and the *Guide for the Care and Use of Laboratory Animals* (ILAR, Committee for the Update of the Guide for the Care and Use of Laboratory Animals, National Research Council, 2011). Additionally, AAALAC has stated the following: “Full accreditation is accepted by the National Institutes of Health and other funding agencies that the unit is in compliance with PHS Policy and the Animal Welfare Act and that it conforms both in spirit and intent with the *Guide*” (New, 1990, pp. 8–9).

Based on the program description and site visit reports, AAALAC grants or denies accreditation to a facility. The facility may be granted full or conditional accreditation; in the latter case, the facility must correct the deficiencies noted in the evaluation to secure full accreditation. Accredited facilities must pay an annual fee based on the physical size of the facility; for instance, facilities spanning 100,000 square feet to 199,999 square feet must pay an application fee of \$10,875 and an annual fee of \$7,350 (AAALAC, 2013c). An accredited facility must submit an annual report to AAALAC, describing “elements of the animal care and use program” (AAALAC, 2013g), and it is subject to scheduled triennial inspections.

If a facility exhibits serious deficiencies, it can be placed on probation (probationary accreditation) for a period not exceeding 12 months, during which time the facility is given an opportunity to correct the deficiencies identified. If additional deficiencies are noted, an additional probationary period, not exceeding 12 months, may be granted. On its website, AAALAC (2013f) notes, “Notice of Probation shall be made known only to the unit (the facility) and to AAALAC International.” If the deficiencies are not corrected in the allotted time, “proceedings to revoke accreditation are initiated” (AAALAC, 2013b).

More than 900 international companies, universities, hospitals, government agencies, and other research institutions in 37 countries have earned AAALAC accreditation (AAALAC, 2013a). This group includes the top 100 U.S. National Institutes of Health (NIH) awardees and about 90% of the next 100 NIH awardees (Office of Laboratory Animal Welfare [OLAW], NIH, 2009). It also includes all major U.S. pharmaceutical companies and the commercial laboratories that breed animals for research as well as government laboratories, biotechnology companies, and contract research organizations.

Christian Newcomer, AAALAC’s executive director, has stated, “There is a strong feeling that [AAALAC accreditation] aids the credibility and the public perception of the orga-

nization conducting animal research” (OLAW, 2009). This sentiment permeates throughout the research community. When discussing ways to counteract dwindling public support for animal experimentation, 29 researchers from the United States, Europe, Australia, and Africa advised that obtaining “voluntary assessment and accreditation from international organizations, for example, the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), is highly recommended. This will not only ensure animal welfare but also protect scientists worldwide against accusations of performing animal research that would not be ethically or legally acceptable within the [European Union] or United States” (Dancet et al., 2013, p. 1).

Beyond simply improving facilities’ public images, this accreditation is promoted by the AAALAC to be, and is understood by others to signify, an assurance of compliance with relevant guidelines governing animal research. On its website, AAALAC (2013a) states that “through AAALAC’s voluntary accreditation process . . . research programs demonstrate that they meet the minimum standards required by law, and are *also* going the extra step to achieve excellence in animal care and use.” Likewise, the U.S. Food and Drug Administration writes, “The symbol of AAALAC represents to the laboratory animal community and the public that a program is operating at standards that exceed the Federal rules and regulations” (Boone & Holt, 2000, p. 1).

Consequently, because of the belief that AAALAC accreditation signifies superior compliance and animal care, the designation often carries considerable weight in influencing a facility’s eligibility for, and success in securing, contracts and grants with both private and governmental organizations. Federal and private grant and contract solicitations often specify that AAALAC accreditation is preferred or required for potential service providers. To continue to receive federal funding, the NIH allows facilities to submit evidence of AAALAC accreditation in lieu of their own internal laboratory inspection reports as verification that they are in compliance with the relevant guidelines (NIH, 2002).

Similarly, the U.S. Department of Defense (DoD) waives its requirement for an on-site inspection of animal suppliers and research contractors when those companies are AAALAC-accredited (DoD, 2010). Moreover, all DoD institutions that house animals for research, testing, or training are required to secure and maintain AAALAC accreditation (DoD, 2010). The University of California system requires that all of its member campuses be AAALAC-accredited (Smith, 2011). Several private foundations, such as the American Heart Association, recommend that grantees be AAALAC-accredited (Smith, 2011).

An animal research facility’s AAALAC-accredited status is often cited in scientific articles as a form of assurance to editors and readers that relevant regulations were followed and animals were treated humanely (Cooper, Foltin, & Evans, 2013; Guagnini, Ferazzini, Grasso, Blanco, & Croci, 2012). Though AAALAC accreditation is incredibly influential, its effectiveness at identifying superior animal care programs is primarily taken for granted and there have not been any objective third-party evaluations of whether AAALAC accreditation actually accomplishes what it claims to do: guarantee accredited facilities will meet and exceed relevant laws and guidelines. More than two decades ago, AAALAC voluntarily published aggregated data about the results of its site inspections (New, 1990), but because the organization is private, all of its deliberations, preliminary reports, and site inspection results are “confidential . . . even if deficiencies are found” (AAALAC, 2013d).

Although the details of AAALAC's own evaluations are not made public, there are other publicly accessible metrics that can be used to measure whether an institution is meeting and exceeding the minimum standards required by law, as AAALAC-accredited facilities are supposed to do. AAALAC standards require that U.S. research facilities abide by federal laws, including the AWA (AAALAC, 2010, 2013g; New, 1990) for which compliance information is accessible to the public.

The AWA governs the housing, treatment, oversight, and use of certain animal species in research, education, and testing (U.S. Congress, U.S. Code, 2012). Slightly more than 1 million animals in U.S. laboratories were regulated by the AWA in 2010 (Animal and Plant Health Inspection Service [APHIS], U.S. Department of Agriculture [USDA], 2011b). The AWA does not cover mice of the genus *Mus*, rats of the genus *Rattus*, birds bred for research, fish, reptiles, amphibians, or farm animals used in agricultural research (U.S. Congress, U.S. Code, 2012). Facilities housing regulated species are required by law to be inspected by a veterinarian from the USDA at least once a year, during which a sample of the research protocols at an institution are reviewed and some of its laboratories receive a visit to ascertain compliance with AWA standards. If deficiencies are identified, facilities are cited for noncompliance items (NCIs) and are given an opportunity to correct the problems. Those cited for repeated NCIs are subject to inspection at least once every 6 months. Unlike other performance measures evaluated by AAALAC, the results of these USDA inspections are easily quantifiable and sortable, and they can be accessed publicly on the Internet.

The current study fills a gap in the literature on research compliance and the AAALAC accreditation process by using publicly available data generated by the USDA to assess compliance with the AWA at AAALAC-accredited institutions and by comparing those data with compliance outcomes from non-AAALAC research facilities.

MATERIALS AND METHODS

Data Collection and Organization

Using data published on the USDA Animal Care Information System searchable database (APHIS, USDA, 2013) and data obtained from the USDA via a Freedom of Information Act request, we compiled annual animal use statistics and NCIs cited by federal inspectors for all 1,230 registered research facilities in USDA Fiscal Years 2010 and 2011 (October 1, 2009–September 30, 2011). For each facility, we calculated the total number of NCIs and catalogued the NCIs by the nature of each infraction. Using the section of the Animal Welfare Regulations (USDA, 2009) that was cited by the USDA for each NCI examined as a guide, we categorized the NCIs into noncompliances related to improper (a) veterinary care, (b) personnel qualifications, (c) animal husbandry, (d) Institutional Animal Care and Use Committee oversight, and (e) recordkeeping/sanitation.

Our analysis included all NCIs cited by the USDA, encompassing those identified as “direct” and “indirect” (APHIS, USDA, 2011a). We did not differentiate between the two for the study because the labels are applied inconsistently and, as the USDA has acknowledged, the dichotomy does not sufficiently describe whether the health and well being of animals were compromised as a result of the NCIs (R. Gibbens, regional director, USDA APHIS Animal Care

Western Region, personal communication, June 14, 2012). Instead, we feel that the categories listed, based on the nature of the NCIs, better illustrate the potential impact on animals' welfare.

The data set was initially composed of all 1,230 research facilities that were registered with the USDA for some duration from Fiscal Years 2010 and 2011. There were 407 facilities excluded from our analysis because they housed no regulated animals ($N = 126$), had missing inspection reports ($N = 10$), did not maintain USDA registration ($N = 212$), or did not maintain the same AAALAC accreditation status ($N = 59$) during the 2-year period. AAALAC accreditation status for each facility was ascertained by reviewing archived versions of AAALAC's "Accredited Organizations" web page from 2009 and 2011 (Internet Archive, 2009, 2011). AAALAC's online roster does not distinguish between facilities that have full accreditation and those that do not, nor is this information available from any other publicly available source.

A total of 823 animal research facilities were included in the analysis, of which 315 were AAALAC-accredited and 508 were not accredited. In terms of size, 417 of the facilities reported 400 or fewer regulated animals during the span of the study; 309 reported 401 to 3,999 regulated animals during the span of the study; and 97 reported more than 3,999 regulated animals during the span of the study. A total of 499 facilities were located in the USDA's Eastern region and 324 were located in the Western region, which is relevant because a 2005 federal audit found differences in the prevalence of NCIs between the two regions (USDA, Office of Inspector General [OIG]/Western Region, 2005).

Statistical Analysis

Dependent variable. The dependent variable is the total number of NCIs by site as reported by the USDA. We found this variable to have high variability and to be overdispersed (i.e., its mean was considerably lower than its variance; Table 1). For these reasons, we could not use linear or Poisson regression techniques. Therefore, the most appropriate analytic technique to use is negative binomial regression (for more, see Hilbe, 2011).

Independent variables. To explore the impact of our explanatory variables and test our hypotheses, we assessed the relative fit of four models. Models 1, 2, and 3 used NCIs associated with improper veterinary care, personnel qualifications, and animal husbandry as the dependent variable. Model 4 considered the sum total of all NCI types. Each model was composed of three variables. They included dummy variables for whether a specific facility was accredited by AAALAC (yes = 1) and the USDA region (Eastern = 1) in which a facility was located. We included the Eastern region variable because excluding it would have likely introduced bias into the model. To control for the size of the facility, we also included the number of regulated animals at each site as a predictor.

RESULTS

Table 1 lists descriptive statistics for all independent and dependent variables separated by AAALAC designation. About 40% of the sample consisted of AAALAC-accredited facilities. Our analysis revealed that on average, for the 2 years under consideration, AAALAC-accredited

TABLE 1
Mean Animal Welfare Act (AWA) NCIs at AAALAC-Accredited and
Nonaccredited Facilities during FYs 2010 and 2011

<i>Variable</i>	<i>Non-AAALAC (SD) (N = 508)</i>	<i>AAALAC (SD) (N = 315)</i>
Total Number of NCIs	1.56 (2.26)	2.13 (3.37)
Veterinary NCIs ^a	0.21 (0.59)	0.35 (0.79)
Personnel NCIs ^b	0.02 (0.015)	0.10 (0.42)
Husbandry NCIs ^c	0.28 (0.79)	0.58 (1.37)
IACUC NCIs ^d	0.66 (1.19)	0.70 (1.31)
Recordkeeping NCIs ^e	0.38 (0.86)	0.41 (0.91)
Eastern Region	55.5%	68.9%
Total Regulated Animals	1,111.3 (4,508.1)	4,194.4 (11,225.1)

Note. NCI = noncompliance items; AAALAC = Association for Assessment and Accreditation of Laboratory Animal Care International; FY = Fiscal Year.

^aIncludes AWA Sections 2.33; 2.40; 3.110.

^bIncludes AWA Sections 2.32; 3.12; 3.32, 3.57; 3.85; 3.108; 3.132.

^cIncludes AWA Sections 2.38 (f); 2.131; 3.19; 3.41; 3.66; 3.92; 3.118; 3.142; 3.8; 3.81; 3.9–3.10; 3.16; 3.29–3.30; 3.38; 3.54–3.55; 3.63; 3.82–3.83; 3.89; 3.105; 3.115; 3.129–3.130; 3.139; 3.1–3.7; 3.13; 3.14; 3.15; 3.17; 3.18; 3.25–3.28; 3.33–3.37; 3.39; 3.40; 3.50–3.53; 3.58; 3.60–3.62; 3.64; 3.65; 3.75–3.80; 3.86–3.88; 3.90; 3.91; 3.100–3.104; 3.106; 3.109; 3.112–3.114; 3.116; 3.117; 3.125–3.128; 3.133; 3.136–3.138; 3.140–3.141.

^dIncludes AWA Section 2.31.

^eIncludes AWA Sections 2.1; 2.27; 2.30; 2.35; 2.36; 2.38 (a), (b), (c), (g), (h), (i); 2.75; 3.31; 3.11; 3.31; 3.56; 3.84; 3.107; 3.131.

facilities were cited for 2.13 ($SD = 3.37$) NCIs or just more than 1 per year, while nonaccredited facilities were cited for 1.56 ($SD = 2.26$) NCIs or about 0.75 per year. These numbers are significantly different, with AAALAC-accredited facilities showing significantly more NCIs than nonaccredited sites, $t(821) = 2.90$, $p < .05$. The NCI types show similar patterns (Table 2).

Table 3 presents results from the negative binomial regression model predicting the number of NCIs during Fiscal Years 2010 and 2011. All four models show the same pattern of significant predictors. Thus, we present them all in Table 3 but only discuss Model 4 (dependent variable = sum of all NCI types) in detail. The results indicate that the percent change in the incident rate of number of NCIs is a 0.2% increase for every 100 additional animals housed at the site. The result for the Eastern region variable confirms the findings of a 2005 USDA OIG Audit Report (USDA OIG/Western Region, 2005), which showed that more than twice as many Eastern

TABLE 2
Number of AWA NCIs by Type at AAALAC-Accredited and Nonaccredited Facilities
During FYs 2010 and 2011

	<i>IACUC</i> N (%)	<i>Veterinary</i> N (%)	<i>Personnel</i> N (%)	<i>Handling</i> N (%)	<i>Other</i> N (%)	<i>Total</i>
Non-AAALAC	336 (42.5)	109 (13.8)	10 (1.3)	144 (18.2)	191 (24.2)	790
AAALAC	220 (32.7)	110 (16.4)	32 (4.7)	182 (27.1)	128 (19.1)	672

Note. AWA = Animal Welfare Act; NCI = noncompliance items; AAALAC = Association for Assessment and Accreditation of Laboratory Animal Care International; FY = Fiscal Year.

TABLE 3
Negative Binomial Regression Models With Number of NCIs by Type as Dependent Variable

	<i>Veterinary NCIs (SE)</i>	<i>Personnel NCIs (SE)</i>	<i>Husbandry NCIs (SE)</i>	<i>Sum of NCIs (SE)</i>	<i>IRR</i>
Intercept	-1.643*** (.156)	-4.230*** (.431)	-1.347*** (.162)	0.240** (.089)	1.271
Predictors					
AAALAC Site (Yes = 1)	0.397* (.178)	1.538*** (.422)	0.558*** (.162)	0.215* (.105)	1.241
Eastern Region (Eastern = 1)	0.074 (.180)	0.258 (.415)	0.075 (.188)	0.304** (.105)	1.356
Total Number of Regulated Animals/100	0.003*** (.001)	0.005*** (.001)	0.004*** (.001)	0.002** (.001)	1.002
McFaddens's Adjusted R^2	.035	.149	.045	.041	
Dispersion Parameter (θ)	.460 (.094)	.158 (.061)	.256 (.036)	.673 (.055)	
<i>N</i>	823	823	823	823	

* $p < .05$. ** $p < .01$. *** $p < .001$.

Note. NCI = noncompliance items; AAALAC = Association for Assessment and Accreditation of Laboratory Animal Care International.

region facilities had NCIs than did Western region facilities and that 88% of the top 50 repeat offenders were located in the Eastern region.

To further understand our findings, we computed the predicted NCI counts for each value of AAALAC status while holding all other predictors at their mean. We found that the predicted number of NCIs for sites with AAALAC accreditation was higher than the predicted number of NCIs for sites without AAALAC accreditation ($1.97 > 1.59$).

DISCUSSION

A poster produced by AAALAC (2013e) for use by accredited facilities reads, "We are Accredited by AAALAC International . . . Accreditation is voluntary, and we have chosen to meet standards that go above and beyond the animal research regulations required by law. AAALAC accreditation is recognized worldwide as the 'gold standard' for animal research programs." This is viewed as conventional wisdom in the biomedical research community, and facilities are rewarded in various ways for obtaining this designation. Yet, the AAALAC accreditation and oversight process remains entirely confidential, therefore preventing outside evaluations of the efficacy of the program.

Our current study demonstrated that despite these ambitions, AAALAC-accredited facilities are regularly cited for NCIs regarding federal regulations governing the welfare of animals in laboratories. It is most important to note that our analysis showed that AAALAC-accredited facilities had significantly more NCIs than did nonaccredited facilities. Additionally, in key areas related to the well being of animals—veterinary care, personnel qualifications, and animal husbandry—AAALAC sites had more NCIs than non-AAALAC sites.

The low McFaddens's adjusted R^2 of .041 was most likely due to a combination of three factors: (a) restrictions on the availability of data that led us to use a relatively small number of predictors (three), (b) a relatively large number of cases (823), and (c) a high degree of variability in the dependent variable. However, the models probably represent a conservative view of the true effect of AAALAC status on the number of NCIs. Nevertheless, we recommend that the results be viewed with appropriate caution.

The actual impact of a difference in one NCI between facilities on animal welfare is difficult to assess because a single NCI may reflect a minor issue, but it can also indicate problems that are quite severe and pervasive and that cause substantial suffering. For example, there are situations in which a single veterinary care NCI cited by the USDA has been issued for a facility providing inadequate anesthesia for as many as 50 individual goats during highly invasive surgical procedures (APHIS, USDA, 2011d), and one animal husbandry NCI was issued to a facility for not providing the required scientific justification for singly housing 1,100 nonhuman primates with no opportunities for tactile interactions with other primates (APHIS, USDA, 2011c). On the other hand, a single veterinary care NCI could also indicate a paperwork deficiency that does not adversely affect animals (APHIS, USDA, 2012). Unfortunately, the specifics about each individual NCI that would be informative about direct impacts on animal welfare could not be ascertained and, therefore, were not used in the study. For example, though some USDA inspectors include the information in their publicly accessible inspections reports, these reports regularly do not include information about what species were involved in the NCI, how many animals were actually affected by each NCI, and how severely they were affected.

In addition, as mentioned earlier, the USDA designations of "direct" and "indirect" NCIs are unfortunately not particularly useful as ways to distinguish the severity of NCIs because, by design, both labels encompass problems directly affecting animals' health and well being, and they are not applied consistently. For example, the NCI cited earlier related to inadequate anesthesia for 50 goats was labeled "direct," while the primate-related NCI was listed as "indirect," even though both have serious implications for the welfare of the animals affected. It should further be noted that data distinguishing different types of AAALAC accreditation were not available; therefore, we do not know whether facilities with NCIs were fully or probationally accredited during the time studied. A more detailed evaluation would require an alternative approach, possibly using a case-study format and qualitative methods.

With this all said, AAALAC (2013e) accreditation alleges to distinguish facilities that "go above and beyond the animal research regulations required by law." Thus, the fact that AAALAC-accredited facilities regularly violate the primary federal law in the United States that governs the treatment of animals in laboratories and that they have more NCIs than non-AAALAC facilities overall and in key categories related to animal welfare is evidence enough to call for a review of the efficacy of the AAALAC system.

CONCLUSION

AAALAC accreditation is supposed to signify a heightened commitment to animal welfare and compliance with relevant laws, guidelines, and regulations governing the use of animals in experiments. However, our data are the first to show that AAALAC-accredited facilities are

failing to meet these minimum standards, using one key performance measure, and they are actually more likely to violate animal welfare laws compared with nonaccredited facilities.

Given these findings, funding agencies, journal editors, the public, and the media should be careful about accepting AAALAC accreditation at face value as the “gold standard” for compliance and the humane treatment of animals in laboratories. Science policy and funding decisions, like medical ones, should be evidence-based, and greater transparency by AAALAC would allow stakeholders to better evaluate the effectiveness of the program.

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