AN INTERNATIONAL ORGANIZATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

PETA

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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Dear Dr. Anderson,

Thank you in advance for your time. I am writing to you on behalf of People for the Ethical Treatment of Animals (PETA) and our international affiliates with more than 5 million members and supporters around the world in support of the National Council for the Control of Animal Experimentation's (CONCEA) focus on improving animal welfare in laboratories, with specific attention to implementing the 3Rs to reduce, refine and replace the use of animals in experiments and teaching exercises. We would welcome an opportunity to work collaboratively towards this goal with CONCEA, as we have done with similar international regulatory agencies.

In accordance with Brazilian law—which mandates the use of non-animal medical training methods when available—we respectfully ask that CONCEA take concrete steps to fully replace Brazil's use of animals in the biomedical and life science education areas discussed below, as other countries have already done, in favor of superior and cost-effective non-animal methods.

Paradigm Shift

Biomedical education has traditionally used animals to teach human physiology, study human anatomical form and function, and practice human surgical procedures. Yet, there have been many recent developments that have contributed to a paradigm shift in support of non-animal biomedical education, including: Studies showing high-fidelity human patient simulation (HPS), computer assisted learning (CAL) software, and virtual reality (VR) programs teach biomedical education as well as or better than animal dissection and experimentation;[1] rising public opposition to animal use in laboratories;[2] animal

[1] Patronek GJ, Rauch A. (2007). Systematic review of comparative studies examining alternatives to the harmful use of animals in biomedical education. J Am Vet Med Assoc. 230 (1): 37-43.
[2] Goodman JR, Borch CA, Cherry E. Mounting opposition to vivisection. Contexts. 2012; 11(2): 68-69.

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laboratory cost burdens;[3] and a renewed focus by the medical community on improving patient safety and reducing clinical errors through simulation-based training.[4] Human simulation-based learning has become the gold standard.

We are pleased to see that CONCEA recently held a symposium on alternatives to the use of animals in education, for which you noted, "Brazil needs to be more aware of alternative methods to animal use. Researchers and teachers can no longer claim ignorance of regulations on laboratory animals published by national territory."[5] We support CONCEA's efforts to educate researchers and educators about the benefits of using non-animal training methods and the mandate to use such models in accordance with Brazilian law.

Advantages of Simulation-Based Biomedical Training

Medical experts have recommended the transition from an animal-based pedagogy to "a robust curriculum composed of didactics, task trainers, virtual reality, cadavers, computer software, high-fidelity patient simulators, and supervised clinical work."[6] Unlike animal-based laboratories, innovations in biomedical simulation technology have created important new cost-effective ways to accurately model human anatomy and physiology,[7] create challenging immersive scenarios that mimic real-world medical cases,[8] provide students with vital opportunities to repeat medical procedures until proficiency,[9] improve provider confidence and transference of learned skills to clinical practice,[10] and allow educators to receive real-time objective performance feedback.[11]

Brazilian Law Mandates Use of Non-Animal Training Methods

Article 32, §1, of Brasil's Lei de Crimes Ambientais (Lei de nº 9.605, de 13 de Fevereiro, de 1998) states: "Praticar ato de abuso, maus-tratos, ferir ou mutilar animais silvestres, domésticos ou domesticados, nativos ou exóticos: … § 1º Incorre nas mesmas penas quem realiza experiência dolorosa ou cruel em animal vivo, ainda que para fins didáticos ou científicos, quando existirem recursos alternativos."[12]

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[3] Reznick RK, MacRae H. Teaching surgical skills--changes in the wind. N Engl J Med. 2006 Dec 21;355(25):2664-9.

[4] Institute of Medicine. To err is human: Building a safer health system. Kohn LT, Corrigan JM, and Donaldson MS (eds). Washington, DC: National Academy Press, 1999.

[5] Conselho Federal de Biologia. CONCEA realiza simpósio sobre alternativas ao uso de animais no ensino. September 14, 2016. Available at: http://www.cfbio.gov.br/artigos/CONCEA-realiza-simposio-sobre-alternativas-ao-uso-de-animais-no-ensino; Accessed: November 18, 2016.

[6] Hansen LA. Animal laboratories are not needed to train medical students. J Surg Educ. 2014; 71(4): 454.

[7] Ritter EM, Bowter MW. Simulation for trauma and combat casualty care. Minim Invasive Ther Allied Technol. 2005;14(4):224-34.

[8] Hammond J. Simulation in critical care and trauma education and training. Curr Opin Crit Care. 2004 Oct;10(5):325-9.

[9] Ziv A, Wolpe PR, Small SD, Glick S. Simulation-based medical education: an ethical imperative. Acad Med. 2003 Aug;78(8):783-8.

[10] Sergeev I et al. 2012. Training modalities and self-confidence building in performance of life-saving procedures. Military Medicine; 177 (8): 901–6.

[11] DeVita MA, Schaefer J, Lutz J, Wang H, Dongilli T. Improving medical emergency team (MET) performance using a novel curriculum and a computerized human patient simulator. Qual Saf Health Care. 2005 Oct;14(5):326-31.

[12] Lei nº 9.605, de 12 de fevereiro de 1998 <http://www.ibama.gov.br/fauna/legislacao/lei_9605_98.pdf>.

The law is clear – when there is an alternative to the use of animals for biomedical training, the non-animal training method must be used instead of using animals. However, it appears that in various medical training disciplines in Brazil, educators throughout the country continue to use animals for biomedical education despite this practice having been discontinued by other educators around the world.

Undergraduate Medical Training

In the past, undergraduate medical students around the world have performed various invasive and terminal procedures on live animals in classroom experiments, such as the following: Surgically opening dogs' chests to demonstrate the cardiac and pulmonary effects of drugs in physiology and pharmacology courses;[13] operating on pigs' torsos and removing organs during surgical courses and repeatedly intubating cats and ferrets during resuscitation exercises;[14] administering drugs to rabbits' eyes and measuring the effects of stimulants and depressants on mice;[15] dissecting live frogs and exposing their hearts to various drugs;[16] and isolating guinea pigs' small intestines to observe their response to administered drugs.[17] In Brazil, medical schools continue to widely use animals in the undergraduate curricula, yet various researchers are developing alternatives to animal use practicals and a student's conscientious objection to laboratory animal use is now a legally protected right.[18]

In the United States and Canada, students now learn without using any animals during the undergraduate medical curricula,[19] and India has amended its medical education regulations to completely replace animal use with non-animal teaching methods.[20] Professional organizations, such as the American Medical Student Association—the U.S.'s oldest and largest independent organization of nearly 40,000 physicians-in-training— have adopted formal position statements strongly favoring the replacement of animal use in medical training with non-animal methods,[21]

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[13] Clark C. UCSD's use of live dogs in lab decried. The San Diego Union-Tribune. February 12, 2003. Available at: http://legacy.sandiegouniontribune.com/news/science/20030212-9999_1n12meddogs.html; Accessed: November 17, 2016.

[14] Blum A. Medical students no longer train on live animals at Bethesda-based military school. The Washington Post. September 6, 2013. Available at: https://www.washingtonpost.com/local/medical-students-no-longer-train-on-live-animals-at-bethesda-based-military-school/2013/09/06/3207ebb6-16f6-11e3-be6e-dc6ae8a5b3a8_story.html; Accessed: November 17, 2016.

[15] Shehnaz SI, Sreedharan J, Mathew E, Gomathi KG, Sami Khan N. Willingness to spare animals in undergraduate medical education in Southern India: a preliminary questionnaire-based investigation. ATLA. 2011; 39(6): 557-66.

[16] Arora R, Berry V. Animal experiments in medical undergraduate curriculum –assessment of students' views. Health Adm. 2005; 17: 63-67.

[17] Dhingra MS,,Singh A, Singh J. Animal experiments and pharmacology teaching at medical schools in India: a student's eye view. ALTEX. 2006; 11: 185-91.

[18] Bachinski R et al. Humane Education in Brazil: Organisation, Challenges and Opportunities. Altern Lab Anim. 2015 Nov;43(5):337-44.

[19] Fears D. One last U.S. medical school still killed animals to teach surgery. But no more. The Washington Post. June 30, 2016. Available at: https://www.washingtonpost.com/news/animalia/wp/2016/06/30/one-last-u-s-medical-school-still-killed-animals-to-teach-surgery-but-no-more/; Accessed: November 17, 2016.

[20] Government of India. Medical Council of India Notification. March 18, 2014. Available at: http://www.petaindia.com/wp-content/uploads/2014/05/Medical-Council-of-India-guidelines-2014.pdf; Accessed: November 17, 2016.

[21] American Medical Student Association. PPP: Principles regarding vivisection in medical education. 2016. Available at: https://www.amsa.org/wp-content/uploads/2015/03/2016-PPP.pdf; Accessed: November 17, 2016.

and studies have shown HPS and CAL technology better teach principles of physiology and pharmacology to students than by using animals.[22,23,24]

Emergency Medical Training

Since the turn of the 21st century, changes have also been underway in the American College of Surgeons' (ACS) Advanced Trauma Life Support (ATLS) course – considered the medical standard of care for the initial assessment and treatment of traumatic injuries in a trauma facility and which has been taught to more than 1 million surgeons spanning nearly 60 countries since 1978.[25]

Historically, ATLS programs around the world – including in Brazil – have together used thousands of live animals such as dogs, pigs, sheep and goats each year during surgical skills laboratories for teaching cricothyroidotomy, chest tube insertion, pericardiocentesis, and peritoneal lavage. In 2001, the ACS approved the use of the TraumaMan System (Simulab Corporation, Seattle, Washington) – which replicates an anatomically-correct human torso that can breathe and bleed and that has realistic skin and tissue layers, ribs, and organs – as a full replacement to the use of animals in the ATLS course,[26] and studies have also established that TraumaMan teaches life-saving ATLS skills better than animal-based exercises.[27] For example, researchers at the University of Toronto's St. Michael's Hospital conducted a study that found the TraumaMan model is superior to training on pigs for completing the ATLS surgical skills lab and overall TraumaMan-based training was preferred by 78% of students and 93% of instructors, concluding, "As a result of our study, we have switched our surgical skills model in the ATLS course to TraumaMan because we could not justify identifying animals as the only suitable source for providing the necessary training in our ethics application for renewal."[28]

Today, more than 99 percent of ATLS training facilities in the U.S. and Canada exclusively use non-animal training methods such as TraumaMan and other ACS-approved simulators.[29]

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[22] Maskell P. (2009) [cited 2013 Jan. 17]. The use of human patient simulators to enhance the teaching of undergraduate physiology and pharmacology. Proceedings of the Science Learning Conference, Heriot-Watt University. Available at: https://web.archive.org/web/20150508194740/http://www.bioscience.heacademy.ac.uk/ftp/events/sltc09/presentations/o29maskell.pdf; Accessed: April 9, 2015.

[23] Kojic ZZ, Dewhurst DG. The impact of introducing computer-based alternatives to the use of animals in the teaching of physiology and pharmacology at Balkan universities - a pilot study. Altern Lab Anim. 2009 Nov;37(5):547-56.

[24] Dewhurst D. Computer-based alternatives to using animals in teaching physiology and pharmacology to undergraduate students. Altern Lab Anim. 2004 Jun;32 Suppl 1B:517-20.

[25] American College of Surgeons. Looking forward – August 2013. Bulletin of the American College of Surgeons. August 1, 2013. Available at: http://bulletin.facs.org/2013/08/looking-forward-5/; Accessed: April 7, 2016.

[26] American College of Surgeons. ATLS Announcement: Alternative Models for the ATLS Surgical Skills Practicum. 7 Nov. 2001.

[27] Hall AB, Riojas R, Sharon D. Comparison of self-efficacy and its improvement after artificial simulator or live animal model emergency procedure training. Mil Med. 2014 Mar;179(3):320-3.

[28] Ali J, Sorvari A, Pandya A. Teaching emergency surgical skills for trauma resuscitation-mechanical simulator versus animal model. ISRN Emergency Medicine. 2012. Available at: https://www.hindawi.com/journals/isrn/2012/259864/; Accessed: November 17, 2016.

[29] Physicians Committee for Responsible Medicine. Survey of ATLS programs. August 12, 2015. Available at: http://www.pcrm.org/research/edtraining/ATLS/survey-of-atls-programs; Accessed: October 7, 2015.

While there is widespread interest in the international ATLS community in making this shift, limited budgets have prevented programs in developing countries from establishing modern simulation laboratories. To address this issue, PETA has partnered with Simulab and donated TraumaMan models to ATLS programs in 16 countries, which has allowed them to discontinue their use of animals, expand into remote and underserved regions, and cut costs.[30]

Similarly, though it was once a common sight to see emergency medicine residents resecting the abdominal and thoracic cavities of live pigs to practice inserting tubes, needles, and catheters, today, 86 percent of U.S. emergency residency programs use exclusively non-animal, simulation-based training methods.[31]

Trauma Training

Since 2010, Brazil has conducted the Definitive Surgical Trauma Care (DSTC), which is organized under the auspices of the International Association for Trauma Surgery and Intensive Care. During the course, participants attempt to learn human emergency medical techniques on live animals. These animals endure massive abdominal bleeding, intestinal perforations, and major injuries the heart, lungs, neck and head.[32]

The procedures covered during DSTC can be taught instead on human cadavers and advanced human patient simulators, as is already being done in the United Kingdom's version of the DSTC course, and the American College of Surgeons' Advanced Surgical Skills for Exposure in Trauma course. Military and civilian studies have found that non-animal methods better equip trainees with the technical skills and psychological preparedness necessary to treat traumatic injuries.[33,34,35, 36,37]

A study published by a U.S. Air Force team compared the self-efficacy reported by military trainees taught emergency procedures on human simulators versus live animals and found equivalent results in both groups, concluding that "the belief in the superiority of animal training may just be a bias" and that "if the goal for trainers is to produce individuals with high self-efficacy, artificial simulation is an adequate modality compared with the historical standard of

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[30] Belisomo R. 'TraumaMan' helps doctors save humans, spares animals. Reuters. September 25, 2015. Available at: http://www.reuters.com/article/2015/09/25/us-health-surgeons-traumaman-idUSKCN0RP1O620150925; Accessed: October 7, 2015.

[31] Physicians Committee for Responsible Medicine. Animal use in emergency medicine residency programs in the United States: An ongoing survey. March 9, 2015. Available at: http://www.pcrm.org/research/edtraining/emergency/animal-use-in-emergency-medicine-residency; Accessed: October 8, 2015.

[32] Sociedade Brasileira de Atendimento Integrado ao Traumatizado. Course "Definitive Surgical Trauma Care" (DSTC). 2016. Available at: http://www.sbait.org.br/curso.php?file=curso-desc-dstc&title=Curso%20-%20DSTC; Accessed: November 17, 2016.

[33] Ali J et al. 2012.

[34] Sergeev I et al. 2012.

[35] Bowyer CM, Liu AV, Bonar JP. Validation of SimPL -- a simulator for diagnostic peritoneal lavage training. Stud Health Technol Inform. 2005;111:64-7.

[36] Iverson K, Riojas R, Sharon D, Hall AB. Objective comparison of animal training versus artificial simulation for initial cricothyroidotomy training. Am Surg. 2015 May;81(5):515-8.

[37] Block EF, Lottenberg L, Flint L, Jakobsen J, Liebnitzky D. Use of a human patient simulator for the advanced trauma life support course. Am Surg. 2002 Jul;68(7):648-51.

live animal models."[38] The author published a separate letter in the journal, stating, "We have entered into an age where artificial simulator models are at least equivalent to, if not superior to, animal models. …. [T]he military should make the move away from all animal simulation when effective equivalent artificial simulators exist for a specific task. For emergency procedures, this day has arrived."[39]

For military trauma training, non-animal methods are used instead of animals by nearly 80 percent of NATO nations,[40] confirming that animal use for trauma training is neither necessary nor justified.

Microsurgery Training

Regarding the field of microsurgery, there now exists an array of low- and high-fidelity non-animal methods that have been developed to effectively teach a wide range of basic and advanced microsurgical skills to novice and expert physicians and have been endorsed as replacements for live animal use. These methods include task trainers and perfused cadaver-based methods that can teach procedures such as anastomoses, resection of artificial tumours, bypasses, and aneurysm creation, dissection, and clipping.

For example, a study from the University of Toronto comparing the microsurgical anastomosis skills of surgical residents trained on live rats versus those trained on a silicone model found that, following identical initial training on inanimate models, the latter group was as proficient at performing single-layer, microsurgical anastomoses as those trained on live animals. The authors concluded, "[T]raining with low-fidelity bench models is as effective as training with high-fidelity, live animal models for the acquisition of technical skill among surgical trainees."[41]

A systematic review of microsurgical training methods supported these findings, noting, "It would appear from the best available evidence that simulated microsurgery training on low fidelity models can be as effective as on high fidelity models …. In the UK and elsewhere, the mainstay of microsurgical simulated training has historically been exposure to an *in vivo* rat microsurgery course, but generally this at a far too early stage in training where the bridge with clinical hands-on exposure to relevant cases cannot be made, and without repetition."[42]

The work of Dr. Marcelo Magaldi Oliveira of the Department of Surgery at Brazil's Federal University of Minas Gerais has been important in this field. Dr. Oliveira's team has developed a novel human placenta model for teaching microsurgical techniques instead of using animals, noting: "Live animal surgical models for the training of microsurgical removal of cerebral tumors have not been extensively developed. The ex vivo human placenta tumor model can be

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[38] Hall AB, Riojas R, Sharon D. Comparison of self-efficacy and its improvement after artificial simulator or live animal model emergency procedure training. Mil Med. 2014 Mar;179(3):320-3.
[39] Hall, AB. Letter. Military Medicine. 2014. 179.7.
[40] Gala SG, Goodman JR, Murphy MP, Balsam MJ. Use of animals by NATO countries in military medical training exercises: an international survey. Mil Med. 2012 Aug;177(8):907-10.
[41] Grober ED, Hamstra SJ, Wanzel KR, Reznick RK, Matsumoto ED, Sidhu RS, Jarvi KA. The educational impact of bench model fidelity on the acquisition of technical skill: the use of clinically relevant outcome measures. Ann Surg. 2004 Aug;240(2):374-81.
[42] Ghanem AM, Hachach-Haram N, Leung CC, Myers SR. A systematic review of evidence for education and training interventions in microsurgery. Arch Plast Surg. 2013 Jul;40(4):312-9.

used to simulate a variety of difficult situations encountered during human operations, particularly as related to vessel injury and control of bleeding … Human placentas are readily available and can be used in multiple research environments."[43]

Six Areas of Medical Training Declared Animal-Free By U.S. Military

In 2014, the U.S. Department of Defense (DOD) concluded that "suitable simulation alternatives can replace the use of live animals" in the following medical training areas and ordered a transition agency-wide to simulation models by 2015: Advanced Trauma Life Support; neonatal resuscitation training of family medicine residents and pediatric residents, pediatric nurses, and pediatric staff; obstetrics and gynecology residency training; registered nurse anesthetist residents and staff training programs; programs established solely to maintain staff currency where no residency program occurs; and, the development and maintenance of surgical and critical care skills for field operational surgery and field assessment and skills tests.[44]

Formal Request for Action by CONCEA

Given the widespread adoption of non-animal training methods for biomedical education – specifically for undergraduate medical training, emergency medical training (including ATLS and residency programs), trauma training (including military trauma programs and the DSTC course), microsurgery training, and the aforementioned six areas of medical training that the U.S. DOD has successfully transitioned away from animal use – we urge CONCEA to make similar policy proscriptions in comparable medical training programs in Brazil in accordance with Article 32, §1, of Brasil's Lei de Crimes Ambientais.

PETA would be happy to assist CONCEA in transitioning biomedical training programs in Brazil to use non-animal education methods through educational workshops and technical guidance and support from international medical experts. You can contact me via e-mail at ShalinG@peta.org or by telephone at 757-962-8352 (U.S.). Thank you very much for your consideration, and we look forward to your reply.

Sincerely yours,

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Senior Laboratory Methods Specialist
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[43] Oliveira MM et al. Face, content, and construct validity of brain tumor microsurgery simulation using a human placenta model. Operative Neurosurgery. 2015;0:1–7. Available at: http://neurosim.mcgill.ca/uploads/file/Publications/13%20Validity%20Placenta%20Model.pdf; Accessed: November 18, 2016.

[44] U.S. Assistant Secretary of Defense for Health Affairs. Determination for the use of animals in medical education and training. May 15, 2014. Available at: https://www.jsomonline.org/TCCC/06%20TCCC%20Reference%20Documents/ASDHA%20Memo%20140515%20LTT%20Policy.pdf; Accessed: November 17, 2016.