

Trine Bramsen Minister of Defence

23 September 2020

Via e-mail: <u>fmn@fmn.dk</u>; <u>cko@fmn.dk</u>

Dear Minister,

Thank you for your letter dated 12 May 2020. I am writing on behalf of People for the Ethical Treatment of Animals (PETA) Foundation and our US affiliate, which has more than 6.5 million members and supporters worldwide. We appreciate that the Danish armed forces have reduced their use of animals for live tissue training (LTT) from 110 animals in 2016 – as reported by the Danish Defence Command on 3 July 2020 pursuant to a citizen's request – to only nine animals in 2020. Considering how few animals have been used for LTT this year and given that a ratio of two to six students per animal (as stated in the new five-year "Militær traumatologi" LTT permit¹) amounts to only 18 to 54 personnel undergoing the training this year, there is no significant investment in – or compelling justification for – using animals in LTT.

Based on the information presented in this letter, we urge you to immediately suspend all use of animals for LTT while the Danish Armed Forces Medical Command conducts a comprehensive new evaluation of available non-animal trauma training methods to achieve full compliance with Directive 2010/63/EU and, in light of this evaluation, provide a definitive timeline for fully ending the Danish armed forces' use of animals for LTT.

Danish Defence Command Does Not Have a List of LTT Simulation Models It Has Reviewed

The aforementioned citizen's request asked for the following information: "[a] list of non-animal models that have been reviewed by the Danish Ministry of Defence for live tissue training (otherwise known as LTT or trauma training), with dates indicating when these reviews were conducted, and reasons why these non-animal models were rejected as full replacements to the use of animals for this training".²

https://dyreforsoegstilsynet.fvst.dk/PublishedApprovals/Pages/default.aspx#/detail/ab50 f0d2-60ec-4b1a-aae8-5d74b21db3d2.

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¹Animal Experiments Inspectorate, Ministry of Environment and Food. Militær traumatologi. Licence number 2019-15-0201-00174. 2019.

²Danish Defence Command. Regarding citizen's request on live tissue training [2020/035211]. 3 July 2020.

The Danish Defence Command replied as follows:

Unfortunately a detailed list of equipment reviewed is not available.

However, in order to answer your question as thoroughly as possible we can inform you that over the past years the Danish Armed Forces Medical Command has changed procedures to meet our approach on replacement, reduction and refinement. As an example a wide range of modern simulation dolls utilised prior to Live Tissue Training have made reduction possible.

Training events are continuously evaluated in order to perform the Live Tissue Training in the best technical and ethical way, and hereby ensure the highest possible level of refinement.

The Danish Armed Forces Medical Command carefully monitor the latest international development within this specific field of simulation equipment, including the on-going research conducted under the auspices of NATO, in order to maintain an updated picture of the technological developments of this kind of simulation. Therefore the Danish Armed Forces Medical Command has participated in two events dealing with this kind of simulation within the last year:

- 1. NATO Simulation in Large Scale Exercises. October 28th-30th 2019, Bundeswehr Medical Academy, Munich, Germany
- Medical Case Manager in Large Scale Exercise Course. February 24th-28th 2020, Munich, Germany³

Apparent Failure to Comply With Directive 2010/63/EU

It is highly problematic that the Danish Defence Command cannot identify which specific nonanimal simulation models have been evaluated by the Danish Armed Forces Medical Command as a potential replacement for LTT and during what time frame. Without knowing which models have been methodically evaluated, when the evaluation took place, and what the final report determined regarding their efficacy, it is not possible to know whether non-animal training methods have been adequately assessed by the Danish Armed Forces Medical Command for replacing the use of animals in LTT.

Article 4(1) of Directive 2010/63/EU on the protection of animals used for scientific purposes requires, "Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure [involving animals]."⁴ This calls for a scientific judgement on whether a given non-animal method or testing strategy will achieve results in a satisfactory manner. The lack of substantive and verifiable evidence that all of the available non-animal methods have been adequately assessed means that it is not possible to verify whether Denmark has ensured that, wherever possible, a scientifically satisfactory method or testing strategy not entailing the use of live animals has been used instead of an animal procedure. Importantly, ignorance of a scientifically satisfactory method or testing strategy not entailing the use of live animals has been used instead of an animal procedure. Importantly, ignorance of a scientifically satisfactory method or testing strategy not entailing the use of live animals has been used instead of an animal procedure. Importantly, ignorance of a scientifically satisfactory method or testing strategy not entailing the use of live animals has been used instead of an animal procedure. Importantly, ignorance of a scientifically satisfactory method or testing strategy not entailing the use of live animals is also not an excuse permitted by Directive 2010/63/EU for continuing to use animals in LTT.

³*Ibid*.

⁴Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes. *Official Journal of the European Union*. L 276/33-79. <u>http://eur-lex.europa.eu/Lex.UriServ.Lex.UriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF</u>.

Additionally, the Danish Defence Command cited adherence to the 3Rs concept of replacement, reduction, and refinement of animal use with respect to LTT, but the examples cited pertained only to reduction and refinement. Replacement – which is a mandated target under Directive 2010/63/EU – was not specifically addressed. Also, it is insufficient for the Danish Defence Command to cite two meetings attended by the Danish Armed Forces Medical Command "to maintain an updated picture of the technological developments of this kind of simulation" without giving any information on specifically which "technological developments" were evaluated.

Therefore, we ask that you please confirm whether *each* of the non-animal models we described in Appendix A of our 20 April 2020 letter (attached again for your reference), as well as the non-animal methods described below, have been individually evaluated for the purposes of processing this new "Militær traumatologi" LTT permit, when these evaluations were conducted and by whom, what the result of each one was, and, if models have not been evaluated, why this was not considered necessary.

LTT Is Not Accurate and Has Not Been Proved to Improve Patient Outcomes or Provide Skills As stated in our 20 April letter, LTT is not realistic or relevant to the human condition. In addition to the evidence we have already shared, we urge you to consider the following pertinent information.

• A 2016 study in the *Journal of the Royal Army Medical Corps* states that the Danish LTT course uses pigs, whose anatomy is drastically different from that of humans:

Training courses based on animal models (Exercise Surgical Training Denmark) and cadavers (the Military Operational Surgical Training course) have been used extensively to prepare surgeons for deployment in recent conflicts. However, they are expensive and provide a one-off opportunity to practice advanced techniques in models that are either anatomically incorrect (pigs) or have altered tissue characteristics with no vascular perfusion (cadavers). [Instead] [a]bdominal multivisceral organ retrieval [in clinical settings] is the ultimate laparotomy and takes the surgeon to parts of the retroperitoneum and thorax otherwise not seen during standard surgical training. ... From April 2012 to April 2013, there were 2748 retrievals carried out by the 8 UK abdominal retrieval teams. The number of retrievals has increased by 50% between 2010 and 2014, and it is predicted to increase by a further 50% by 2020.⁵

Abdominal multivisceral organ retrieval is certainly feasible as a replacement for using animals in LTT in Denmark for military surgical skill maintenance training.

• A 2019 study in the *Journal of Surgical Education* states that the purported benefits of LTT in improving patient outcomes are unsubstantiated:

[N]o published evidence from prospective controlled trials exists suggesting that surgical skills training courses change trauma patient outcome, or improve performance of the skills taught, when performed in the real-world operating room. ... Published evidence of course training benefit was not identified for many established courses including: Definitive Surgical Trauma Skills,

⁵O'Reilly D, Lordan J, Streets C, Midwinter M, Mirza D. Maintaining surgical skills for military general surgery: the potential role for multivisceral organ retrieval in military general surgery training and practice. *J R Army Med Corps*. 2016; *162*(4):236-238. doi:10.1136/jramc-2015-000444

Emergency Management of Battlefield Injuries, Endovascular Skills for Trauma and Resuscitative Surgery, Emergency War Surgery Course (EWSC), Military Operational Surgical Training, Specialty Skills in Emergency Surgery and Trauma, Surgical Training for Austere Environments, or Surgical Trauma Response Techniques.⁶

According to the study, all these courses "used live tissue (usually porcine)".⁷ In light of the lack of clinical applicability to human trauma patients, there is no scientific justification for subjecting pigs in Denmark to "war- and terror-related injuries", including gunshot wounds, blast wounds, amputation, punctured lungs, airway damage, and eye damage, during LTT, purportedly to train military medical personnel in human surgery techniques.⁸

Article 38(2)(d) of Directive 2010/63/EU mandates the use of a "harm-benefit analysis" for animal experiments, including LTT. There is no direct evidence that LTT is responsible for improved clinical outcomes for patients who have sustained traumatic battlefield injuries. Therefore, inflicting suffering, pain, and/or distress on animals who are mutilated and killed during LTT – regardless of any use of anaesthetics or analgesia – is not justified in such an analysis.⁹

• The event titled "NATO Simulation in Large Scale Exercises", which the Danish Armed Forces Medical Command participated in at the Bundeswehr Medical Academy in Munich from 28 to 30 October 2019, was organised in cooperation with the NATO Centre of Excellence for Military Medicine (MILMED COE).

You'll be interested to know that MILMED COE confirmed to PETA US in 2011 that it "does not use animals, alive or dead, or animal models for any training or course" and that "[w]here needed for specific training ([Emergency Management of Battlefield Injuries course]; [Major Incident Medical Management and Support course]) appropriate human patient simulators are used".¹⁰ MILMED COE's exclusive use of non-animal trauma training methods confirms that it is indeed feasible for Denmark to end LTT.

Full Replacements for Using Animals in LTT Are Available

Live tissue training has been criticized by experts as "abhorrent",¹¹ "outdated and cost-prohibitive",¹² and "not anatomically accurate"¹³ and for failing to "change trauma patient outcome, or improve performance of the skills taught, when performed in the real-world operating room".¹⁴ Nearly three-

https://www.military.com/daily-news/2018/03/20/coast-guard-puts-permanent-end-wounding-animals-training.html.

¹²US Defense Health Agency. 2016 stakeholder report. <u>https://health.mil/Reference-Center/Reports/2017/06/08/Defense-Health-Agency-2016-Stakeholder-Report.</u>

https://www.sbir.gov/sites/default/files/Master%20Health%20Technologies.National%20SBIR.pptx.

⁶Mackenzie CF, Tisherman SA, Shackelford S, Sevdalis N, Elster E, Bowyer MW. Efficacy of trauma surgery technical skills training courses. *J Surg Educ*. 2019; 76(3):832-843. doi:10.1016/j.jsurg.2018.10.004 ⁷*Ibid*.

⁸Animal Experiments Inspectorate, Ministry of Environment and Food. Militær traumatologi. Licence number 2019-15-0201-00174. 2019.

⁹Ibid.

¹⁰MILMED COE. E-mail to PETA US. 28 October 2011.

¹¹Seck HH. Coast Guard puts permanent end to wounding animals for training. Military.com. 20 March 2018.

¹³US National Institutes of Health. Seed funding health technologies.. 16 May 2017.

¹⁴Mackenzie CF, Tisherman SA, Shackelford S, Sevdalis N, Elster E, Bowyer MW. Efficacy of trauma surgery technical skills training courses. *J Surg Educ*. 2019; *76*(3):832-843. doi:10.1016/j.jsurg.2018.10.004

quarters of NATO allies do not use animals for military medical training¹⁵ and instead use superior non-animal trauma training methods, such as the human-worn partial-task surgical simulator "Cut Suit",¹⁶ high-fidelity human patient simulators,¹⁷ perfused human cadavers,¹⁸ surgical anatomical models,¹⁹ or abdominal multivisceral organ retrieval in clinical settings.²⁰

Based on the principle of the 3Rs, the availability of non-animal training methods, and the lack of evidence that LTT improves patient outcomes, the Danish armed forces have an ethical, scientific, and legal responsibility to suspend the practice while conducting a comprehensive new review of all existing non-animal training methods and fully replace LTT as your peers have done. Continuing to use animals when non-animal methods are available is a breach of Directive 2010/63/EU.

You can contact me at <u>MimiB@peta.org.uk</u>. Thank you for your consideration of our request. We look forward to your response.

Yours sincerely,

Minhelero,

Mimi Bekhechi Vice President, International Programmes PETA Foundation

Attachment: 20 April 2020 letter

(halin H. Hala

Shalin G. Gala Vice President, International Laboratory Methods Laboratory Investigations Department PETA (US)

http://www.onlinelibrary.wiley.com/doi/10.1111/acem.12645/pdf.

¹⁹Naumann DN, Bowley DM, Midwinter MJ, Walker A, Pallister I. High-fidelity simulation model of pelvic hemorrhagic trauma: the future for military surgical skills training? *Mil Med.* 2016; *181*(11):1407-1409. https://www.ncbi.nlm.nih.gov/pubmed/27849473.

¹⁵Gala SG, Goodman JR, Murphy MP, Balsam MJ. Use of animals by NATO countries in military medical training exercises: an international survey. *Mil Med.* 2012; *177*(8):907-910. doi: 10.7205/milmed-d-12-00056

¹⁶Kirkpatrick AW, LaPorta A, Brien S, *et al.* Technical innovations that may facilitate real-time telementoring of damage control surgery in austere environments: a proof of concept comparative evaluation of the importance of surgical experience, telepresence, gravity and mentoring in the conduct of damage control laparotomies. *Can J Surg.* 2015; *58*(3 Suppl 3):S88–S90. doi: 10.1503/cjs.014214

¹⁷Reihsen T, Speich J, Ballas C, Hart D, Sweet R. Creation of a multi-trauma patient using current technology based simulators. *Acad Emerg Med.* 2015; 22(S1):S442-443.

¹⁸Polk TM, Grabo DJ, Minneti M, Kearns MJ, Inaba K, Benjamin ER, Demetriades D. Initial report on a damage control surgery course for military forward surgical teams utilizing a novel perfused cadaver model for training and evaluation. *J Am Coll Surg.* 2018; 227(4):e40. <u>https://www.journalacs.org/article/S1072-7515(18)31238-9/fulltext</u>.

²⁰O'Reilly D, Lordan J, Streets C, Midwinter M, Mirza D. Maintaining surgical skills for military general surgery: the potential role for multivisceral organ retrieval in military general surgery training and practice. *J R Army Med Corps*. 2016; *162*(4):236-238. doi:10.1136/jramc-2015-000444.



Trine Bramsen Minister of Defence Holmens Kanal 42 1060 Copenhagen K Denmark

20 April 2020

Via e-mail: fmn@fmn.dk

Dear Ms Bramsen,

Thank you in advance for your time, and congratulations on your recent appointment as minister of defence. I am writing on behalf of People for the Ethical Treatment of Animals (PETA) Foundation and our international affiliates. We are deeply concerned about the licence titled "Militær traumatologi" (number 2019-15-0201-00174),¹ issued by the Animal Experiments Inspectorate on 19 September 2019, which reauthorises the Danish military's cruel and archaic use of live animals in trauma training exercises, otherwise known as "live tissue training" (LTT). For the scientific, ethical, and legal reasons given below, we urge you to rescind this licence and instead require the use of exclusively non-animal trauma training methods.

LTT Is Unethical

In its licence application, the Danish military asserts, "Each test animal is inflicted with as many relevant types of damage as possible from simulated war- and terror-related injuries," including "gunshot wounds", "blast wounds", "amputation", "punctured lung", "airway injury", "eye damage", and much more.² Disturbing photos released by PETA US reveal that as part of this training, live pigs are also strung up by their hind limbs and shot with AK47s.³

A 2018 study published by Ulm University researchers compared LTT to non-animal models:

A close examination of the evidence base for the presumed advantages of LTT showed that it is not superior to simulation-based methods in terms of educational benefit. Since credible alternatives that do not cause harm to animals are available, we conclude that LTT on animal models is ethically unjustified.⁴

A 2016 study regarding the use of animals in military LTT found that "[t]here is a need to replace LTT with other educational methods such as simulation",⁵ which the authors attribute to growing concern for animal welfare, the problems with expensive purpose-built laboratories, and the fact that militaries in many countries do not use animals for medical training.

Page 1 of 8

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Other studies have found that teaching emergency medical procedures using human simulators is as good as or better than teaching them using animal-based laboratories.^{6,7,8,9,10}

It is unethical to subject live animals to injuries in trauma training drills, especially when suitable non-animal training methods exist and are already used by other military medical programmes.

LTT Is Not Realistic

In its licence application, the Danish military claims that using live pigs is the "optimal" method for illustrating the effects of trauma on living tissue and demonstrating the treatment of injuries. It states that the animals are kept "deeply anesthetised" such that "even [their] reflexes and ability to breathe are suppressed" and that they are "intubated" and "connected to a regular respirator ... [that has] a fixed breathing rhythm ... by means of pressure ventilation".¹¹

The use of anaesthesia means that live animals are not realistic "models" for battlefield medical training. Animals under deep anaesthesia do not experience stress or present signs of stress, such as hyperventilation and elevated heart rate and blood pressure. These are important medical factors that could determine the course of action for managing trauma, including by affecting the speed of blood loss, the medications required, and other countermeasures that trainees need to learn. Intubated pigs attached to assisted-breathing machines simply do not mimic actual victims of war or terror attacks.

Simulating the trainees' own stress in the scenario is equally important, and this can be achieved in exercises using advanced human-patient simulators. A 2018 study describes the advantages of such models:

High-fidelity simulation offers many advantages, including broad exposure to procedures, their complications, and the opportunity for repetitious learning in a non-clinical setting. The stress of learners undergoing simulation events is a growing field of interest. Proponents of training with live-anaesthetised animals argue the associated stress response cannot be equated with inanimate models, and therefore leads to an inferior learning experience with negative implications for future performance. ... A randomized controlled study of 277 army combat medics was performed comparing procedural training and assessment on a live tissue (LT) goat model versus the best-in-class synthetic training models (STM). ... No significant differences were seen for peak stress response of salivary cortisol or amylase, regardless of LT or STM method for training or assessment. In addition, the stress response did not correlate significantly with total performance score. ... Synthetic models can produce a stress response equivalent to that of live tissue during simulation training. This is the largest study to date indicating synthetic models produce a sufficient immersive and realistic experience for trainees. ... Stress inoculation while learning critical medical procedures can be achieved with synthetic models. Training programs may be able to reduce the use of live animals for training without sacrificing educational quality.¹²

Using currently available high-fidelity human-patient simulation technology provides a more realistic training scenario than using animals who are intubated or anesthetised, in addition to being more ethical.

Non-Animal Training Methods Are Widely Available and Validated

In its licence application, the Danish military claims that battlefield trauma training "requires a complex simulation model that has not yet been developed in artificial form" and that "it is not expected that a complete replacement with non-experimental animal simulation models will be developed within five years".¹³

This is inaccurate, since the medical literature confirms the efficacy of human-simulation technology that is currently commercially available. For example, there are numerous human-patient simulators – such as Simulab Corporation's TraumaMan,¹⁴ Strategic Operations' Cut Suit,¹⁵ CAE Healthcare's Caesar,¹⁶ TraumaFX's Multiple Amputation Trauma Trainer,¹⁷ Laerdal Medical's range of lifelike military-focused manikins,¹⁸ the U.S. Department of Defense-funded Advanced Modular Manikin,¹⁹ SynDaver's virtual patient simulation systems (VPSS) and whole body patient simulators (WBPS),²⁰ and many more – that faithfully replicate human anatomy and physiology and can replace live-animal trauma exercises in full. Please see Appendix A for a description of these and other non-animal models, with studies supporting their efficacy.

Will you please confirm whether each of the non-animal models described in Appendix A has been individually evaluated for the purposes of processing this licence application, when these evaluations were conducted and by whom, and what was the result of each one? Given that these non-animal methods have been used successfully in many other trauma training programmes, it would appear that one or a combination of these approaches should meet the needs of the Danish military.

EU and Danish Law Prohibits Animal Use for LTT

Article 4, Section 1, of Directive 2010/63/EU states, "Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure."²¹ A similar legal standard is established in Chapter 2, Section 6, Paragraph 3 of Denmark's Animal Experiments Act, which states, "Animals shall not be used in procedures, for which the use of cell, tissue, or organ cultures *or other methods* is likely to be equally appropriate" [*emphasis added*].²²

Furthermore, there is legal precedent in European courts for the rejection of this type of animal use. For instance, in 2012, a panel of independent medical experts convened by a German court determined that using animals for trauma training cannot be justified, because superior, non-animal methods, such as human simulators, are available. According to a military news report, "Judges in the city of Gera said they agreed with doctors who testified there were other ways to improve competence. The company [that was seeking permission to use animals for LTT] then withdrew its case and no verdict was issued."²³

Other Countries Conduct Trauma Training Without Using LTT

In 2017, the US Defense Health Agency criticised the use of animals in military trauma drills for being "outdated and cost-prohibitive"²⁴ and "not anatomically accurate".²⁵ In 2017, US Coast Guard Commandant Admiral Paul Zukunft told the US Congress that the use of animals for military trauma training is "abhorrent" and that the Coast Guard will move to a simulation training model, stating that "[F]or us it will be the right thing to do to prepare our Coast Guard members who may be deployed to theaters where they may encounter traumatic injuries".²⁶ As such, the Coast Guard became the first branch of the US military to end the use of animals for trauma training altogether.²⁷

Conclusion

Now is the time to end the use of animals in Denmark's military trauma training and focus instead on superior human-simulation technology. Such a move would bring the Danish military in line with growing medical consensus and the best practices of the nearly threequarters of fellow NATO nations that do not use animals for military medical training.²⁸

You can contact me at <u>MimiB@peta.org.uk</u>. Thank you for your consideration of our request. We look forward to your response.

Yours sincerely,

Minikeleron)

Mimi Bekhechi Director of International Programmes PETA Foundation

Enclosure

Appendix A: Studies Supporting Non-Animal Trauma Training Methods

¹Animal Experiments Inspectorate, Ministry of Environment and Food. Militær traumatologi. Licence number 2019-15-0201-00174. 2019.

 $\label{eq:https://dyreforsoegstilsynet.fvst.dk/PublishedApprovals/Pages/default.aspx \#/detail/ab50f0d2-60ec-4b1a-aae8-5d74b21db3d2.$

²Ibid.

³Hughes C. Exclusive: Pigs strung up and shot to train British Army medics in treating gunshot wounds. *Daily Mirror*. 18 February 2014. <u>https://www.mirror.co.uk/news/uk-news/pigs-strung-up-shot-train-3157055</u>.

⁴Rubeis G, Steger F. Is live-tissue training ethically justified? An evidence-based ethical analysis. *Altern Lab Anim.* 2018;46(2):65-71. <u>https://www.ncbi.nlm.nih.gov/pubmed/29856644</u>.

⁵Silverplats K, Jonsson A, Lundberg L. A hybrid simulator model for the control of catastrophic external junctional haemorrhage in the military environment. *Adv Simul*. 2016;1:5.

http://advancesinsimulation.biomedcentral.com/articles/10.1186/s41077-016-0008-z.

⁶Ali J, Sorvari A, Pandya A. Teaching emergency surgical skills for trauma resuscitation – mechanical simulator versus animal model. *ISRN Emergency Medicine*. 2012;2012. <u>http://www.hindawi.com/isrn/em/2012/259864/</u>.

⁷Sergeev I, Lipsky AM, Ganor O, *et al.* Training modalities and self-confidence building in performance of lifesaving procedures. *Mil Med.* 2012;177(8):901-906.

⁸Bowyer CM, Liu AV, Bonar JP. Validation of SimPL – a simulator for diagnostic peritoneal lavage training. *Stud Health Technol Inform.* 2005;111:64-67.

⁹Sweet R. Comparing live animal and simulator alternatives for training and assessing hemorrhage and airway procedures in a tactical field situation [presentation]. Fort Lauderdale, Florida: Military Health System Research Symposium, 2014.

¹⁰Savage E. A comparison of two medical training modalities for CAF medical technicians: Live tissue training and high fidelity patient simulator [presentation]. Fort Lauderdale, Florida: Military Health System Research Symposium, 2014.

¹¹Animal Experiments Inspectorate.

¹²Keller J, Hart D, Rule G, Bonnett T, Sweet R. The physiologic stress response of learners during critical care procedures: Live tissue vs synthetic models. *CHEST*. 2018;154(4):229A.

https://journal.chestnet.org/article/S0012-3692(18)31402-8/fulltext

¹³Animal Experiments Inspectorate.

¹⁴Simulab Corporation. TraumaMan Surgical Simulator.

http://www.simulab.com/product/surgery/open/traumaman-system.

¹⁵Strategic Operations. Surgical Cut Suit. <u>https://www.strategic-operations.com/Surgical-Cut-Suit-p/cs-surg.htm</u>.

¹⁶CAE Healthcare. CAE Caesar. <u>https://caehealthcare.com/patient-simulation/caesar/</u>.

¹⁷Trauma F/X. Multiple Amputation Trauma Trainer (MATT). <u>https://www.traumafx.net/multiple-amputation-trauma-trainer-matt/</u>.

¹⁸Laerdal Medical. Military Training Solutions. <u>http://www.laerdal.com/us/military</u>.

¹⁹ Advanced Modular Manikin. <u>https://www.advancedmodularmanikin.com/</u>

²⁰ SynDaver. SynDaver selected as an awardee for \$186 million government contract.

https://syndaver.com/2018/01/15/syndaver-selected-as-an-awardee-for-186-million-government-contract/

²¹Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the Protection of Animals Used for Scientific Purposes. *Official Journal of the European Union*. L 276/33-79. <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF</u>.

²²Animal Experiments Act. Executive Order No 474 of 15 May 2014.

https://www.retsinformation.dk/forms/r0710.aspx?id=162938.

²³Piggin J-B, Schneider C. Germany halts plan to shoot live pigs for paramedic training. *Stars and Stripes*. 2 October 2012. <u>http://www.stripes.com/news/europe/germany-halts-plan-to-shoot-live-pigs-for-paramedic-</u> training-1.191572.

²⁴US Defense Health Agency. 2016 stakeholder report. <u>https://health.mil/Reference-</u>

Center/Reports/2017/06/08/Defense-Health-Agency-2016-Stakeholder-Report. ²⁵US Defense Health Agency. Defense Health Agency (DHA) SBIR/STTR programs. 16 May 2017. https://www.sbir.gov/sites/default/files/Master%20Health%20Technologies.National%20SBIR.pptx.

²⁶Seck HH. Ending "abhorrent" live tissue training was right: Coast Guard. Military.com. 18 May 2017.
<u>http://www.military.com/daily-news/2017/05/18/ending-abhorrent-live-tissue-training-was-right-coast-guard.html</u>.

guard.html. ²⁷Seck HH. Coast Guard puts permanent end to wounding animals for training. Military.com. 20 March 2018. https://www.military.com/daily-news/2018/03/20/coast-guard-puts-permanent-end-wounding-animalstraining.html.

²⁸Gala SG, Goodman JR, Murphy MP, Balsam MJ. Use of animals by NATO countries in military medical training exercises: An international survey. *Mil Med.* 2012;177(8):907-910.

Appendix A: Studies Supporting Non-Animal Trauma Training Methods

Numerous studies validate the use of various non-animal trauma training methods, including the Human Worn Partial Task Surgical Simulator ("Cut Suit"), high-fidelity human-cadaver models, and advanced human-patient simulators:

Human Worn Partial Task Surgical Simulator ('Cut Suit')

- According to a 2015 review article, "The Human Worn Partial Task Surgical Simulator (Cut Suit) is a realistic surgical training tool that allows for the simulated performance of actual surgical procedures. In addition to perfused extremities, the Cut Suit also has perfused internal organs that may be accessed through the abdominal wall and can be incised to bleed and repaired or excised to control hemorrhage. The Cut Suit is regularly being upgraded and in the near future will be equipped with specific in-line flow sensors that will permit an accurate calculation of simulated blood loss during different procedures and situations and with different surgeons."²⁹
- A 2017 study stated, "Remote damage control resuscitation (RDCR) endeavours to rescue the most catastrophically injured, but has not focused on prehospital surgical torso hemorrhage control (HC). ... A surgical simulator was customized with high-fidelity intraperitoneal anatomy, a "blood" pump and flowmeter. A standardized HC task was to explore the simulator, identify "bleeding" from a previously unknown liver injury perfused at 80 mm Hg, and pack to gain hemostasis. Ten surgeons performed RDCR laparotomies onboard a research aircraft, first in 1g followed by 0g. The standardized laparotomy was sectioned into 20-second segments to conduct and facilitate parabolic flight comparisons, with "blood" pumped only during these time segments. A maximum of 12 segments permitted for each laparotomy. ... Performing laparotomies with packing of a simulated torso hemorrhage in a high-fidelity surgical simulator was feasible onboard a research aircraft in both normal and weightless conditions."³⁰

High-Fidelity Human-Cadaver Models

- The website of the Major Incident Surgical and Trauma Teams (MISTT) Trauma Course held at Queen Elizabeth Hospital Birmingham in the UK, which is supported by the UK National Health Service, states, "Delegates will benefit from a three day simulation/cadaveric course, focusing on damage control of all cavities and extremities in Trauma, together with two days of discussion, lively debate and case studies."³¹ In private communication with the PETA Foundation, the organiser of the MISTT Trauma Course confirmed that it "do[es] not use any cadaveric or anaesthetised models, tissue or other samples derived from animals" and that it is "using silicone anatomical model such as supplied by TraumaSimU Ltd", which is the surgical anatomical model (SAM).³² Regarding the SAM model, Surgeon Vice Admiral Alasdair Walker (former surgeon general of the UK Defence Medical Services) and his colleagues in the Royal Army Medical Corps and the Royal Navy stated in a 2016 study, "During damage-control surgery using the SAM, the materials and anatomical details have simulated human blast injury with fidelity that may be superior to cadaveric and animal models."³³
- A 2018 study from the US Navy Trauma Training Center stated, "[O]ur military trauma training site now utilizes a novel ventilated and pressurized cadaver model for training and evaluation of forward surgical teams (FST). FSTs attend a 4-day damage control course including didactics and cadaveric dissection focused on trauma exposures, damage control vascular and orthopedic procedures. A capstone half-day simulation pairs the perfused cadaver model with conventional simulation to involve the entire surgical team in four sequential surgical scenarios that involve the chest, abdomen, and extremities, as

well as airway management and resuscitation. Initial evaluations support the use of this novel perfused cadaver model for the training and evaluation of military FSTs. Preliminary data highlights the utility for open vascular, thoracic and other high acuity/low volume procedures critical to combat casualty care."³⁴

Advanced Human-Patient Simulators

- A study published in 2014 by a US Air Force team in the journal *Military Medicine* compared the self-efficacy reported by military trainees taught emergency procedures on human simulators versus those taught using live animals and found equivalent results in each group, concluding 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 live animal models".³⁵ The lead author published a letter in the same 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."³⁶
- A 2015 study found that a human-patient simulator is as effective as animal use during LTT in teaching trauma injury management to military medical technicians, and the researchers "found no difference in performance between medics trained on simulators versus live tissue models".³⁷
- A 2015 abstract by members of one of the research teams that are part of the US Combat Casualty Training Consortium described how they had developed a multi-trauma humanpatient simulator: "We assembled a 'Frank N. Stein' model representing the best of commercially available simulation. ... For Airway, the SimMan 3G head/neck was selected as the nasopharyngeal airway and cricothyrotomy model. For chest tube and needle decompression, the Strategic Operations Cut Suit was selected. For hemorrhage, the KGS MATT was chosen as the only model that contained both junctional and amputation wounds with animatronics. An actor was trained and a platform was created to allow the head and arms of the actor to wear the cut-suit above the platform, with the actor's torso and legs below the MATT legs on the platform. Frank was dressed appropriately and moulage was applied to face, wounds, and amputated stump. ... The actor could be switched out for the SimMan head/neck/torso for airway interventions. ... The emulation of a complex airway and hemorrhage patient was successful, providing a realistic full body simulation requiring placement of nasopharyngeal airway, chest seal, needle and tube thoracostomy, cricothyrotomy, tourniquet, amputation stump dressing, and junctional wound packing. ... Over 1000 trainees have been trained or assessed with this model."38

³¹The MISTT Trauma Course. <u>https://www.mistt.co.uk</u>.

²⁹Kirkpatrick AW, LaPorta A, Brien S, *et al.* Technical innovations that may facilitate real-time telementoring of damage control surgery in austere environments: A proof of concept comparative evaluation of the importance of surgical experience, telepresence, gravity and mentoring in the conduct of damage control laparotomies. *Can J Surg.* 2015;58(3 Suppl 3):S88–S90.

³⁰Kirkpatrick AW, McKee JL, Tien H, *et al.* Damage control surgery in weightlessness: A comparative study of simulated torso hemorrhage control comparing terrestrial and weightless conditions. *J Trauma Acute Care Surg.* 2016;82(2):392-399. <u>https://sghrp.ca/reports/open-report.php?id=165</u>.

³²The MISTT Trauma Course. Private correspondence with the PETA Foundation. 16 October 2019.

³³Naumann DN, Bowley DM, Midwinter MJ, Walker A, Pallister I. High-fidelity simulation model of pelvic hemorrhagic trauma: The future for military surgical skills training? *Mil Med.* 2016;181(11):1407-1409. https://www.ncbi.nlm.nih.gov/pubmed/27849473.

³⁴Polk TM, Grabo DJ, Minneti M, Kearns MJ, Inaba K, Benjamin ER, Demetriades D. Initial report on a damage control surgery course for military forward surgical teams utilizing a novel perfused cadaver model for

training and evaluation. *J Am Coll Surg.* 2018;227(4):e40. <u>https://www.journalacs.org/article/S1072-7515(18)31238-9/fulltext</u>.

³⁵Hall 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;179(3):320-323.

³⁶Hall A. Letter to the editor. *Mil Med.* 2014. 179(7):vii.

³⁷Savage EC, Tenn C, Vartanian O, *et al.* A comparison of live tissue training and high-fidelity patient simulator: A pilot study in battlefield trauma training. *J Trauma Acute Care Surg.* 2015;79(4 Suppl 2):S157-163.

³⁸Reihsen T, Speich J, Ballas C, Hart D, Sweet R. Creation of a multi-trauma patient using current technology based simulators. *Acad Emerg Med.* 2015;22(S1):S442-443. http://www.onlinelibrary.wiley.com/doi/10.1111/acem.12645/pdf