What should informed consent in the military look like in relation to pharmacological enhancements?

Richard M. Heames

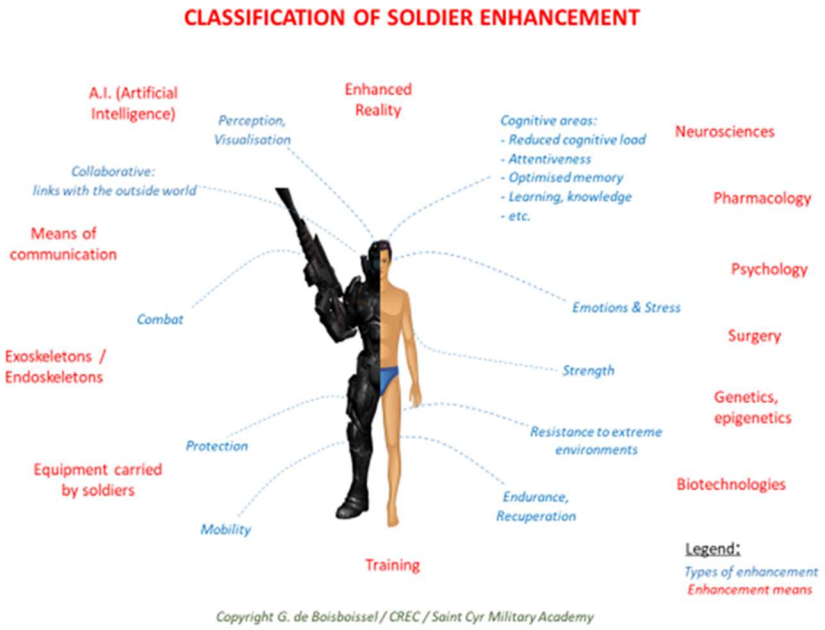

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Table of contents

Introduction

Humans are a frail species that have survived and dominated the land due to intellect, resourcefulness and ability to adapt. This survivability and adaptability hold true for armed conflict, where a soldier[1] still needs to overcome emotions such as fear and respond to the physical demands of hunger, thirst and fatigue. Training can help mitigate these potential weaknesses but an ability to use the latest advances in science and technology to upgrade the performance of a soldier could give the desired advantage to defeat an adversary. This becomes even more important when other states and non-state actors may also gain access to this technology.

Human enhancement is a rapidly advancing field with Allhoff convinced *"we are near the start of the Human Enhancement Revolution."*[2] The speed of advance of technology from being available to being used, results in a delay to the ethic surrounding it. This is true of pharmacological enhancement (PCE) as much as exoskeletons and human-machine interfacing. Several militaries and other organisations have invested heavily in human enhancement, capitalising on scientific advances in neurosciences, biotechnology, robotics and the ability to miniaturise technology.[3] Enhancing drugs are already available with up to 20% improvement in ability in those that take them

[1] The word soldier is used as a term to encapsulate all members in all services of the UK Armed Forces.

[2] Fritz Allhoff *et al.*, "Ethics of Human Enhancement: 25 Questions & Answers," *Studies in Ethics, Law, and Technology* 4, no. 1 (2010), 1.

[3] Maxwell J. Mehlman, Patrick Lin, and Keith Abney, "Enhanced Warfighters: A Policy Framework," in *Military Medical Ethics for the 21st Century*, ed. M.L. Gross and D. Carrick, Military and Defence Ethics (Farnham: Ashgate Publishing Limited, 2013), 113.

in specific tests.[4] It is therefore better to have a policy for PCE use in place with time for deliberation, rather than be forced into a sudden decision.

Ethical issues arising from human enhancement include autonomy, safety and dignity.[5] The first two are the cornerstones of the ethics surrounding informed consent (IC) which emanated from the necessity to protect human subjects against the risks of research. IC is now the standard currency for ethical medical practice-based on autonomy and the maintenance of health and well-being. The military currently follow civilian IC guidance but this may not be appropriate, as the military have to balance the protection of individuals from any risks at the expense of overriding their autonomy. What remains unclear is how those risks are quantified, who decides whether the risk is an acceptable one and whether IC is required? For civilians, a competent, autonomous individual would decide whether the risk is acceptable under an IC process but for the military the partial loss of autonomy on joining an organization where lawful orders have to be followed, creates challenges in gaining IC.

This paper will define human enhancements, explain what PCEs are and why an individual or the military might use them. It will give a brief outline of specific issues surrounding PCE use in the military including the laws and regulations applicable to the licensing and the issuing of prescription-only medications, the effect PCE use might exert on both military careers and the chain of command, and how PCE users might be perceived by their colleagues and society. An important part of military life is the duty of care by all those responsible for subordinates and this should be factored in to those authorising missions where the requirement for PCEs are considered vital

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[4] Anders Sandberg and Nick Bostrom, "Converging Cognitive Enhancements," *Annals New York Academy of Sciences* 1093 (2006): 205.

[5] Maxwell Mehlman, Patrick Lin, and Keith Abney, "Enhanced Warfighters: Risk, Ethics, and Policy," *Case Legal Studies Research Paper* No. 2013-2, (2013), 4.

for mission success. Arguments for and against the requirement for IC in the military will be presented.

IC will be examined in detail from its theory and history, touching on where the military have succeeded and failed with IC in the past. Any drug must be thoroughly researched before being fit for human consumption and this requires a greater level of IC following established ethical principles and if conducted by the military or on military personnel as research subjects, approval has to be sought from a dedicated ethics committee. This paper will detail what is required for consent to be 'informed' and demonstrate that full information is never known with doctors often masking their lack of knowledge. The same critical analysis will be done for how 'consensual' consent is in the military, whose personnel must follow orders and are therefore susceptible to coercion.

The final section of the essay will focus on the role of military doctors in the IC process and the unique duality of their position acting as both a doctor and military officer, arguing that the ethical duty as a doctor takes primacy. The evidence presented in the paper will be drawn together to suggest a template for gaining IC for PCE use in the Armed Services, paying attention to the method, style and timing of communication. The template will contain a combination of broad and informed consent for PCE use during service that would provide a theoretical effective balance of maximising the information provided and ensuring that wherever possible, the provision of PCEs are consensual with few exceptions. In order to best protect the individuals themselves and wider society from soldiers who have taken PCEs, the military must ensure they have comprehensive and supporting policies and regulations surrounding their use.

Chapter One – Pharmacological Enhancements

What are human and pharmacological enhancements?

The definition of human enhancements according to Juengst are *"interventions designed to improve human form or functioning beyond what is necessary to sustain or restore health"*.[6] Mehlman's interpretation of that definition excludes vaccinations which improve immune systems to sustain health and furthermore groups all medical treatments as either sustaining or restoring health.[7] There is an important difference between a drug for treatment and one for enhancement, with society generally accepting a treatment which is intended to alleviate a disease. A grey area for medicine with Juengst's definition is undertaking a treatment to prevent a future disease which may or may not occur, such as undergoing total colectomy surgery for familial polyposis coli, a condition which has a high chance of causing bowel cancer.[8] This is hard to categorize as an enhancement or treatment as it only potentially improves human functioning and is not strictly necessary to sustain health.

Consider treatments that may be required for a medical condition but also have beneficial effects on those disease-free and considered 'normal'. Erythropoietin is used to treat anaemia but has been taken by a Tour de France cyclist with a normal

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[6] Eric T. Juengst, "What Does Enhancement Mean?," in: *Enhancing Human Traits: Ethical and Social Implications*, ed. Eric Parens, Hastings Center Studies in: Ethics Series (Washington DC: Georgetown University Press, 2000), 29.
[7] Maxwell Mehlman, "Bioethics of Military Performance Enhancement," *Journal of the Royal Army Medical Corps* 165, no. 4 (2019): 226.
[8] Macmillan Cancer Support, "Familial Adenomatous Polyposis (FAP)," <https://www.macmillan.org.uk/cancer-information-and-support/worried-about-cancer/causes-and-risk-factors/familial-adenomatous-polyposis-fap>, (accessed April 6, 2020).

haemoglobin level to boost sport performance.[9] The former has been treated whereas the cyclist would be judged enhanced. The difference draws attention to the term normal, described by Mehlman as the typical range of functioning for humans as a species and compared relative to one's own baseline and trajectory of health.[10] For haemoglobin concentration, the normal range captures 95% or 97.5% of a normal distribution curve generated by a section of the population.[11] However, standards of normality change with time like height and weight over the last century and will no doubt change with use of enhancements.[12]

Mohamed highlighted the difficulty in separating a treatment from enhancement effect in his example of taking a PCE for jet lag or insomnia.[13] Is the drug used treating symptoms already present, or enhancing the brain to prevent the condition? This could be regarded as the same for soldiers taking a PCE when fatigued on operational deployment and whether the PCEs have returned them to normal or enhanced them above normal. Further difficulties in understanding enhancement is that over the last few decades, the line differentiating health states and diseases has blurred and more interventions are considered treatments.[14] The ongoing implication is that some

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[9] Jacque Wilson, "Lance Armstrong's Doping Drugs - CNN," *CNN*, January 18, 2013, <https://edition.cnn.com/2013/01/15/health/armstrong-ped-explainer/index.html>, (accessed April 12, 2020).

[10] Mehlman, Lin, and Abney, "Enhanced Warfighters: Risk, Ethics, and Policy.", 14.

[11] Ernest Beutler and Jill Waalen, "The Definition of Anemia: What Is the Lower Limit of Normal of the Blood Hemoglobin Concentration?," *Blood* 107, no. 5 (2006): 1747.

[12] S. Rosenbaum, "100 Years of Heights and Weights," *Journal of the Royal Statistical Society. Series A (Statistics in Society)* 151, no. 2 (1988): 276–309.

[13] Ahmed Dahir Mohamed, "Neuroethical Issues in: Pharmacological Cognitive Enhancement," *WIREs Cognitive Science* 5, no. 5 (2014): 538.

[14] Mehlman, "Bioethics of Military Performance Enhancement.", 226.

PCEs could be argued as therapy or enhancement, although fundamentally the issue with IC remains the same for both groups.

Equally, it is possible that some enhancements could be negative or 'disenhancements', with a military example of using a PCE to remove memories that would result in soldiers developing post-traumatic stress disorder.[15] Again is this treating the brain or enhancing it? If a distinction is not made between therapy and enhancement, it might result in all forms of human enhancement being morally permissible.[16] This paper will follow the definition of enhancement as something which improves a person and lifts them above the normal baseline. It will focus on pharmacological drugs as one aspect of human enhancement, excluding the range of other possible enhancements such as transcranial magnetic stimulation, genetic modification and human-computer interaction.

Pharmacological enhancements (PCEs) for this paper are defined as drugs which are prescription-only medicines(POM) and not those acquired either by illicit means or purchased over-the-counter. Regulatory control for PCEs like all drugs in the UK, is undertaken by the Medicine and Healthcare Products Regulatory Agency (MHRA). The MHRA accept drugs as safe and approved for use, classifying certain drugs as 'controlled' with specific regulations for their use and potential misuse.[17] A POM can only be prescribed by a licensed

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[15] Mehlman, Lin, and Abney, "Enhanced Warfighters: Risk, Ethics, and Policy.", 15.

[16] Allhoff *et al.*, "Ethics of Human Enhancement: 25 Questions & Answers", 8.

[17] United Kingdom. HM Government, "About Us – Medicines and Healthcare Products Regulatory Agency," <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about#our-responsibilities>, *Misuse of Drugs Act 1971* (London: HMSO, 1971), <http://www.legislation.gov.uk/ukpga/1971/38/contents>, "The Controlled Drugs (Supervision of Management and Use) Regulations 2013. Information about the Regulations," 2013,

doctor, although there is a military exemption to this regulation, described later. A drug can be prescribed for a non-licensed indication, termed 'off-label', but the recipient should be informed when that is the case.[18] The majority of PCEs were not originally licensed for their enhanced capabilities, therefore, their use would be off-label, raising the necessity to inform the recipient of that fact. It is assumed that any future drugs developed would fall under the same regulatory controls.

PCEs can be divided into two broad categories, those affecting cognition and those affecting the body's physical attributes. Cognition can be defined as the processes a human utilises to organise information.[19] General health, a balanced diet and long-term exercise can improve cognition by itself and there are a range of drugs affecting the brain chemistry with positive and negative effects.[20] Those positive effects could be termed cognitive enhancement, defined by Sandberg as *"the amplification or extension of core capacities of the mind through improvement or augmentation of internal or external information processing systems."*[21] Drugs that change brain chemistry could exert negative effects by altering soldiers' perceptions of their actions and consequences of their behaviour. Loss of emotional connection could deny the armed forces the social bonding and trust that is currently instilled by its values and ethos.

<https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/214915/15-02-2013-controlled-drugs-regulation-information.pdf> (accessed March 26, 2020).

[18] United Kingdom. HM Government, "Off-Label or Unlicensed Use of Medicines: Prescribers' Responsibilities," 2014, <https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities>, (accessed May 4, 2020).

[19] Nick Bostrom and Anders Sandberg, "Cognitive Enhancement: Methods, Ethics, Regulatory Challenges," *Science and Engineering Ethics* 15, no. 3 (2009): 312.

[20] *Ibid.*, 314.

[21] Sandberg and Bostrom, "Converging Cognitive Enhancements.", 201.

Well known drugs that affect cognition include nicotine which increases alertness and cognitive processing, [22] and caffeine which increases the arousal level, particularly when fatigued. [23] However, this paper is using the term PCEs to include only those drugs that are prescribed and as both nicotine and caffeine are widely available over-the-counter, they will not be discussed in further detail. An example of a cognitive PCE is modafinil, a drug licensed for narcolepsy and discovered to maintain alertness and improve cognition.[24] As modafinil can increase wakefulness with minimal side effects, it has potential to enhance soldiers for an off-label indication.[25] Amphetamines are another group of drugs that act as stimulants and have been approved for use in the US Air Force for lengthy missions.[26] There are drugs which affect cognition and used in the treatment of mental health such as propranolol which has had some success in treating the memory effects of post-traumatic stress disorder (PTSD). PTSD is a condition highly familiar to the military but as propranolol has been used in this case as a treatment rather than enhancement, it is not applicable to this paper's discussion.[27]

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[22] Carol S. Myers *et al.*, "Dose-Related Enhancement of Mood and Cognition in Smokers Administered Nicotine Nasal Spray," *Neuropsychopharmacology* 33, no. 3 (2008): 594.

[23] Tom M. McLellan, John A. Caldwell, and Harris R Lieberman, "A Review of Caffeine's Effects on Cognitive, Physical and Occupational Performance," *Neuroscience & Biobehavioral Reviews* 71 (2016): 297.

[24] Kelli J. Westcott, "Modafinil, Sleep Deprivation, and Cognitive Function in Military and Medical Settings," *Military Medicine* 170, no. 4 (2005): 334.

[25] *Ibid.*

[26] John A. Caldwell and J. Lynn Caldwell, "Fatigue in Military Aviation: An Overview of U.S. Military-Approved Pharmacological Countermeasures," *Aviation, Space, and Environmental Medicine* 76, no. 7 (2005): C45.

[27] Alain Brunet *et al.*, "Reduction of PTSD Symptoms With Pre-Reactivation Propranolol Therapy: A Randomized Controlled Trial," *American Journal of Psychiatry* 175, no. 5 (2018): 427–33.

From the physical perspective, there are a number of PCEs which could be used to build up a soldier including anabolic steroids, erythropoietin (blood doping) and growth hormones.[28] Currently, these substances are banned by the military unless they are prescribed by a doctor for a specific indication.[29] It seems intuitive to want a 'stronger' soldier for close combat and the British Army has recently increased the level of fitness required.[30] On the other hand, the importance of absolute strength for military personnel in combat is perhaps perceived as less critical, as women have been allowed in front line infantry units since 2018.[31] Undoubtedly, a real benefit of PCEs on physical attributes would be to increase stamina and endurance whilst reducing the need for food, but this remains elusive as additional nutritional supplementation is required to achieve these beneficial effects.[32]

The success of PCEs affecting physical attributes will be discussed below, but despite many healthy individuals taking PCEs to improve their memories or level of alertness, Maslen's review of the literature shows that the evidence of their

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[28] Karl E. Friedl, "U.S. Army Research on Pharmacological Enhancement of Soldier Performance: Stimulants, Anabolic Hormones, and Blood Doping," *The Journal of Strength & Conditioning Research* 29 (2015): S72.

[29] British Army, "People. Drugs and Supplements," <https://www.army.mod.uk/people/join-well/drugs-and-supplements/>, (accessed March 30, 2020).

[30] British Army, "New Physical Employment Standards for the Army," <https://www.army.mod.uk/physical-employment-standards/> (accessed May 6, 2020).

[31] Lizzie Dearden, "Women Now Allowed to Apply for Royal Marines and All Other Frontline Military Roles, Defence Secretary Announces," *The Independent,* October 25, 2018, <https://www.independent.co.uk/news/uk/home-news/women-soldiers-army-military-sas-defence-government-infantry-frontline-gavin-williamson-female-a8601371.html> (accessed April 2, 2020).

[32] Joaquín Pérez-Guisado and Philip M Jakeman, "Citrulline Malate Enhances Athletic Anaerobic Performance and Relieves Muscle Soreness," *The Journal of Strength & Conditioning Research* 24, no. 5 (2010), 1222.

effectiveness is inconclusive, with limited enhancement for specific tasks, at particular dosages, for a proportion of people.[33] Interestingly, research has not established if the benefits of PCEs increase the performance of manned weapons systems and the quality of life of those manning them.[34] Further questions to consider are whether PCEs should be used routinely or just for specific missions, where failure to use them could lead to disastrous consequences?

Why are pharmacological enhancements relevant now?

The relevance of discussing PCEs for the military now is not just to align the ethical discussions with the rapid technological advance, but also to compare it to where sport currently sits in the debate, where there are some similar issues with safety and policy. Despite attempts to eliminate drugs from sport, use remains widespread due to the lure of success and high earnings, with low risk of getting caught and minimal penalties.[35] The World Anti-Doping Agency (WDA) declared drug use for sport illegal due to a lack of fairness and equality, if it either enhanced performance, posed a health risk, or violated the 'spirit of sport'.[36]The PCEs banned by the WDA broadly fall into two

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[33] Hannah Maslen, Nadira Faulmüller, and Julian Savulescu, "Pharmacological Cognitive Enhancement—How Neuroscientific Research Could Advance Ethical Debate," *Frontiers in Systems Neuroscience* 8 (2014): 3.

[34] Marten Meijer, "A Human Performance Perspective on the Ethical Use of Cogniceuticals: Commentary on 'Recommendations for the Ethical Use of Pharmacologic Fatigue Countermeasures in the U.S. Military,'" *Aviation, Space, and Environmental Medicine* 78, no. 5 (2007): B133.

[35] J. Savulescu, B. Foddy, and M. Clayton, "Why We Should Allow Performance Enhancing Drugs in Sport," *British Journal of Sports Medicine* 38, no. 6 (2004): 666.

[36] World Anti-Doping Agency, "World Anti-Doping Code" (Montreal: World Anti-Doping Agency, 2015), 14, 30, <https://www.wada-ama.org/sites/default/files/resources/files/wada_anti-

categories, those that increase power and those that increase stamina.[37]Many sports competitors have experienced dramatic positive effects when taking PCEs for a competitive edge, the exact same effect that is desired by the military.[38]

Savulescu argues that sport discriminates against the 'genetically unfit' and a winner is one who has the combination of genetic potential and the ideal balance of their psychology, training and judgement. For this reason, he advocates that competitors should be permitted PCE use to level the playing field, remove genetic inequality and the financial differential between rich and poor countries.[39] The arguments either for or against doping in sport revolve around fairness and equality which contrast with the military that aims to avoid fairness and equality by seeking a competitive advantage to win. A further argument by Mehlman is that an enhanced sportsperson does not benefit society, whereas enhancing military personnel to increase the likelihood of success of a nationally-tasked mission, could decrease the overall risk of harm to wider society.[40] Where both sides of the doping debate in sport agree, is that the health and safety of the individual is paramount.[41] In contrast, for the

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doping_code_2019_english_final_revised_v1_linked.pdf> (accessed March 12, 2020).

[37] Lincoln Allison, "Faster, Stronger, Higher," *The Guardian*, August 9, 2004, <https://www.theguardian.com/sport/2004/aug/09/athensolympics2004.olympicgames> (accessed January 1, 2020).

[38] Kate Harvey, "Sports Science and Medicine," *The Nuffield Council on Bioethics*, 2014, 5, <https://nuffieldbioethics.org/publications/sports-science-and-medicine> (accessed January 6, 2020).

[39] Savulescu, Foddy, and Clayton, "Why We Should Allow Performance Enhancing Drugs in Sport.", 667-8.

[40] Mehlman, Lin, and Abney, "Enhanced Warfighters: A Policy Framework.", 114.

[41] Julian Savulescu, Leon Creaney, and Anna Vondy, "Should Athletes Be Allowed to Use Performance Enhancing Drugs?," *BMJ* (Clinical Research Ed.) 347 (2013): f6150.

military it may be that the health and safety of the unit, or even society takes primacy over that of the individual.

Why would individuals and the military want pharmacological enhancements?

The military might want PCEs for three reasons: to gain a competitive edge, match an opponent's capability and when working with other nations as a coalition. The ability to enhance human performance and gain a competitive edge over the enemy is not new. War over the centuries has involved face-to-face combat and even with modern technology, it is still a human endeavour as seen in the war against terrorism and the UK involvement in the conflicts in Iraq and Afghanistan. The Incas chewed coca leaves in the 15th Century which contained cocaine, reducing hunger, thirst and fatigue, improving the Incas stamina and endurance.[42] Rum was issued to soldiers and sailors in the 17th Century because it was believed the alcohol made them better fighters.[43] There was mixed success using opium, with the Indian military gaining enhanced fighting spirit and combat performance, whereas the Chinese suffered significant opium abuse, severely impacting the ability of their troops.[44]

In modern times, amphetamines were used to improve stamina and maintain alertness such as German tank crews taking *Panzerschokolade* (tank chocolate) and the RAF using Benzedrine.[45] The US war in Vietnam saw unprecedented consumption by troops of both prescribed and self-prescribed psychoactive drugs including amphetamines, marijuana, LSD and heroin.[46] Irregular armed groups such as ISIS, Taliban and

[42] L. Kamienski, *Shooting Up: A History of Drugs in Warfare* (Oxford: Hurst, 2017), 46-47.
[43] *Ibid.*, 9.
[44] *Ibid.,* 63.
[45] *Ibid.*, 111, 117.
[46] *Ibid.*, 188.

Al Qaeda have used psychoactive drugs to make up for shortfalls in military ability and distributed for rewards and recruitment, as well as to enhance their human capability.[47] The 'Jihadi Pill', predominantly made in Syria was used by Daesh fighters to become fearless and euphoric.[48]

All militaries strive to have a performance edge to increase the chance of mission success whether it is via technology, training or doctrine and a cognitive advantage is no different.[49] This has become even more important since the UK military has reduced the number of serving personnel over the last decade yet maintained similar outputs. Although modern warfare platforms need fewer operators and maintainers, the resulting effect remains an overburdened and stressed system. The impact is greater with reduced personnel resilience as highlighted by the media pointing out that one in thirteen troops were prescribed anti-depressants for mental health since 2018, with an increased suicide rate.[50] Sleep deprivation is also a problem for troops whether operational or not and reduces their cognitive functioning, exacerbated by caffeine and alcohol

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[47] *Ibid.*, 233-235.

[48] Mirren Gidda, "Drugs in War: What Is Captagon, the 'Jihad Pill' Used by Islamic State Militants?," *Newsweek*, May 12, 2017, <https://www.newsweek.com/drugs-captagon-islamic-state-jihad-war-amphetamines-saudi-arabia-608233> (accessed March 26, 2020).

[49] Michael B. Russo, "Recommendations for the Ethical Use of Pharmacologic Fatigue Countermeasures in the U.S. Military," *Aviation, Space, and Environmental Medicine* 78, no. 5 (2007): B125.

[50] Sean Rayment, "Thousands of Soldiers on Antidepressants as They Battle Mental Health Issues, New Figures Reveal," *The Mirror*, July 28, 2018, <https://www.mirror.co.uk/news/uk-news/thousands-soldiers-antidepressants-battle-mental-12996613>; Ministry of Defence., "FOI2017/13417," 2018, <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/691866/2017-13417.pdf> (accessed March 31, 2020).

consumption.[51] If sleep deprivation impairs judgement, increases the risk of human error and reduces innovation, there might be an ethical imperative to provide PCEs to soldiers to prevent poor-decision making when under the inevitable fatigue from combat.[52]

Secondly, all advanced militaries are now facing each other with increasing technological parity in a world of increased fragility.[53] The expectation that future adversaries will provide their military with PCEs to alleviate fatigue, increase muscular strength, or create other winning advantages must be accepted.[54] The US Army has approved use of dextroamphetamine and the US Air Force has approved modafinil for select crews and personnel.[55] The US has its own military medical cognitive research collaboration to establish and deliver cutting-edge capabilities.[56] It is already investigating PCEs that increase pain tolerance and encapsulated oxygen that can be stored in the body to increase survival for injured war fighters.[57] The

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[51] Paul Scharre and Lauren Fish, "Human Performance Enhancement," *Center for a New American Security*, 2018, 7, <https://www.cnas.org/publications/reports/human-performance-enhancement-1> (accessed January 6, 2020).

[52] Olav Kjellevold Olsen, Ståle Pallesen, and Eid Jarle, "The Impact of Partial Sleep Deprivation on Moral Reasoning in Military Officers," *Sleep* 33, no. 8 (2010): 1086.

[53] Kenneth Ford and Clark Glymour, "The Enhanced Warfighter.," *Bulletin of the Atomic Scientists* 70, no. 1 (2014): 43.

[54] *Ibid.*, 47.

[55] Mary A. Kautz, Maria L. Thomas, and J. Lynn Caldwell, "Considerations of Pharmacology on Fitness for Duty in the Operational Environment," *Aviation, Space, and Environmental Medicine* 78, no. 5 (2007): B109.

[56] Eric B. Schoomaker, "Military Medical Research on Cognitive Performance: The Warfighters Competitive Edge," *Aviation, Space, and Environmental Medicine* 78, no. 5 (2007): B4.

[57] James Patrey *et al.*, "Human Performance Enhancement for NATO Military Operations (Science, Technology, and Ethics)," in *NATO Research and Technology Organisation* (Virginia, USA: Office of Naval Research Warfighter Performance Department, 2009), 1,

likelihood that other state and non-state actors are doing the same must be high and therefore, the UK must follow suit to level the playing field.[58]

Thirdly, the UK military might need PCEs to work with NATO, UN and other coalition forces in the event that some or all of the other nations are using PCEs. There are inevitable risks from a mismatch when what is ethically acceptable to one nation may be unacceptable to another. Consider the example of Fijians who were banned from drinking alcohol by a Western coalition commander yet allowed to make and drink kava, a substance containing psychoactive compounds and affecting night vision.[59] What happens if a coalition soldier who has taken PCEs to promote alertness, is responding to an emergency situation and needs the support of an unenhanced UK soldier who is drowsy and not fit to respond?

There are a broad range of reasons why a soldier might take a PCE. Schelle considered that peer pressure is an important factor in influencing whether someone takes a PCE.[60] This is usually a positive mechanism, with a person more likely to take a PCE if their friends and colleagues are taking them, but the converse is also true when strong disapproval by others may lower willingness to use PCEs. The effect of this can be multiplied by social pressure extending outside of the immediate friendship group. A German survey of university students

<https://apps.dtic.mil/dtic/tr/fulltext/u2/a562561.pdf> (accessed January 6, 2020).

[58] President's Council on Bioethics, *Beyond Therapy: Biotechnology and the Pursuit of Happiness* (New York: Regan Books, 2003), 136.

[59] Russo, "Recommendations for the Ethical Use of Pharmacologic Fatigue Countermeasures in the U.S. Military.", B121.

[60] Kimberly J. Schelle *et al.*, "Attitudes toward Pharmacological Cognitive Enhancement—a Review," *Frontiers in Systems Neuroscience* 8 (2014): 8.

discovered the willingness to take PCEs depended on personal attitude to risk, peer prevalence, cost and side effects.[61]

The media can influence whether an individual might take PCEs by raising their profile and general public awareness. The Cambridge University rag, Varsity, stated that 10% of students took substances such as modafinil and Ritalin to improve their academic performance, which highlighted the benefits and normality of use.[62] Despite awareness of side effects, BBC News even gave coverage of the rough cost a student might be expected to pay for "smart pills", although they did point out the illegality of selling them.[63] Society can change its perspective and attitude quickly, normalising PCEs just by exposure to them and therefore, PCE use could get adopted rapidly with plenty of media coverage.[64]

Another reason to take PCEs is via self-medication as part of a lifestyle choice, to aid recovery from training or physical activity, or to improve physical performance. Many military personnel already use supplements ranging from dietary to banned substances, with up to 38% of UK recruits in training taking them according to one study.[65] It is surprising that soldiers continue to take banned substances despite a zero tolerance policy.[66] There are some specific reasons why soldiers

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[61] Sebastian Sattler *et al.*, "Evaluating the Drivers of and Obstacles to the Willingness to Use Cognitive Enhancement Drugs: The Influence of Drug Characteristics, Social Environment, and Personal Characteristics," *Substance Abuse Treatment, Prevention, and Policy* 9, no. 1 (2014): 5.

[62] Natasha Lennard, "One in Ten Takes Drugs to Study," *Varsity*, March 6, 2009, <https://www.varsity.co.uk/news/1307> (accessed March 31, 2020).

[63] BBC News, "Sussex University Students Illegally Buying 'Smart Pills,'" *BBC News*, March 13, 2018, <https://www.bbc.co.uk/news/uk-england-43383717> (accessed March 31, 2020).

[64] Adam Bear and Joshua Knobe, "Normality: Part Descriptive, Part Prescriptive," *Cognition* 167 (2017): 25.

[65] Anna Casey *et al.*, "Supplement Use by UK-Based British Army Soldiers in Training," *The British Journal of Nutrition* 112, no. 7 (2014): 1178-1180.

[66] British Army, "People. Drugs and Supplements."

would willingly take PCEs relating to the military values and ethos that are firmly instilled on joining up. These include if they considered it as part of a moral code, a belief that it is an honourable thing to do or even guilt over colleagues who are already deployed. A soldier could take a PCE seeking enhanced aggression on a subsequent mission to avenge the death of a colleague killed in action.

Lastly, there are some occupations where individuals must comply with certain actions, for example hand washing by surgeons before operating and compulsory rest periods for long distance truck drivers.[67] This occupational accord where an individual consents to specific actions on accepting certain employments, is primarily based on preserving their health and safety. The military therefore, could establish an occupational reason for their personnel to take a PCE in a similar manner to when the US directed their pilots to take stimulants for prolonged missions. However, this is unlikely to be the case for the majority of PCEs where the balance of risk and benefits is not as clear cut.

What are the military concerns surrounding pharmacological enhancement use?

There are a number of issues around PCE use in the military including law, policy, operational, civil-military relations and IC. UK forces have to uphold both Service and civil law noting that *"In order that the Armed Forces can operate effectively a necessary reliance is placed on the maintenance of both personal and imposed discipline."*[68] If PCEs are illegal in civilian life or banned by the military, then

[67] Maslen, Faulmüller, and Savulescu, "Pharmacological Cognitive Enhancement—How Neuroscientific Research Could Advance Ethical Debate.", 6.

[68] United Kingdom. Ministry of Defence, *JSP 830: The Manual of Service Law* (London: HMSO, 2016), 1-1-3.

they cannot be self-prescribed and if legally allowed, there must be a policy to support their use.

Banning PCEs or limiting their access could result in an expanding black market of supply leading to a reduction in safety. This occurred with Viagra, forcing the MHRA to change its category from being a POM to being available over-the-counter.[69] More studies to determine safety and efficacy will provide consumers' confidence to use PCEs and legalising them will promote their development, ultimately making them cheaper and safer.[70] The military should replicate Scharre's recommendation of having a high level policy review, examining each PCE on a case-by-case basis, investigating its efficacy, safety and utility.[71] Furthermore, PCE use in research or on operations should be voluntary.

Schedule 17 of UK medicine regulations authorises the Armed Forces to supply and administer medicines for soldiers, bypassing a licensed doctor's prescription.[72] This exemption was designed to cover troops in environments without immediate access to doctors. Any treatments prescribed should ideally be by trained 'medics',[73] who have been signed off as competent by

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[69] Sabrina Barr, "Viagra Now Available over the Counter without Prescription in UK," *The Independent*, March 27, 2018, <https://www.independent.co.uk/life-style/health-and-families/viagra-buy-without-prescription-over-counter-uk-pharmacies-male-impotence-erectile-dysfunction-a8275461.html> (accessed April 3, 2020).

[70] Bostrom and Sandberg, "Cognitive Enhancement: Methods, Ethics, Regulatory Challenges.", 333.

[71] Scharre and Fish, "Human Performance Enhancement.", 3.

[72] United Kingdom, "The Human Medicines Regulations 2012," Pub. L. No. 1916, Schedule 17 (2012), Pt 2, 10, Pt 5, 17, <http://www.legislation.gov.uk/uksi/2012/1916/schedule/17/made> (accessed April 6, 2020).

[73] Medic is a term used to cover a combat medical technician of the British Army and its sister service equivalents. They are trained to diagnose, prescribe and manage medical emergencies but do not come under a National regulatory body.

a doctor, or if there are no personnel with medical skills, permission should be obtained via communication to a doctor if at all possible. What stops those commanding a deployed unit from ordering their medics to prescribe PCEs and ordering the soldiers to take them, or even getting the soldiers to self-administer in a similar way to fentanyl lozenges?[74] Although legal, there has to remain authority and accountability in this instance to ensure the safety and protection of the soldier.

From an operational and command perspective, elements of coercion or insubordination will be discussed in the section on IC, but PCE use has other potential employment impacts. Would a soldier's career be accelerated if by taking PCEs, it meant they would be sent on more critical missions? This same factor could affect their remuneration, promotion and recognition by the award of medals. Unit cohesion and morale is vital for mission success via communication, teamwork and shared ethos. Would this remain the same between those who are enhanced and those not? Could it motivate those not being enhanced into a 'them and us' scenario leading to a sense of feeling second class or missing out. More importantly, a mission could be called off if those undertaking it were not enhanced.

Soldiers represent society and its values and are relied upon to protect society whilst respecting human rights and international humanitarian law.[75] The UK has a moral contract known as the Armed Forces Covenant (AFC),which recognises that soldiers put the needs of the Service above their own, potentially involving the sacrifice of life and the duty that society has by ensuring they are treated fairly, thus establishing a mutual

[74] CBRN Delivery Team, 2017DIN04-165. Fentanyl Lozenge 800 Micrograms (OTFC) Single – Introduction into Service as Self Administered Operational Analgesia. (Bristol: Ministry of Defence, 2017).

[75] British Army, Values and Standards of the British Army, AC 64649 (Andover: Army Headquarters, 2018), 25.

benefit for both the military and society.[76] This AFC frames a duty of care for military personnel who have accepted imposed discipline and thus reduced autonomy, and means the public would be unsupportive of PCE use if it was considered unsafe or unfair. This duty of care was considered so important that the government directed all single services to update their legal and moral responsibilities beyond reiterating their values, standards and ethos.[77]

[76] Helen McCartney, "The Military Covenant and the Civil–Military Contract in Britain," *International Affairs* 86, no. 2 (2010): 413.

[77] House of Commons Defence Committee, Duty of Care. Third Report of Session 2004–05. Volume I. HC63-I (London: The Stationery Office Limited, 2005), 5.

Chapter Two – Informed Consent

Theory of informed consent

Before detailing the issues around IC in the military, it is relevant to understand its evolution. The 20th Century had a number of fundamental events which shaped the development of IC, the first of which was during the Second World War when Nazis used prisoners arriving at the concentration camps for research and cruel experimentation against their will. From the trials afterwards, where doctors were held to account for their actions, the Nuremberg Code was established in 1947 and listed ten explicit principles for doctors experimenting on humans and forbade experiments on prisoners.[78] The first principle was gaining voluntary, IC of the subject.[79] The following year, the United Nations made a Universal Declaration of Human Rights in response to the extensive Nazi inhumanities, which contained Article 5 stating no-one should be subjected to cruel or inhuman treatment.[80]

The Declaration of Helsinki (1964), produced by the World Medical Association (WMA)created the ethical principles for conducting research on humans or identifiable human material and data, distinguishing therapeutic from non-therapeutic procedures.[81] It placed the primary duty of

[78] *British Medical Journal,* "The Nuremberg Code (1947)," *British Medical Journal* 313, no. 7070 (1996): 1448.

[79] Michael Gross, *Military Medical Research Ethics: Investigational Drugs, Clinical Trials and Enhancement* (Oxford: Oxford University Press, 2019), 2.

[80] United Nations, "Universal Declaration of Human Rights," 1948, <https://www.un.org/en/universal-declaration-human-rights/> (accessed January 9, 2020).

[81] World Medical Association, "Ethical Principles for Medical Research Involving Human Subjects," *WMA Declaration of Helsinki*, 2018, <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-

physicians as promoting health and protecting patients' rights in research and being held accountable for both. The guidance stated any study's risks must not outweigh the benefits, it should be approved by a Research Ethics Committee (REC) and voluntary IC of a participant is essential, being mindful of a dependency relationship between the physician and subject. The declaration noted that if an intervention was not proven effective, it could still be used, providing there was adequate IC and the doctor's judgement believed it would save life, restore health or alleviate suffering.

The Belmont Report released in 1979 was produced as an attempt to summarise the ethics up to that time point.[82] The report set out three basic principles as respect for persons, beneficence and justice.[83] The respect for persons was about treating individuals as autonomous and capable of self-determination whilst protecting those considered vulnerable. Beneficence fundamentally related to avoidance of doing harm and maximising the benefits whilst minimising possible harms when treating a person. Lastly, justice directed a fairness so that all of society shared the benefits of research along with its burdens.

Nuremberg, Helsinki and Belmont were all aimed at research ethics and the requirement for voluntary consent. The concept of IC for healthcare emerged in the 1950s, moving away from simple disclosure by physicians towards an emphasis on the subject's understanding. Prior to the 1950s, any consent involved minimising any disclosures which might upset the

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principles-for-medical-research-involving-human-subjects/>, (accessed April 7, 2020).

[82] The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research," 1979, <https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf,> (accessed January 8, 2020).

[83] *Ibid.,* 4.

patient.[84] The 1957 Salgo court case originated the term IC, stating there was a duty to disclose treatment risks and options after a man suffered paralysis from a routine procedure, with the case considered as battery.[85] A few years later the Natans on court case moved the physician's failure to undertake IC from battery to an act of negligence, a position where it has remained since.[86] In 1972, three separate USA courts produced decisions supporting a more patient-oriented standard of disclosure which meant the patient had to be given sufficient information to enable them to make an intelligent choice.[87] This was not popular with physicians, who felt that the demands placed on them to deliver that information was too onerous and even inconsistent with good patient care.

Drawing together the history, IC is based on a respect for patient autonomy and self-determination. The word autonomy came from Greek origins, with auto meaning self and nomos meaning rule.[88] IC is an autonomous authorisation by the individual to allow a healthcare professional to perform a medical action to them, only if the individual is competent and free from being under the control of others. Berg has defined IC as something that *"refers to legal rules that prescribe behaviours for physicians and other healthcare professionals in their interactions with patients"*.[89] Both parties have to be involved with the patient having IC as a right and a doctor having it as a duty or obligation.[90] IC can also be viewed in terms of the institutional

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[84] Tom L. Beauchamp, "Informed Consent: Its History, Meaning, and Present Challenges," *Cambridge Quarterly of Healthcare Ethics* 20, no. 4 (2011): 515.

[85] R.R. Faden, T. L. Beauchamp, and N. M. P. King, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986), 125.

[86] *Ibid.,* 129.

[87] *Ibid.*, 132.

[88] J.W. Berg *et al.*, *Informed Consent: Legal Theory and Clinical Practice*, 2nd Ed. (New York: Oxford University Press, 2001), 15.

[89] *Ibid.,* 3.

[90] *Ibid.*, 14.

and policy rules, so in the case of healthcare, if the NHS rules of consent are followed, it is considered valid and informed.[91]

Over the last 50 years, IC has been the ethically acceptable medical practice based on the values of autonomy and individual well-being, now with a greater focus on shared decision-making between patient and doctor. As Berg described, IC implies formal actions with legal connotations, often involving documentation such as for surgery. In these formal actions, it is expected that both parties have full understanding of the benefits of the transaction and potential adverse outcomes, with the patient trusting the healthcare professional. Many aspects outside of medicine are gaining increased formality and are frequently seen with consumer protection and the detailed small print that accompanies a product or service. Ultimately, it seems the driver of formality and written IC is the protection of those doing the action from accusation, litigation and compensation.[92]

In summary, for IC to be valid for healthcare, an individual must fulfil four criteria:

1. Be mentally competent – this potentially excludes those who are vulnerable, at the extremes of age or unconscious.
2. Understand the risks, benefits and alternative options including that of doing nothing, with the opportunity to ask questions.
3. Have the ability to withdraw consent at any time.
4. Not be under duress.

This appears to be simple and straightforward but Corrigan discusses an "empty ethics" model where any autonomous

[91] Beauchamp, *supra,* foot note 84, at p. 518.
[92] O. O'Neill, "Some Limits of Informed Consent," *Journal of Medical Ethics* 29, no. 1 (2003): 4.

individual, if provided with sufficient information and the time to process that information, will make the decision to accept a treatment or not. This implies a universal standard and ignores cultural differences.[93] The ability of any individual to understand will require a variable amount of information and time, implying that the process of IC should be tailored to the individual.

Military issues with informed consent

In the past, the military has aligned its IC process to that of the civilian world and bypassed it under certain circumstances, causing harm and foregoing the duty of care to its soldiers. The Nuremberg declaration has the first principle as voluntary, informed consent of the subject being absolutely essential.[94] Despite that principle, both the UK and US experimented on unconsented service personnel during the Cold War, exposing them to radiation, chemical agents and LSD.[95] More recently, the US Department of Defense (DOD) obtained a Food and Drug Administration (FDA) waiver of informed consent to administer pyridostigmine and botulinum toxin vaccine to troops for Operation Desert Storm.[96] Grounds cited for the waiver were that it was impossible to obtain IC from over

[93] Oonagh Corrigan, "Empty Ethics: The Problem with Informed Consent," *Sociology of Health & Illness* 25, no. 3 (2003): 770.
[94] Gross, *Military Medical Research Ethics: Investigational Drugs, Clinical Trials and Enhancement*, 2.
[95] George J. Annas, "Changing the Consent Rules for Desert Storm," *New England Journal of Medicine* 326, no. 11 (March 12, 1992): 771; Adam Lusher, "The Bizarre True Story of When the UK Military Tested LSD on Royal Marines," *The Independent*, May 24, 2018, <https://www.independent.co.uk/news/uk/home-news/lsd-video-porton-down-chemical-weapons-experiments-trials-uk-military-army-marines-sixties-acid-a8366906.html> (accessed April 29, 2020).
[96] Joel Martin Schofer, "Violations of Informed Consent During War," *JAMA* 281, no. 17 (1999): 1657.

500,000 troops and some might refuse placing them in danger.[97] The vaccine, but not pyridostigmine, was eventually given on a voluntary basis, basing the reasoning on 'experimentation' versus 'protection' of troops. Pyridostigmine was believed to be safe after decades of experience with larger doses treating myasthenia gravis, whereas the vaccine was under investigation for its effectiveness.[98]

There is a dangerous precedent if IC can be waived for Defence. However, for a DOD waiver to be valid, stringent conditions must be met:

> *in order to facilitate the accomplishment of the military mission, preservation of the health of the individual and the safety of other personnel require that a particular treatment be provided to a specified group of military personnel, without regard to what might be any individual's personal preference for no treatment or for some alternative treatment.*[99]

Those refusing the drugs would either have to leave the operational theatre and not fulfil their military obligations, or remain unprotected, which would put them at risk, increase the danger to their unit colleagues and reduce the chance of mission success.[100] The US case of forced administration of unapproved drugs was taken to court and lost, including the appeals, with none of the court cases mentioning the Nuremberg Code and

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[97] Annas, "Changing the Consent Rules for Desert Storm.", 770.
[98] *Ibid.,* 772.
[99] Richard A. Rettig, *Military Use of Drugs Not Yet Approved by the FDA for CW/BW Defense: Lessons from the Gulf War* (Santa Monica: RAND Corporation, 1999), xii.
[100] Richard A. Rettig, *Waiving Informed Consent: Military Use of Non-FDA-Approved Drugs in Combat*(Santa Monica: RAND Corporation, 2000), <https://www.rand.org/pubs/research_briefs/RB7534.html> (accessed April 30, 2020).

all supporting the use of pyridostigmine as it was used as a treatment.[101]

In 2002, two pilots returning to Kuwait from a long-range training exercise in Afghanistan, mistook live gunfire for enemy insurgent activity and killed four Canadian pilots in a friendly-fire tragedy. In the ensuing court case, the defence argued that the pilots were coerced into taking Dexedrine which impaired their ability and resulted in the accidental bombing. Charges were dropped and although no blame was ever attributed to the drug, it highlighted the issue of lack of IC for a prescribed medication.[102] Did the Dexedrine affect their mental capacity or influence their ability to control their behaviour, or was it just pilot error as the board of inquiry concluded?[103] The US military have no right to refuse medical treatment that makes them fit for combat or returns them to active duty.[104] Therefore, was the Dexedrine used as a 'treatment' and was it required to make them fit for combat? US Army regulations state that *"An Army member on active duty or active duty for training will usually be required to submit to medical care considered necessary to preserve his life, alleviate undue suffering, or protect or maintain the health of others."*[105]

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[101] George J. Annas, "Protecting Soldiers from Friendly Fire: The Consent Requirement for Using Investigational Drugs and Vaccines in Combat," *American Journal of Law & Medicine* 24, no. 2/3 (1998): 249.

[102] Lauren R. Robbins, "Refusing to Be All That You Can Be: Regulating against Forced Cognitive Enhancement in the Military," in *Military Medical Ethics for the 21st Century*, ed. M. L. Gross and D. Carrick, Military and Defence Ethics (Farnham: Ashgate Publishing Limited, 2013), 127.

[103] Oliver Burkeman and Richard Norton-Taylor, "US Pilots Blame Drug for Friendly Fire Deaths," *The Guardian*, January 4, 2003, <https://www.theguardian.com/world/2003/jan/04/afghanistan.richardnortontaylor> (accessed March 27, 2020).

[104] Annas, "Protecting Soldiers from Friendly Fire: The Consent Requirement for Using Investigational Drugs and Vaccines in Combat.", 250.

[105] Stephen E. Deardorff, "Informed Consent, Termination of Medical Treatment, and the Federal Tort Claims Act--A New Proposal for the Military Health Care System," *Military Law Review* 115, no. Winter (1987): 68.

The key question is whether taking PCEs are a standard of 'medical care' to 'protect or maintain the health of others'?

Following the past violation of the rights and ethics of service personnel and the dangers of Defence gaining legal waivers to avoid IC, Mehlman adapted the Belmont principles for the military. Beneficence, respect for persons and justice changed to proportionality, paternalism and fairness.[106] Firstly, proportionality covers imposing a biomedical risk on troops only if necessary for a legitimate operation, where that risk is proportional to the military advantage gained. Secondly, paternalism is required due to reduced autonomy and the duty to obey which restricts a soldier's ability to withhold consent. Therefore, a commander must ensure the biomedical risks imposed are proportionate and maintain privacy, dignity and confidentiality.[107] Lastly, fairness is a difficult area for commanders who may have to manage imposing a biomedical risk on a section of their subordinates, yet ensure it is done in a non-discriminatory manner and not used as a punishment.[108]

Although the Belmont principles were designed to guide research, Mehlman's adapted military principles in combination, encapsulate what is meant by duty of care, a term which covers all moral and legal responsibilities, ranging from being wounded to safety at work. Duty of care is an important concept that is a responsibility of all military personnel above the lowest rank, who will be in charge of, or supervising those subordinates more junior than them.[109] When new recruits join the military they forfeit a degree of autonomy and understand that they may be

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[106] Maxwell J. Mehlman and Stephanie Corley, "A Framework for Military Bioethics," *Journal of Military Ethics* 13, no. 4 (2014): 337.

[107] Michael L. Gross, *Bioethics and Armed Conflict. Moral Dilemmas of Medicine and War* (Cambridge: MIT Press, 2006), 45.

[108] Mehlman and Corley, "A Framework for Military Bioethics.", 339-340.

[109] House of Commons Defence Committee, *Duty of Care. Third Report of Session 2004–05. Volume I. HC 63-I*, 29.

ordered into a life-threatening situation.[110] The new recruit implicitly consents to a range of activities to achieve legitimate military ends, on the understanding and trust that the military will minimise the risks as part of its duty of care. A soldier accepts new weapons and training which are always evolving, so could this be compared to new medicines with an implied consent for the taking of PCEs? It is accepted that military personnel may go to war with potential loss of life, but at present it is not widely known that PCEs are available. However, what is known always varies with time and if PCE use became commonplace, implied consent could be valid.

The military chain of command holds the responsibility for any risk being minimised and responsible for upholding the duty of care, of which one part for the UK is the Competent Medical Authority (CMA). The CMA is a senior military physician, who has signed off the medical aspects of a deployment plan and held accountable. However, who is ultimately accountable and is this body independent and empowered to prevent the military compromising itself in order to achieve its goal?[111] As PCEs are classed as medicines, the Defence Medical Services (DMS) would be the military authority and its three-star Director General holds full accountability.[112] Fortunately, there are external, independent inspections completed by the Care Quality Commission who can prosecute

[110] William J. FitzPatrick and Lee L. Zwanziger, "Defending Against Biochemical Warfare," *The Journal of Philosophy, Science & Law* 3, no. 2 (2003): 9.
[111] Jessica Wolfendale and Steve Clarke, "Paternalism, Consent, and the Use of Experimental Drugs in the Military," *The Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine* 33, no. 4 (2008): 347.
[112] United Kingdom. HM Government, "Defence Medical Services," <https://www.gov.uk/government/groups/defence-medical-services> (accessed May 18, 2020).

the DMS if medical standards are breached, including if people are harmed or placed in danger of harm?[113]

Is it acceptable for the military to violate the consent process and take a paternalistic view if it believes it is upholding the duty of care? Paternalism has been defined as *"the interference of a state or an individual with another person, against their will, and defended or motivated by a claim that the person interfered with will be better off or protected from harm."*[114] Paternalistic policies limit individual choices but are allowed if the authority considers there is over-riding benefit to the individual.[115] Although medicine has moved away from paternalism, it remains dominant in the military today and the IC process could be waived, if an individual putting their own preferences first, risks their own life and those of others,[116] noting a soldier's personal health can affect those around them.[117] If consent is waived for PCEs, does it make the individual a guinea pig and move the drug into an experimental or investigational category, with the resulting necessity for a greater level of IC? Trust in those accountable must be maintained, with duty of care at the forefront of decision-making if the consent process gets waived, as was the case of pyridostigmine and for the use of experimental drugs in combat.[118]

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[113] Care Quality Commission, "Defence Medical Services," 2019, <https://www.cqc.org.uk/what-we-do/services-we-regulate/defence-medical-services>, (accessed April 9, 2020).

[114] Gerald Dworkin, "Paternalism," ed. Edward N. Zalta, *The Stanford Encyclopedia of Philosophy* (Stanford: Metaphysics Research Lab, Stanford University, 2019), <https://plato.stanford.edu/entries/paternalism/>, (accessed January 8, 2020).

[115] Wolfendale and Clarke, "Paternalism, Consent, and the Use of Experimental Drugs in the Military.", 339.

[116] *Ibid.*, 341.

[117] Edmund G. Howe and Edward D. Martin, "Treating the Troops," *Hastings Center Report* 21, no. 2 (1991): 23.

[118] Wolfendale and Clarke, "Paternalism, Consent, and the Use of Experimental Drugs in the Military.", 345.

The notion of 'anticipatory consent' is one where the person cannot consent due to temporarily lacking full capacity such as injecting a soldier with a ComboPen, the antidote required when incapacitated by a nerve agent.[119] This could be coherent with PCEs, for example, the provision of drugs to combat fatigue at a critical moment when there is no time for detailed discussion. However, this veers towards a treatment rather than enhancement. Areas of service life which might need a future anticipatory consent could be incorporated into a broader consent which is more generalised and less specific,[120] outlining themes of what soldiers might have to agree to, allowing flexibility and a baseline of information. This consent could be started at recruitment, renewed annually and when there are new developments or scientific understanding.[121] The benefit of an annual broad consent is that repetition and building of information gains greater understanding but the danger is it becomes yet another form to sign with limited understanding of its significance.[122]

For PCE use, from the issues highlighted, it would seem logical that waivers should be avoided and where possible use both broad and IC. However, O'Neill disagrees with IC, believing those promoting it have poor arguments and exaggerated claims, citing too many exceptions for IC in medical practice, such as those who are mentally impaired, unconscious or under constraint such as prisoners.[123] He also described an

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[119] iMedi.co.uk, "Autoject (Combopen) Nerve Agent Antidote L4a1," 2009, <https://imedi.co.uk/autoject-combopen-nerve-agent-antidote-l4a1> (accessed April 30, 2020).

[120] Gert Helgesson, "In Defense of Broad Consent," *Cambridge Quarterly of Healthcare Ethics* 21, no. 1 (2012): 40.

[121] Rettig, "Military Use of Drugs Not Yet Approved by the FDA for CW/BW Defense: Lessons from the Gulf War.", ch. 4.

[122] FitzPatrick and Zwanziger, "Defending Against Biochemical Warfare.", 15.

[123] O'Neill, "Some Limits of Informed Consent.", 4.

"opacity of consent" when an individual consents to a certain action, without understanding that it might entail another necessary action.[124] This opacity was highlighted by the Alder Hey Children's Hospital retaining children's organs after death. The parents had consented to tissue being used for research but would not have consented to organs being removed, even though organs are made up of tissues.[125] This results in policy makers introducing or tightening IC procedures, to increase the protection of patients' welfare and the opportunity for them to make an informed choice.[126]

Importance of informed consent for military research

Gaining IC for biomedical research requires an elevated level of IC to protect patients and healthy volunteers from exploitation and harm as described by the Helsinki declaration and Belmont principles. The only civilian exceptions when IC is not required for research are for retrospective and emergency studies.[127] For the US, the 2002 Defence Appropriations Act can waive consent if the research directly benefits subjects, advances the development of a medical product necessary to the military and abides by all normal laws and regulations.[128] Since 2002, no waivers have been given but Gross believes that to improve military medical research, the current regulations need to be

[124] *Ibid.*, 6.
[125] Clare Dyer, "Consent Needed For Organ Retention, BMA Says," *British Medical Journal* 321, no. 7269 (2000): 1098.
[126] Corrigan, "Empty Ethics: The Problem with Informed Consent.", 769.
[127] Gross, *Military Medical Research Ethics: Investigational Drugs, Clinical Trials and Enhancement*, 6.
[128] John McManus *et al.*, "Informed Consent and Ethical Issues in Military Medical Research," *Academic Emergency Medicine* 12, no. 11 (2005): 1123.

exploited by waivers and broadening the scope of civilian medical research for military purposes.[129]

To protect UK troops from exploitation, the MOD have their own ethics research committee (MODREC) composed of experts and independents.[130] The independents' role is vital as an advocate outside of military influence to protect the safety of those participating in research and to avoid a "command culture".[131] MODREC has published its principles that *"protect and promote the interests of participants by describing robust scientific and ethical conduct and proportionate, assurance-based management of human participant research."*[132] These are aligned with national and international ethical principles where the rights of trial subjects *"prevail over interests of science and society."*[133] On IC, MODREC explicitly states that a soldier can refuse to partake in any research project and that the study information provided must be in a suitable format and proportional to the anticipated risk-benefit analysis.[134] Proportionality means that if risks are high or the study treatment deviates from standard practice, far more

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[129] Gross, *Military Medical Research Ethics: Investigational Drugs, Clinical Trials and Enhancement*, 7.

[130] United Kingdom. Ministry of Defence, "Ministry of Defence Research Ethics Committee," <https://www.gov.uk/government/groups/ministry-of-defence-research-ethics-committees#guidance-documents> (accessed January 9, 2020).

[131] United Kingdom. Ministry of Defence, *JSP 536. Governance of Research Involving Human Participants. Part 1: Directive*, 3rd ed. (London: HMSO, 2020), 5-5, Mehlman, Lin, and Abney, "Enhanced Warfighters: A Policy Framework.", 115.

[132] United Kingdom. Ministry of Defence, *JSP 536. Governance of Research Involving Human Participants. Part 1: Directive, 1-1*.

[133] United Kingdom, "The Medicines for Human Use (Clinical Trials) Regulations," Pub. L. No. 1031, Schedule 1, pt. 2, para. 3, (2004), <http://www.legislation.gov.uk/uksi/2004/1031/schedule/1/part/2/paragraph/3/made#text%3Dinformed consent> (accessed January 1, 2020).

[134] United Kingdom. Ministry of Defence, *JSP 536. Governance of Research Involving Human Participants. Part 1: Directive*, 3-4.

information should be provided and supports the proportionality described by Mehlman's adapted Belmont principles.

The individual must have "reasonable time" to decide whether to be involved which should not be the same day as receiving the information.[135] Corrigan discovered from her own research that trial subjects did not understand all the information given, what was being tested or if it involved active treatment.[136] Reasons given were trust in medical experts and the expectation that doctors would put their best interests first and foremost.[137] Individuals' perceptions of medical research vary according to their background and cultural norms.[138] Even the research title affects perceptions which when containing the word 'experiment' was least favourable and 'study' being most popular.[139] Worryingly is why people consent to research and Corrigan's small study had over 96% consent to the study for financial reward, with some doing so to please their doctor.[140] Her conclusion was that the IC process in isolation resulted in an *"empty ethics"* where the principles of IC did not take account of the social context.[141]

Faden argued that not all research requires IC, particularly for comparative-effectiveness research, believing it over-protects patients when the research has minimal effect on what matters to them and under-protects them from errors and management when the research needed to reduce those

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[135] *Ibid.*

[136] Corrigan, "Empty Ethics: The Problem with Informed Consent.", 774-775.

[137] *Ibid.,* 778-780.

[138] *Ibid.,* 777.

[139] Ruth R. Faden, *Advisory Committee on Human Radiation Experiments. Final Report.* (Washington DC: U.S. Government Printing Office, 1995), 734.

[140] Corrigan, "Empty Ethics: The Problem with Informed Consent.", 782-784.

[141] *Ibid.*, 787.

problems becomes too burdensome.[142] If an institution had a shared vision of continuous learning to enhance patient care with absolute transparency, then just simply informing patients of a study, allowing an opportunity to decline would be ethically acceptable. This only works if there are comparable options of treatment and not if there is higher risk, uncertainty, or the informational need is higher.[143] The determination of what constitutes low risk for randomised-controlled trials is described as having clinical equipoise and falling within a current standard of care.[144]

The dilemma of the overriding role of military necessity and maintaining patient autonomy is also relevant to research. Mission success of a military objective may take precedence over an individual soldier's rights and in the words of Gross, *"Military medicine is not exclusively patient centred. Rather its mission is to maintain force preparedness."*[145] As PCEs would be used off-label in healthy military volunteers, any trial is unlikely to get through an ethics committee according to a Dutch author.[146] PCEs are not yet a standard of care and potentially high risk, necessitating full IC for research. The UK should not pursue the US in allowing waivers of IC but follow established research ethics to gain knowledge, that might better protect soldiers on operations as a duty of care. In doing so, the military should follow Mehlman's

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[142] Ruth R. Faden, Tom L. Beauchamp, and Nancy E. Kass, "Informed Consent, Comparative Effectiveness, and Learning Health Care," *New England Journal of Medicine* 370, no. 8 (2014): 766.

[143] *Ibid.,* 767.

[144] Marilyn C. Morris and Robert M. Nelson, "Randomized, Controlled Trials as Minimal Risk: An Ethical Analysis*," *Critical Care Medicine* 35, no. 3 (2007): 943.

[145] Gross, *Military Medical Research Ethics: Investigational Drugs, Clinical Trials and Enhancement*, 4.

[146] D.O.E. Gebhardt, "Off-Label Administration of Drugs to Healthy Military Personnel. Dubious Ethics of Preventive Measures," *Journal of Medical Ethics* 31, no. 5 (2005): 268.

advice that a lengthy period of rigorous testing is required for any PCE which should only be introduced gradually.[147]

[147] Mehlman, Lin, and Abney, "Enhanced Warfighters: Risk, Ethics, and Policy.", 65.

Chapter Three – The Future of Informed Consent

How informed and how consensual is informed consent?

To ensure a soldier is truly informed, the desired benefits, unwanted effects and risks must be known and articulated to the soldier in a way that can be understood. The main risk with PCEs are their side effects which vary from drug to drug. PCEs affecting physical attributes such as anabolic steroids can cause permanent liver damage and growth hormones can lead to loss of vision and diabetes.[148] Stimulants such as amphetamines cause agitation, nervousness, sleeplessness, irritability and nausea.[149] Modafinil can cause headaches, gastrointestinal upset, sleep disturbance, depression and a drive to commit suicide, considered so significant, that the European Medicines Agency concluded it should not be prescribed for many disorders, including shift-work sleep disorder.[150]

The risks and benefits should be quantitative where possible to aid decision-making, for example, drug A may have 20% of users gaining cognitive enhancement but 1% commit suicide. This leads to the quandary of who decides if the risk-to-benefit ratio is too high: the CMA, the operational commander or the war fighter? Add this to the unknown risk of death or injury from a mission, comparing whether a soldier was enhanced or not makes the analysis difficult. What is known is that an increased likelihood of side effects decreases the

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[148] U.S. Anti-Doping Agency, "Effects of Performance-Enhancing Drugs," <https://www.usada.org/athletes/substances/effects-of-performance-enhancing-drugs/> (accessed May 8, 2020).

[149] Scharre and Fish, "Human Performance Enhancement.", 8.

[150] European Medicines Agency, "Modafinil," 2010, <https://www.ema.europa.eu/en/medicines/human/referrals/modafinil>.

willingness to use PCEs,[151] and although the tolerability of any side effects is an individual concern, collectively they could impact on mission success. There is consensus that individual autonomy can override minor medical risks and the correct person to judge whether the benefits are worth the risks is not necessarily the medical experts, according to Bostrom.[152]

The understanding of the information is a vital part of IC, with all individuals having differing perceptions and comprehension, especially of statistical risk. The level of a soldier's comprehension may be limited due to their literacy, with the Army recently taking new recruits with a reading age as low as aged five and almost 40% having the literacy and numeracy level of an eleven-year-old.[153] Therefore, a young soldier could not be considered informed if the limits of comprehension mean they do not fundamentally understand what they are consenting to.

PCEs should be reversible so that the enhanced effects and associated risks are removed when the need is no longer required, such as returning from deployment or discharge from the Service. However, PCEs that affect cognitive processing would likely have irreversible effects due to the complexity of neural processing and adaptation of brain cells to altered neurochemistry. This raises concerns if military personnel are

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[151] Sattler *et al.*, "Evaluating the Drivers of and Obstacles to the Willingness to Use Cognitive Enhancement Drugs: The Influence of Drug Characteristics, Social Environment, and Personal Characteristics.", 9.

[152] Bostrom and Sandberg, "Cognitive Enhancement: Methods, Ethics, Regulatory Challenges.", 323.

[153] Neil Sears, "Army Signs up Recruits with a Reading Age as Young as FIVE in Desperate Bid to Boost Troop Numbers," *The Daily Mail*, April 5, 2020, <https://www.dailymail.co.uk/news/article-8190009/Army-signs-recruits-reading-age-young-FIVE-desperate-bid-boost-troop-numbers.html>; Katherine Sellgren, "Almost 40% of Army Recruits Have Reading Age of 11, MPs Warn," *BBC News*, July 18, 2013, <https://www.bbc.co.uk/news/education-23346693> (accessed May 1, 2020).

compelled to take medications without choice. If the PCE is not reversible, there will be an impact on society having an enhanced person amongst them.[154] Over half the public believe that PCEs provide an unfair advantage to users, irrespective of whether it is considered cheating or not.[155] Nonetheless, wider use of PCEs could bring gains to society, with increased productivity leading to a reduction in poverty.[156] Buchanan takes it a step further, perceiving a dramatic positive benefit to society and the wider economy from enhancements.[157]

Other concerns revolve around the risk of dependence and abuse, with a national US survey published in 2006 finding that 13% of people taking stimulants such as amphetamines met the criteria for dependence or abuse which could have an impact on society.[158] Unintended consequences of PCEs could affect individuals, with a reduction in performance for those already high performing in a particular area as seen with amphetamines and creativity.[159] What if designer PCEs became a *"black ball"* technology that brought an end to civilisation?[160] Consider a cognitive PCE that fundamentally changed behaviour so its user was more prone to violence and destruction after several years of use. If the full mechanism of action and side effects are not

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154 Allhoff *et al.*, "Ethics of Human Enhancement: 25 Questions & Answers.", 15.

155 Schelle *et al.,* "Attitudes toward Pharmacological Cognitive Enhancement—a Review.", 10.

156 A.D. Mohamed, "Neuroethical Issues in: Pharmacological Cognitive Enhancement.", 537.

157 A. E. Buchanan, *Beyond Humanity?: The Ethics of Biomedical Enhancement*, (Oxford: OUP Oxford, 2011), 45.

158 Larry A. Kroutil *et al.*, "Nonmedical Use of Prescription Stimulants in the United States," *Drug and Alcohol Dependence* 84, no. 2 (2006): 140.

159 Martha J. Farah *et al.*, "When We Enhance Cognition with Adderall, Do We Sacrifice Creativity? A Preliminary Study," *Psychopharmacology* 202, no. 1 (2009): 541.

160 Nick Bostrom, "The Vulnerable World Hypothesis," *Global Policy* 10, no. 4 (2019): 455.

understood, is it truly informed consent? However, despite advances in science, complete understanding of how PCEs work and their long-term effects may never be known and therefore, information imparted can only be what is known at the time, acknowledging any gaps and limitations.

Katz believes physicians place greater value on longevity rather than on quality of life and that it is medicine and not law that should formulate the doctrine on IC, with greater emphasis on disclosure rather than consent.[161] The reality is doctors undertake their disclosure with a view to avoid legal liability for alleged non-disclosure.[162] How can soldiers be informed about PCEs when doctors are uncomfortable to admit ignorance over benefits and risks, the alternatives to treatment and presenting that information in an easily-digestible format for patients?[163] Katz judged the highest value on autonomy as the ultimate safeguard, whereas beneficence could reduce the person to a disease or label, be less caring and increase the chance of the doctor making the decision on behalf of the patient.[164] His conclusion was that physicians must acknowledge the extent of their scientific knowledge and ignorance, embrace joint decision-making and allow the patient to have the deciding vote.[165]

With a degree of autonomy forfeited when joining the military, there is a danger that soldiers could be 'informed' of PCE requirement with the 'consent' part being bypassed.[166] To ensure that the use of PCEs is consensual for a soldier, the Belmont principle of respecting persons is core when military

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[161] Jay Katz, "Informed Consent - Must It Remain a Fairy Tale," *Journal of Contemporary Health Law and Policy* 10 (1994): 71.
[162] *Ibid.*, 77.
[163] *Ibid.,* 80-83.
[164] *Ibid.,* 85.
[165] *Ibid.,* 90-91.
[166] Robbins, "Refusing to Be All That You Can Be: Regulating against Forced Cognitive Enhancement in the Military.", 148.

recruits could be considered a vulnerable group and prone to being under duress to following instructions by the chain of command. As described earlier, the camaraderie from a unit facilitates peer pressure on individuals into conforming to a set of common values and might incite the taking of PCEs against 'better judgement'. If a soldier was directly ordered to take a PCE, they would have to obey if it was a lawful order. However, obeying all lawful orders is not always the case because sometimes they can be superseded by the necessity to conform to other regulations such as the Geneva Convention or Law of Armed Conflict.[167]

Intelligent humans are capable of making their own autonomous choices but what if a particular measure benefits the entire military unit? Is there any circumstance when the sacrifice of personal autonomy is acceptable to promote the safety and therefore health of the wider group? Pellegrino argues that there is for preventative health, where the social construct means individuals *"give up autonomy to receive certain benefits"* and absolute *"self-interest is incompatible with life in a civilized community."*[168] Examples are the compulsory wearing of motorcycle helmets to reduce head injury from motorbike crashes and wearing seat belts in cars to reduce polytrauma in a crash. Of note is that the most effective preventive measures have been those imposed by law rather than by restraining choice.[169] There is similarity here in relinquishing some autonomy by joining the military and the directed wearing of preventative measures such as body armour or fire-retardant uniform.

Following the line of preventative health, if the taking of PCEs increased the individual and collective health and

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[167] United Kingdom. Development Concepts and Doctrine Centre, *JSP 383. The Joint Service Manual of the Law of Armed Conflict* (Shrivenham: DCDC, 2004), 13-14, 21-26.

[168] Edmund D. Pellegrino, "Autonomy and Coercion in Disease Prevention and Health Promotion," *Theoretical Medicine* 5, no. 1 (1984): 88.

[169] *Ibid.*, 90.

survivability, it should be compelled and not require consent. Annas disagrees, believing that prescription medications should not be forced on soldiers and military doctors should not be forced to prescribe them.[170] If a soldier refused a PCE, would that make them unfit for operational duty and potentially limit future career options? If a soldier refuses medical care that preserves their health or that of others on active duty, it could be considered a disciplinary offence.[171] Refusal of other types of medical care results in referral to a medical board to determine whether the refusal is reasonable or not.[172] The board determines if the medical care is needed to protect the soldier's health, that of others, or enables him to perform his duty properly. If the outcome is that the medical treatment is required, the soldier undergoes a disciplinary process or is administratively discharged from service.[173] Robbins considers the onus should be on the soldier, who should have the right to refuse without it affecting their liberty.[174] If a soldier refused before deployment, an alternative person could take their place but refusal on the battlefield would put others in danger. Clearly, there must be policy setting out the regulations and guidance covering PCEs, which should incorporate a consensual approach where possible and avoid an acute situation of refusal during conflict.

As PCEs are drugs that must be prescribed by a licensed physician, could a military doctor decide that the benefit of PCE use for the individual or team undertaking a mission would avoid the need for gaining consent, irrespective of the informed

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[170] Catherine L. Annas and George J. Annas, "Enhancing the Fighting Force: Medical Research on American Soldiers," *Journal of Contemporary Health Law and Policy* 25, no. 2 (2009): 308.

[171] Annas, "Changing the Consent Rules for Desert Storm.", 772.

[172] Robbins, "Refusing to Be All That You Can Be: Regulating against Forced Cognitive Enhancement in the Military.", 129.

[173] *Ibid.,* 130.

[174] Robbins, "Refusing to Be All That You Can Be: Regulating against Forced Cognitive Enhancement in the Military.", 134.

component? This focuses attention on whether military doctors are physicians, officers, or both and which takes primacy? The answer is clear to Annas, judging that the military doctor should be a *"physician first, last and always."*[175] Medical ethics should not change for a doctor whether military or civilian, during peacetime or in war, but there have been historical circumstances which seemingly justified variation from normal medical ethical obligations. Penicillin was given in priority to WW2 troops with sexually-transmitted diseases rather than those wounded, because the former would return to the front line faster and more recently was the suggestion of prescribing mood-stabiliser medications to ensure that soldiers remain in, or return them to, the theatres of Iraq and Afghanistan.[176]

The conflicting roles of being both a physician and soldier cause a dilemma of dual loyalty to each profession. This can be easily resolved if international guidance is followed like those from the World Medical Association stating that during armed conflict, physicians have a primary obligation to the patient and from the Geneva Convention stating that medical treatment should be administered for medical reasons and conform to medical ethics.[177] Both sets of guidance have potential flaws; PCEs are not treatments for medical reasons and the primary obligation to the patient might be enforced use of PCEs for their own protection. However, there are concerns if military necessity enforces the use of PCEs, that override the principles and ethics of doctors, with potential for abuse.[178]

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[175] George J. Annas, "Military Medical Ethics — Physician First, Last, Always," *New England Journal of Medicine* 359, no. 11 (2008): 1090.
[176] *Ibid.*, 1088.
[177] Daniel Messelken and Hans Ulrich Baer, "Hovering Between Roles: Military Medical Ethics," in *Military Medical Ethics for the 21st Century*, ed. M.L. Gross and D. Carrick, Military and Defence Ethics (Farnham: Ashgate Publishing Limited, 2013), 268.
[178] *Ibid.,* 270.

A doctor's professional responsibility is to the society it serves and that responsibility is determined by both the profession and independent regulatory bodies.[179] For a military doctor, this includes regulations set out by the General Medical Council, the medical specialty professional college and the respective Service.[180] There is no defined mechanism to resolve any conflict between these various regulatory bodies.[181] Is the military doctor a military officer first who must obey and give lawful orders, or a doctor whose primary concern is that of the patient? Cantor proposed that doctors should do their duty no matter their convictions, but this was aimed at conscientious objection and implied that the duty of a doctor overrides all else.[182] The Nuremberg trials proved that doing something you were ordered to do, against your moral code, was no defence.[183]

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[179] Dan W. Brock, "Conscientious Refusal by Physicians and Pharmacists: Who Is Obligated to Do What, and Why?," *Theoretical Medicine and Bioethics* 29, no. 3 (2008): 193.

[180] Examples of these regulations are General Medical Council, "Good Medical Practice," 2019, https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice, The Royal College of Anaesthetists, "Guidelines for the Provision of Anaesthetic Services," 2020, <https://www.rcoa.ac.uk/safety-standards-quality/guidance-resources/guidelines-provision-anaesthetic-services>; United Kingdom. Ministry of Defence, *The Queen's Regulations for the Army 1975. AC13206,* (London: Ministry of Defence, 2019), <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/826092/The_Queen_s_Regulations_for_the_Army_1975.pdf> (accessed April 6, 2020).

[181] Nathan K. Gamble and Michal Pruski, "Medical Acts and Conscientious Objection: What Can a Physician Be Compelled to Do?," *The New Bioethics* 25, no. 3 (2019): 263.

[182] Julie D. Cantor, "Conscientious Objection Gone Awry — Restoring Selfless Professionalism in Medicine," *New England Journal of Medicine* 360, no. 15 (2009): 1485.

[183] Harvard Law School Library, "Nuremberg - Transcript Viewer - Transcript for NMT 1: Medical Case," *Nuremberg Trials Project*, 2016, <http://nuremberg.law.harvard.edu/transcripts/1-transcript-for-nmt-1-medical-case?seq=2586> (accessed March 11, 2020).

In contrast, Mehlman does not think that military doctors following medical ethics and moral duties can override their military obligations and believes they should articulate the biomedical risk to decision-makers and be robust in challenging their commanders' intent.[184]

Physicians can only be expected to support medical acts which promote and restore health and are not obliged to provide non-medical services. The latter is fully supported by Gamble pointing out that *"Soldiers who voluntarily join the military cannot simply be compelled to do everything that lies within their skillset, and neither should physicians be so compelled."*[185] If prescribing a PCE brings about a health benefit, it would constitute a medical act but if prescribed in the absence of symptoms or pathology and driven by military need, it would constitute a socio-clinical act, as described by Gamble for social desires like aesthetic surgery.[186] This paper has described PCEs as an enhancement and not treatment, therefore prescribing them is a socio-clinical act and Gamble believes military doctors should not be 'obliged' to support it.

Currently, there is no written policy addressing the issue of whether a military physician can be legally ordered to administer a drug if it was considered medically unethical. An exception might be if it was believed to be therapeutic for emergencies in combat. This ethical deviation can result in patient harm as exampled by the administration of a clotting agent to save lives from polytrauma, effectively ordered by medical superiors despite not having completed research on its effects. Later studies proved its use led to unnecessary deaths and even at the time caused doctors concern at the Baghdad combat hospital in 2006, *"I worry that some soldiers were hurt by the*

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[184] Mehlman and Corley, "A Framework for Military Bioethics.", 345.
[185] Gamble and Pruski, "Medical Acts and Conscientious Objection: What Can a Physician Be Compelled to Do?", 268.
[186] *Ibid.*, 275.

overzealous use of unproven therapies".[187] The impact of this is magnified, when despite the fact that a soldier must accept standard medical treatment or face disciplinary action, they are not obliged to accept interventions that are not recognized by the medical profession as standard procedures.[188] Similar to the situation with PCEs, the use of the clotting agent was not standard procedure and should only have been given under IC or if given unconsented in emergency, should have a known, generally accepted risk-benefit analysis.

Delivering effective military informed consent

The final section of this paper will examine the practical aspects of military IC, covering how and when it should be done to maximise the informed and consensual components and the policy framework to support PCE use. IC must be underpinned by effective communication between the person informing and the person consenting. In the 1991 Gulf War, anthrax vaccination was not compulsory but given under implied consent.[189] Veterans later reported increased ill-health which many blamed on the anthrax vaccination, leading to fear and distrust of the military institution. To counter this for the 2003 Iraq war, explicit consent was used, coupled with an information programme by written, verbal and video means. A cooling off period was allowed before signing a consent form to strengthen the IC process.[190] Despite this, more than half of the British

[187] Robert Little, "Army Medicine: Untested in Battle," *The Baltimore Sun*, March 29, 2009, <https://www.baltimoresun.com/news/nation-world/bal-te.militarymed29mar29-story.html> (accessed March 30, 2020).
[188] Annas, "Protecting Soldiers from Friendly Fire: The Consent Requirement for Using Investigational Drugs and Vaccines in Combat.", 257.
[189] Dominic Murphy *et al.*, "UK Armed Forces Responses to an Informed Consent Policy for Anthrax Vaccination: A Paradoxical Effect?," *Vaccine* 24, no. 16 (2006): 3109.
[190] *Ibid.,* 3110.

military refused the anthrax vaccination.[191] A survey of those deployed in the 2003 Iraq war discovered their vaccination concerns revolved around its safety, effectiveness and IC.[192] Regardless of all the information and communication, it failed to provide a perceived balanced view and address the unease that the vaccination might be ineffective and cause future illness.[193] Apprehension over why the vaccination was now voluntary and requiring IC when it had previously been compulsory, resulted in the loss of trust and confidence in the MOD, who were believed to be covering up harmful effects. The conclusion was that IC may be desirable on ethical or legal grounds but it may not lead to the expected positive effect.[194] Therefore, an IC policy for PCEs that increases anxiety and reduces uptake will fail to achieve its goal.

The method of communicating IC is vital to confirm that the individual is both informed, especially understanding the risks, and has consented freely. Lessons can be drawn from how Public Health authorities disseminate risk information, where communication has the broad aim of presenting information in such a way that it is understood and usable, allowing the individual to make a judgement on the risk and be actively supported by the informer.[195] Nicholson highlighted that risks need to be discussed verbally, using a common language, an empathetic style, with the right amount of

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[191] Cathel Kerr, "Anthrax Vaccine Gets Cold Shoulder from Troops," *Canadian Medical Association Journal* 168, no. 10 (2003): 1308.

[192] Murphy *et al.,* "UK Armed Forces Responses to an Informed Consent Policy for Anthrax Vaccination: A Paradoxical Effect?", 3111.

[193] Dominic Murphy, Neil Greenberg, and Duncan Bland, "Health Concerns in UK Armed Forces Personnel," *Journal of the Royal Society of Medicine* 102, no. 4 (2009): 144.

[194] Murphy *et al.*, "UK Armed Forces Responses to an Informed Consent Policy for Anthrax Vaccination: A Paradoxical Effect?", 3113.

[195] P.J. Nicholson, "Communicating Health Risk," *Occupational Medicine* 49, no. 4 (1999): 253.

competence and openness.[196] He also noted that dressing more informally than expected supported effective communication. This would be an important point for the military with the obvious differential in rank structure when wearing uniform and the potential coercion it brings.

The World Health Organisation has noted shifts in public perception of information, with decreased trust in what experts and authorities say and a move towards the use of online sources and social media for obtaining advice, preferring opinion-based stories rather than those referenced.[197] The key is establishing trust and it is fortunate that doctors are amongst the most trusted by the public,[198] so it is they who should deliver the information, as opposed to non-medical MOD officials. Overloading information can fail to establish understanding, therefore, information should be delivered over multiple occasions, each delivering a few central messages and facts that build on what has been said previously. As time progresses, new information will inevitably arise and this should be disclosed as soon as possible to maintain the IC.[199]

For soldiers embarking on a military career, there should be both broad consent and IC for future PCE use. Broad consent alone could be prone to exploitation as occurred with the Havasupai Indian tribe who signed a broad consent for diabetic research that was expanded for wider purposes, for which if known, they would have refused consent.[200] The tribe were considered a vulnerable population, perhaps not dissimilar

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196 *Ibid.*, 254.

197 World Health Organisation, "An Introduction to Risk Communication," 1, <https://www.who.int/risk-communication/introduction-to-risk-communication.pdf?ua=1,> (accessed March 12, 2020).

198 Nicholson, "Communicating Health Risk.", 254.

199 Mahmood Adil, "Risk Communication in Healthcare: An Overview," *Journal of Communication in Healthcare* 1, no. 4 (2008): 365.

200 Beauchamp, "Informed Consent: Its History, Meaning, and Present Challenges.", 521.

to new military recruits. Broad consent would be improved if there were approximate limits as to what could be covered by it, but this shifts the responsibility for duty of care to the chain of command. However, as a baseline, broad consent of potential future PCE use should be undertaken for every military recruit, providing an opportunity for opting out and leaving the Service at that point. This broad consent should be repeated at each promotion and on any change or extension to length of service. This repetition provides a balance of frequency and avoiding it becoming a tick-box process, also allowing for updated information as it becomes available. Most importantly, it allows for the fact that as an individual matures from new recruit to trained soldier and through career progression, they gain life and military experience which alters their understanding and attitude to risk.[201]

Full IC containing all the specific detail should be undertaken when the soldier joins a unit that requires PCEs for its missions to succeed and repeated as part of pre-deployment training (PDT). Both allow timely points at which to opt out of PCE use, with PDT being the final moment at which refusal could occur. Once deployed in an operational environment where PCEs have been identified as critical to mission success, one team member that has not been enhanced may increase the risk to themselves and the unit, becoming a liability. In that case, consent could be bypassed and the soldier compelled to take the PCE. If soldiers are recruited for research, to avoid exploitation, a greater depth of IC remains mandated in accordance with the Belmont Report and MODREC approval.

To avoid any aspects of coercion and to maintain trust, IC information should be given in a conducive environment by a doctor trained in risk communication, current in knowledge of

[201] Thomas Dohmen *et al.,* "Risk Attitudes across the Life Course," *The Economic Journal* 127, no. 605 (2017): F114.

PCEs, ideally not in uniform and without superiors present.[202] Questions should be encouraged and background information should be provided via all forms of media, with a repository of frequently asked questions and answers being easily accessible on the internet and defence intranet. By engaging with the chain of command, soldiers could even regain partial autonomy by having control over the timings and method of delivery of the PCE.

Should there be a signed consent form for PCEs, even though implied consent is used for other drug prescriptions?[203] A signed consent does not necessarily imply IC and whether there has been full disclosure of every risk and benefit known, or minimal imparted knowledge. Whatever information is communicated by the physician must be truthful in accordance with their professional guidelines. However, as discussed earlier, doctors often gloss over areas where their knowledge is limited or the facts unknown and this must be overcome. Nonetheless, a signed consent form does provide a documented record of a meeting, it could highlight areas of information covered and it does protect the military doctor by forming the basis of a legal defence in the event of complaint.[204] On balance, a signed IC form should be used for soldiers accepting PCEs for transparency and accountability, and be stored securely as part of their medical documents.

Undoubtedly, policies must be implemented regarding PCE use, including any legal connotations such as who is responsible if the wrong dose is delivered. Is it the doctor, individual, command or manufacturer? Maslen pointed out that

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[202] McManus *et al.*, "Informed Consent and Ethical Issues in Military Medical Research.", 1122.
[203] Beauchamp, "Informed Consent: Its History, Meaning, and Present Challenges.", 517.
[204] *Ibid.*, 519.

only when the personal benefits and full risks of enhancement are known can policy be truly informed and ethical.[205]

As this complete information may never be known, the starting basis of any policy should encapsulate the four components to ethical decision-making when using PCEs as described by the US Army Aeromedical Research Laboratory:[206]

i. Use is voluntary.
ii. The drug is safe for its intended use.
iii. Dosage and use are consistent with its function.
iv. Alternative non-pharmacological agents have been fully explored first.

This is aligned to Mehlman's adapted Belmont principles of proportionality, paternalism and fairness and his earlier published hybrid framework, addressing the broader issues of transparency with the public and accountability for those in command making the decisions of necessity.[207]

[205] Maslen, Faulmüller, and Savulescu, "Pharmacological Cognitive Enhancement—How Neuroscientific Research Could Advance Ethical Debate.", 8.
[206] Scharre and Fish, "Human Performance Enhancement.", 10.
[207] Mehlman, Lin, and Abney, "Enhanced Warfighters: Risk, Ethics, and Policy.", 75-76.

Conclusion

The capability for human enhancement is already present and the UK will have to consider use of PCEs, either by a positive move to invest in that technology, or whether forced to consider it, in order to match opponents in a conflict. This issue deserves critical attention now during relative peace, because during wartime or conflict, it is much harder to give it the same rational and rigorous debate. Whichever direction the UK takes, it seems sensible to follow Annas' advice for military doctors and strive for an unequivocal policy based around traditional ethics where medical care of the individual takes primacy.[208] PCEs should not be considered a medical treatment but a group of drugs, only available by prescription from a licensed doctor, which increase a soldier's ability above the normal range.

This paper agrees with Gross stating, "Military medical ethics only *permits* informed consent".[209] Therefore, use of PCEs in the military will require an IC process to protect the individual, who unlike their civilian counterparts, has given up part of their autonomy on joining the military and who is vulnerable to peer pressure, unintended and intended coercion by those in command. The military has failed with IC in the past and exploited soldiers causing actual and potential harm and therefore a revised IC process, adapted from current civilian procedures is required.

Consent can only be considered informed once there is sufficient understanding of the risks, benefits and duration of effects, which are communicated in a manner commensurate with the recipient's intellectual capacity that ensures understanding. Much of this knowledge will come from new

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[208] Annas, "Protecting Soldiers from Friendly Fire: The Consent Requirement for Using Investigational Drugs and Vaccines in Combat.", 275.
[209] Gross, *Bioethics and Armed Conflict. Moral Dilemmas of Medicine and War.*, 107.

studies and as the likely research population would be military, enhanced IC as described by the Belmont Report should be followed, along with the established MODREC approval that protects the rights of personnel. Where knowledge is lacking, doctors must maintain trust by being honest and admitting any gaps or limitations.

To ensure the use of PCEs remains consensual, opting out must be allowed without the threat of discipline and any impact on career progression must be minimised with advanced disclosure. Even if previously consented, refusal to take PCEs at any stage prior to a deployment should be accepted without prejudice. However, once the mission has commenced, PCE use could be ordered. The justification for this non-consensual use would be that the interests of the unit, mission or state override that of the individual.[210] Difficulty remains in the area of unintended consequences of PCEs, which may remain unknown for many years and who decides that the risks of PCEs are deemed essential for mission success and outweigh the benefits?

The IC process for military PCE use should be underpinned by policy and an accepted mindset that IC is an ongoing process and not a one-stop shop. The process should commence with broad consent on first joining the Services and reiterated at every promotion and career extension, or when new key knowledge becomes known. This consent should be augmented by full IC as defined in this paper, when joining a military unit whose likely missions require PCEs and again during PDT. IC but not broad consent should require a signature and the delivery of the information should be via a military doctor who has been trained in communicating risk, in an environment designed to minimise any sense of rank differential and therefore facilitating the consensual approach and avoidance of coercion. Background information needs to

[210] Mehlman, Lin, and Abney, "Enhanced Warfighters: Risk, Ethics, and Policy.", 58.

be made freely accessible online and via all forms of media communication. If this method of IC is followed by the military, it will best protect those individuals taking PCEs by ensuring a balance of proportionality, paternalism and fairness. It will also protect the prescribing military doctors from negligence and protect those in command by transparency and accountability.

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Pharmacological enhancement of soldiers raises ethical questions over the issue of informed consent for the military. Currently this follows civilian guidelines but these may not be applicable to military personnel who have given up a degree of personal autonomy on recruitment. This paper examines informed consent as a process, detailing how informed and how consensual it is when both researching and prescribing enhancing drugs to soldiers. The paper also examines the dual role of the military doctor as physician and officer, when prescribing pharmacological enhancements and suggests a mechanism of how effective informed consent could occur, taking lessons from risk management communication strategies.

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