THE FUTURE IS NOW: ROBOTS AS SURGEONS

THE ADOPTION OF SURGICAL SAFETY STANDARDS TO ROBOTIC SURGERY

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Abstract: In this era of ever-expanding and an all-pervasive existence of technology, newer innovations and Artificial Intelligence (AI) are shaking the established global legal systems from their roots by bringing in novel challenges and complexities. One of the most controversial questions in this area pertains to accountability and determination of liability – how can a machine be held responsible/accountable and more importantly, how can a machine be sanctioned for its actions, especially where machine learning makes it possible for machines to take decisions itself? Artificial Intelligence has, amongst other fields, also entered the domain of medicine, where it poses massive legal challenges, especially in the area of surgery. As much as it aids both patients and doctors, it is difficult to determine liability and accountability of robots as surgeons, especially in cases where surgery results in fatality or great physical, emotional and/or psychological harm – should the doctor be responsible or the manufacturer of the robot or both? If all stakeholders are liable in some or the other manner, how should the liability be distributed? Such questions get more complicated where machine learning leads to implementation of erratic decisions by the robot and causes adverse consequences. This kind of exponential growth in medical technology is not being met by the legal dynamism which is slowly exacerbating the pacing problem and the gap is gradually widening. Before human dependence on robotics increases, it is essential for the legal framework to address such complexities and concerns. In this paper, I aim to address issues of regulation, accountability and liability that engulf the area of surgery and Artificial Intelligence along with recommending solutions to the pacing problem i.e. how the same can be resolved in the area of medicine and surgery.

Keywords: Autonomous Robotic Surgeries; Surgical Safety Standards; Liability and Accountability; Medical Malpractice; Product/ Device Legislation

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INTRODUCTION

Imagine a situation where a patient is being operated upon by an autonomous robot, where the patient consented to the robot being the surgeon in light of its accuracy, dexterity and minimally invasive surgical technique leading to faster recovery. In the middle of the surgery, complications arise and the robotic surgeon, based on its training, past performances, and statistics, decides to pursue an approach which is contrary to how the experienced human surgeon wants to approach the surgery. Should the robot be allowed to proceed with as it deems fit or should the human surgeon's approach be superseded as eventually the latter will be held accountable? The answer to this question remains undetermined because like many other areas of artificial intelligence and robotics, the area of robotic surgery too remains unregulated. Starting from the question of which of the contrarian approaches ought to be followed, to the question of final responsibility of the decisions in case of medical negligence by the robotic surgeon, there are no answers to the question of accountability and liability of a robotic surgeon. Luckily, there is still some time before the world sees autonomous robotic surgeons, however, the same is not very far.

Over the years, there has been a rapid advancement in technology, especially in the area of artificial intelligence and robotics. An analysis of the history of technology shows that technological change is exponential, contrary to the common-sense 'intuitive linear' view.[1] So we won't experience 100 years of progress in the 21st century – it will be more like 20,000 years of progress.[2] This revolution is not limited to any one area. Rather, it extends to all arenas of our life including healthcare and medicine, where revolutionary technologies are impacting surgical practices, such as the Smart Tissue Anastomosis Robot (STAR)[3] or the da Vinci robotic system, a robot-assisted surgery system which enables surgeons to undertake the most intricate of operations with very high dexterity.[4] Robotic surgeries are therefore opening up new avenues in the surgical space. With their dexterity, accuracy and precision, robotic surgeons are able to perform better than human experts in the field and are often trained to perform some monotonous yet extremely delicate tasks themselves. Innovators have therefore been able to experiment handing human lives in the hands of robots, assuring efficiency and effectiveness in treatments, recovery, and involvement in the healthcare system. These innovations have raised many legal and ethical challenges such as how the industry should be governed and who should be liable, which this paper attempts to address. Increasing use of robotic surgery for common surgical procedures with limited evidence and unclear clinical benefits is raising several concerns.

Surgeons perform the same functions as pharmaceuticals do, except those surgeons operate on the individual physically and directly. Surgery hence is more invasive in comparison to medication. Agreeing with scholars, [5] it is my argument that there should be internationally

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[1] Kurzweil R. (2004) *The Law of Accelerating Returns*. In: Teuscher C. (eds) *Alan Turing: Life and Legacy of a Great Thinker.* Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-662-05642-4_16 .

[2] *Id.*

[3] Simon Leonard, Kyle L Wu, Yonjae Kim, Axel Krieger, Peter C W Kim, *Smart tissue anastomosis robot (STAR): a vision-guided robotics system for laparoscopic suturing*, 61(4) IEEE Trans Biomed Eng. 1305, (2014).

[4] Ashrafian H, Clancy O, Grover V, et al. *The Evolution of Robotic Surgery: Surgical and Anaesthetic Aspects.* 119 BJA i72, (2017).

[5] Damini Kunwar, *Robotic Surgeries Need Regulatory Attention*, The Regulatory Review (Jan. 2020) https://www.theregreview.org/2020/01/08/kunwar-robotic-surgeries-need-regulatory-attention/; Guang-Zhong Yang et.al. *Medical robotics—Regulatory, Ethical, and Legal Considerations For Increasing Levels of Autonomy*, Robots and Society (2017). http://robotics.tch.harvard.edu/publications/pdfs/yang2017medical.pdf

harmonized regulatory standards governing the space of robotic surgery, analogous to the standards adopted by regulatory agencies such as the US Food and Drug Administration (FDA) in the United States or the Central Drugs Standard Control Organisation[6] (CDSCO) in India, which require that the drug be safe, efficacious and of acceptable quality before it is approved for human consumption. Not only are these standards the need of the hour, it is also essential for such standards and certifications to be internationally harmonized, to ensure patient safety, which should be of utmost priority. The idea is that these standards should honour the principle of "*primum non nocere*,"[7] i.e., first, do no harm.

In this paper, I engage in the debates surrounding the potential of artificial intelligence and autonomous robotic surgery, focusing on the legal and ethical challenges that it poses, which can and should be addressed with the help of adequate regulatory standards. The first part of the paper discusses the evolution and need of robotic surgeons followed by where this technology can take us and what are the problems associated with it. The second part of the paper analyses the "pacing problem", i.e. how the traditional legal framework does not keep up with these technological advancements, and whether it would be reasonable to hold the robotic surgeons accountable in the same manner as human surgeons. This takes us to the third part of the paper where I provide some recommendations for developing and improving the legal framework regulating this field and incorporating the same in healthcare practice, to ensure safety and security in the modern-day robotic surgery.

I. THE NEED AND DEPENDENCY ON ROBOTIC SURGEONS

Robotic surgeons have successfully worked towards improved clinical outcomes. Being one of the most successful areas of robotics,[8] robotic surgeons have been embraced by the surgical fraternity in an unparalleled manner, becoming the new standard of care.[9]

The original intention of robotic surgery was to permit the conducting of a surgical procedure from a remote distance without touching the patient[10] i.e. be minimally invasive. However, with greater surgical precision, accuracy and safer operations, robotic surgeons have been appreciated so much that they have also been devised to perform delicate surgeries such as joint replacements[11] or pelvic surgeries, which when conducted in the traditional way, leaves the surgeons hurting in their shoulders and with a seized up back.[12] Robotic surgeons allow minimally invasive approaches such as laparoscopy and thoracoscopy, which leads to

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[6] The Central Drugs Standard Control Organisation (CDSCO) (Indian regulatory authority for pharmaceuticals and medical devices) https://cdsco.gov.in/opencms/opencms/en/Home/.

[7] Robert H. Shmerling, *First, Do No Harm*, HARVARD HEALTH BLOG (June 26, 2021). https://www.health.harvard.edu/blog/first-do-no-harm-201510138421

[8] Aleks Attanasio, Bruno Scaglioni, Elena De Momi, Paolo Fiorini, Pietro Valdastri, *Autonomy in surgical robotics*, STORM LAB UK (June 26, 2021). *https://www.stormlabuk.com/wp-content/uploads/2020/07/ARCAS2020_PREPRINT.pdf*

[9] Tim Lane, *A Short History of Robotic Surgery*, 100 ANNALS 5 (2018). https://publishing.rcseng.ac.uk/doi/citedby/10.1308/rcsann.supp1.5

[10] Satava, R. M. *Surgical Robotics: The Early Chronicles: A Personal Historical Perspective* 12 Surg. Laparosc. Endosc. Percutaneous Tech. 6 (2002).

[11] STRYKER: MAKO ROBOTIC ARM-ASSISTED SURGERY (https://www.stryker.com/us/en/portfolios/orthopaedics/joint-replacement/mako-robotic-arm-assisted-surgery.html); ZIMMER BIOMET: ROSA ROBOTIC TECHNOLOGY (https://www.zimmerbiomet.com/patients-caregivers/knee/robotics-technology.html#:~:text=ROSA%2C%20which%20stands%20for%20Robotic,knee%20implant%20just%20for%20you)

[12] Tim Adams, *The robot will see you now: could computers take over medicine entirely?*, The Observer, July 29, 2018.

enhanced outcomes. Today, many doctors are using robotic surgeons because, in addition to the accuracy, precision and dexterity, robotic surgeons offer improved visualisation, less post-operation wound complications and less disfigurement. In addition, patients too prefer the assistance of robotic surgeons because of the reduced wound access trauma and shorter hospital stay.[13]

Therefore, assistance through robotic surgeons qualifies for dual benefits, both to the human surgeon who is operating as well as the patient. It enables the surgeon to perform minimally invasive techniques, which is in the interest of the patient, and assuring speedy recovery through the robotic surgeons' assistance. Robotic surgeon's extended stainless-steel arm and allow the surgeon to perform hour long surgeries while being seated.[14] Robot assisted surgeries are therefore being adopted increasingly, by multiples surgical specialities.[15] This assistance through robotic surgeons is further valued during the current times, when the world is suffering from a pandemic. Robots as healthcare assistants have been able to perform various monotonous tasks such as drawing blood[16], checking vital signs, monitoring the patient's condition,[17] taking care of the patient's hygiene[18] or acting as disinfectors,[19] thereby allowing nurses to devote their time towards activities that require greater human attention. These robots have been designed to carry out such monotonous and repetitive tasks, and in so doing, they assist the nurses in performing basic functions and procedures, which otherwise would overwhelm them physically and mentally. This allows the nurses and other medical practitioners to invest their time and energy to deal with issues that require being more creative, offering more care and empathy to the patient and making better decisions. Further, especially in the situations like the one posed by COVID-19, where proximity with an infected patient is riskier than it has ever been, involvement of high-end robots is the best way to address issues of nursing the patients without threatening the life of human nurses and doctors. Robots have therefore helped put more human 'care' back to 'healthcare.'[20]

The care and assistance provided by robot surgeons is especially praised today, considering how the COVID-19 pandemic[21] has transformed our world and impacted it from all possible ends. The ongoing pandemic has exposed our frontline workers to many risks,

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[13] H Ashrafian, O Clancy, V Grover, A Darzi, *The Evolution of Robotic Surgery: Surgical and Anaesthetic Aspects,* 119 BJA i72 (2009),*https://doi.org/10.1093/bja/aex383*

[14] Alliance of Advanced Biomedical Engineering, *Robot Assisted Surgery* https://aabme.asme.org/posts/robot-assisted-surgery.

[15] Chen, IH.A., Ghazi, A., Sridhar, A, et al. Evolving robotic surgery training and improving patient safety, with the integration of novel technologies. World J Urol (2020). https://doi.org/10.1007/s00345-020-03467-7.

[16] National Institute of Biomedical Imaging and Bioengineering, *Robots designed to simplify blood draws* (2020) https://www.nibib.nih.gov/news-events/newsroom/robot-designed-simplify-blood-draws#:~:text=NIBIB%2Dsupported%20bioengineers%20have%20created,more%20time%20to%20treat%20patients.

[17] Maureen McFadden, *Robots To The Rescure: Helping Monitor Patients At Risk of Falls, Confusion*, 16 NEWS NOW WNDU (Sep 19, 2018, 11:21 PM), https://www.wndu.com/content/news/Robots-to-the-rescue-Helping-monitor-patients-at-risk-of-falls-confusion-493777071.html .

[18] Chih-Hung King, Tiffany L. Chen, Advait Jain, Charles C. Kemp, *Towards an Assistive Robot that Autonomously Performs Bed Baths for Patient Hygiene*, HEALTHCARE ROBOTICS, LABORATORY GEORGIA INSTITUTE OF TECHNOLOGY https://assets.newatlas.com/archive/iros10_auto_clean.pdf (2010).

[19] Rachel Lerman, *Robot cleaners are coming, this time to wipe up your coronavirus germs,* Washington Post (September 08, 2020). https://www.washingtonpost.com/technology/2020/09/08/robot-cleaners-surge-pandemic/

[20] The Medical Futurist, *From Surgeries To Keeping Company: The Place Of Robots In Healthcare* https://medicalfuturist.com/robotics-healthcare/.

[21] World Health Organisation, *Coronavirus disease (COVID-19) Pandemic*, https://www.who.int/emergencies/diseases/novel-coronavirus-2019.

especially those who were in direct contact with the patients. The pandemic has also resulted into a halt in the availability of various medical services, for the protection of the medical practitioner as well as the patient. During the pandemic's peak, all but the emergency surgical interventions have been suspended due to the increased risks of virus transmission for patients and medical staff.[22] This has not only impacted the healthcare of the patients but also led to severe economic losses to various hospitals internationally.[23] The pandemic has therefore provoked the industry to adjust and renew the ways in which healthcare is administered. It has shown why change into a more technologically inclusive system is indispensable.

Technological advancements have been a good response to this adjustment where, with the integration of healthcare and technology, robots can act as a shield, physically distancing the doctor and the patient, thereby acting as a powerful tool to combat the omnipresent fear of pathogen contamination and maintain surgical volumes.[24] The need for these technological advancements is only bound to rise, be it to fight the ongoing HIV AIDS or COVID pandemic or the pandemics to come, as it is being observed that coronavirus is not our last pandemic.[25]

Another instance where robotic surgeons have been of extreme assistance is in remote and hostile environments such as battlefields, where, instead of exposing the human surgeons to a high-risk environment, the robots can be sent for making diagnoses, curing infections and performing surgeries.[26] Medical robotic systems were the brainchild of the United States Department of Defence's desire to decrease war casualties with the development of telerobotic surgery in the 1990s, operating in the 'master-slave' concept with the human surgeon being the master, whose manual movements were transmitted to end-effector (slave) instruments at a remote site.[27] There have been massive transformations and advancements in technology since then, however, this is another instance where surgical robots can and have performed crucial tasks while keeping the medical staff in a safer, uncontaminated environment. Robots and artificial intelligence not only assist surgeons and medical practitioners under ordinary circumstances, but they are also dextrous at mitigating infectious contamination and aiding patient management in the surgical environment during times of immense patient influx. Therefore, machine intelligence in terms of robotic surgeons is gaining special significance in healthcare, especially today, to combat the virus.[28]

Ethicists worry that we may become so reliant on, for instance, robots for difficult surgeries, that humans will start losing these life-saving skills and knowledge; or that we

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[22] Aleks Attanasio, Bruno Scaglioni, Elena De Momi, Paolo Fiorini, Pietro Valdastri, *Autonomy In Surgical Robotics, https://www.stormlabuk.com/wp-content/uploads/2020/07/ARCAS2020_PREPRINT.pdf*.

[23] Alan D. Kaye, Chikezie N. Okeagu, Alex D. Pham, Yarce A. Silva, Jpshua J. Hurley, Brett L. Arron, Noeen Sarfraz, G.E. Ghali, Jack W. Gamble, Hnery, Liu, Richard D. Urman, Elyse M. Cornett, *Economic Impact of COVID-19 Pandemic On Healthcare Facilities And Systems: International prespectives*, (2020) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7670225/#:~:text=International%20hospitals%20and%20healthcare%20facilities,of%20%2450.7%20billion%20per%20month.

[24] Zemmar, A., Lozano, A.M. & Nelson, B.J., *The rise of robots in surgical environments during COVID-19*. Nat Mach Intell 2**,** 566–572 (2020). https://www.nature.com/articles/s42256-020-00238-2

[25] Devi Sridhar, *Covid Won't Be The Last Pandemic. Will we be better prepared for the next one?*, THE GUARDIAN (Mar 24, 2021, 14:23), https://www.theguardian.com/commentisfree/2021/mar/24/covid-pandemic-prepared-investment-science

[26] Wells, A.C., Kjellman, M., Harper, S.J.F, et al. *Operating hurts: a study of EAES surgeons*. Surg Endosc 33**,**933–940 (2019). https://doi.org/10.1007/s00464-018-6574-5

[27] Prem N Kakar, Jyotirmoy Das, Preeti Mittal Roy and Vijaya Pant, *Robotic invasion of operation theatre and associated anaesthetic issues: A review*, 55(1) Indian J Anaesth. 18–25 (2011). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3057239/

[28] Zemmar, A., Lozano, A.M. & Nelson, B.J. *The rise of robots in surgical environments during COVID-19*. Nat Mach Intell 2**,** 566–572 (2020). https://doi.org/10.1038/s42256-020-00238-2

become so reliant on robots for basic, arduous labour that our economy would somehow be impacted and we would forget some of those techniques.[29] However, this objection does not stand against the general benefits that this technology has to offer, as it outweighs any losses. This argument is similar to arguments about our mathematical abilities being impacted with the advent of calculators or excel sheets. However, there has been no such impact on human abilities, despite such enhanced technologies. Similar arguments have been made about the human surgeons who may potentially forget the methods of performing crucial surgeries after training and delegating surgical tasks to the robotic surgeons. Similar to humans not lagging in their ability to make calculations, it is unclear why human surgeons would forget ways of performing something as artful as brain or heart surgery.[30] The trade-off undoubtedly lies in favour of the continual use and development of robotic assisted surgeries and medical aid. The argument therefore does not sustain.

II. EVOLUTION OF ROBOTICS IN HEALTHCARE AND THE "PACING" PROBLEM

Robot manufacturing has been in practice for a very long time, but they entered the realm of medicine only in the 1990s, addressing the need for technology that would support minimally invasive surgeries. The world saw its first robot in 1985, the Arthrobot, an orthopaedic surgical robot developed by Dr. James McEwen, which was capable of manipulating and positioning the patient's limb during the orthopaedic surgery on voice command by the surgeon.[31] With its functions, the robot made the surgery safer and of better quality, sparing the surgeon the job of manipulating the joint.[32] This was followed by Unimation Puma 200, an industrial robot, which was used by the Long Beach Memorial Medical Center in California to insert a probe for use in a brain biopsy using computed topography navigation.[33] The first robot that was approved by the US Food and Drug Administration (FDA) for clinical use was the Automated Endoscopic System for Optimal Positioning (AESOP), which was granted approval in 1994.[34] The robot was a voice controlled robotic arm for holding the endoscope, with adjustable positioning to ensure steady view to the operating field. This was followed by the creation of ZEUS in 1996, a complete robotic surgical system with seven degrees of freedom, tremor elimination and motion scaling.[35] This was also the robot which was used for the first 'long-distance' tele-surgical procedure, where the patient was undergoing laparoscopic cholecystectomy in Strasbourg while the doctor operating was located in New York.[36] Amongst all the surgical robots made so far, the most well-known

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[29] Patrick Lin, George Bekey, Keith Abney, *Robots in War: Issues of Risk and Ethics*, (2009). https://digitalcommons.calpoly.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1010&context=phil_fac

[30] *Id.*

[31] Olga Lechky, *World's first surgical robot in B.C.*, 21, No. 23, The Medical Post, The Maclean Hunter Newspaper for the Canadian Medical profession (1985). https://www.brianday.ca/imagez/1051_28738.pdf

[32] Smith, J.A., Jivraj, J., Wong, R, et al. *30 Years of Neurosurgical Robots: Review and Trends for Manipulators and Associated Navigational Systems*. Ann Biomed Eng 44**,** 836–846 (2016). https://doi.org/10.1007/s10439-015-1475-4

[33] Kwoh, Y. S., Hou, J., Jonckheere, E. A. & Hayati, S. *A Robot With Improved Absolute Positioning Accuracy For CT Guided Stereotactic Brain Surgery* 35 IEEE Trans. Biomed. Eng. 153 (1988).

[34] Nathan, C. O., Chakradeo, V., Malhotra, K., D'Agostino, H., & Patwardhan, R. *The Voice-Controlled Robotic Assist Scope Holder AESOP For The Endoscopic Approach To The Sella,* 16(3) SKULL BASE 123–131 (2006), https://doi.org/10.1055/s-2006-939679

[35] Ranev, D. & Teixeira, J., *History of computer-assisted surgery,* 100 Surg. Clin. North Am. 209–218, (2020).

[36] Marescaux, J. & Rubino, F. in Teleophthalmology (eds Yogesan, K, et al.) 261–265 (Springer, 2006); Lawrence Osborne *THE YEAR IN IDEAS: A TO Z*, New York Times (December 09, 2001). https://www.nytimes.com/2001/12/09/magazine/the-year-in-ideas-a-to-z-telesurgery.html

robot with ground-breaking evolution has been the FDA approved[37] da Vinci Xi and X Surgical systems by Intuitive Surgery,[38] a robot system offering precision, flexibility and control to perform many kinds of procedures across different surgical specialties ranging from cardiac surgery to head and neck surgery to gastric bypass and even urological surgery. Robotic surgeons are capable of performing technically challenging procedures.[39] These robots are not only limited to assisting surgeons in their surgeries or completing monotonous and repetitive tasks. They are also capable to diagnosing a patient's illness based on the symptoms and recommending the most suitable treatment plan.[40] This is done through the technique of machine learning. Machine learning is a statistical technique for fitting models to data and to 'learn' by training models with data.[41] The technique being at the core of most forms of AI, has been adopted in the healthcare system to make machines adept at precisely predicting what treatment protocols are likely to succeed based on various patient attributes and the treatment context.[42] The most recent robotic surgeons that have received FDA approval have been the Brainlab Loop-X Mobile Imaging robot and Cirq, a surgical robot.[43] The Brainlab Loop-X imaging robot, which can be controlled wirelessly with a touchscreen tablet, allows for flexible patient positioning and non-isocentric imaging which reduces the amount of radiation exposure and increases the variety of indications which can be treated.[44] Cirq, on the other hand, is a robotic alignment module, capable of fine tuning the alignment to a pre-planned trajectory and freeing up surgeons' hands, enabling them to focus on the patient's anatomy.[45]

Even though the advancements in robotic systems are relatively new, they are rapid, quick and require the legal community to respond. There are several other robotic surgeons and healthcare providers being developed for commercial availability, and while scalpel-wielding droids are a long way off, scientists are at work on devices that perform surgical tasks with minimal human oversight.[46] The legal and ethical complexities surrounding these

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[37] S.510 (k) premarket notification of intent to market application for The da Vinci Xi and X Surgical Systems (models IS4000 and IS4200) (March 31, 2020). https://www.accessdata.fda.gov/cdrh_docs/pdf18/K183086.pdf

[38] INTUITIVE SURGEON, https://www.intuitive.com/en-us/healthcare-professionals/surgeons?gclid=EAIaIQobChMIv7PY3ZOj8AIVEpSzCh1ETADDEAAYASAAEgK47_D_BwE (last accessed May 20, 2021).

[39] Troccaz, J., Dagnino, G. & Yang, G.-Z. *Frontiers of medical robotics: from concept to systems to clinical translation*. Annu. Rev. Biomed. Eng. 21, 193–218 (2019).

[40] Ahuja, Abhimanyu S. *The impact of artificial intelligence in medicine on the future role of the physician*. PeerJ vol. 7 e7702. 4 Oct. 2019, doi:10.7717/peerj.7702

[41] Thomas Davenport, Ravi Kalakota, *The potential for artificial intelligence in healthcare,* 6(2) FUTURE HEALTHCARE JOUNAL 94–98 (2019). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6616181/

[42] Lee SI, Celik S, Logsdon BA, Lundberg SM, Martins TJ, Oehler VG, Estey EH, Miller CP, Chien S, Dai J, Saxena A, Blau CA, Becker PS, *A machine learning approach to integrate big data for precision medicine in acute myeloid leukemia*, 9(1) NAT COMMUN 42 (2018); Susan Pinto, Stefano Quintarelli, Vincenzo Silani, *New Technologies and Amyotrophic Lateral Sclerosis- Which step forward rushed by the COVID-19 Pandemic?* 418 J Neurol Sci. (2020). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7403097/

[43] Brainlab, *Brainlab Loop-X Mobile Imaging Robot and Cirq Robotic Alignment Module for spine both receive FDA clearance,* (2021) https://www.brainlab.com/press-releases/brainlab-loop-x-mobile-imaging-robot-and-cirq-robotic-alignment-module-for-spine-receive-fda-clearance/#:~:text=Receive%20FDA%20clearance-,Brainlab%20Loop%2DX%20Mobile%20Imaging%20Robot%20and%20Cirq%20Robotic%20Alignment,Spine%20Both%20Receive%20FDA%20clearance&text=Chicago%2C%20February%2022%2C%202021%E2%80%94,%C2%AE%2C%20a%20robotic%20surgical%20system (last accessed May 15, 2021).

[44] Sam Brusco, *FDA OKs Brainlab's Loop-X Mobile Imaging Robot, Cirq Robotic Alignment,* ODT (February 23, 2021). https://www.odtmag.com/contents/view_breaking-news/2021-02-23/fda-oks-brainlabs-loop-x-mobile-imaging-robot-cirq-robotic-alignment-module/

[45] Brainlab, *supra* note 41.

[46] Sara Castellanos, *Autonomous Robots are coming to the Operating room,* THE WALL STREET JOURNAL (Sept 10, 2020 9:00 PM). https://www.wsj.com/articles/autonomous-robots-are-coming-to-the-operating-room-11599786000

developments have not been addressed so far, such as the question of liability, i.e. who would be held responsible in case of a medically negligent act of the robot, or in case of misdiagnosis by the robotic surgeon, which may cause harm to the patient.

Another probable situation that needs to be addressed by the legal system is, in case of clashes in opinions between the medical practitioner and the robotic surgeon, whose opinion prevails? This needs to be determined before we let robotic surgery be an ordinary practice in the world. Since there are multiple actors in bringing together one robotic surgeon, from the hardware engineer to the software developer, the producer/ manufacturer of the robot and the medical practitioner which helped in the machine learning process, there has to be clarity on the question of liability, something that the current tort law system is failing to address.[47]

Robotic surgeons are not humans, they lack consciousness and are ethically and morally asleep.[48] They function based on what they perceive over a certain period of time through machine learning.[49] This lag in the modification of law has led to the existence of the 'pacing problem', i.e. the temporal gap between technology and governance.[50] While the pace of technological development continues to accelerate, the pace of legal response has failed to keep up.[51] Law, being a dynamic tool is expected to develop faster to keep up with changing times and innovations in technology.[52] However, there are no regulations in place to govern and standardize the automation and robotics industry in healthcare and medicine. The current legal framework, that is purportedly managing and regulating these emerging technologies, is not growing as rapidly, fuelling concerns about a growing gap between the rate of technological change and management of that change through legal mechanisms.[53] The traditional legal tools are therefore being left behind by the emerging technologies. As Isaac Asimov said- "*It is change, continuing change, inevitable change, that is the dominant factor in society today. No sensible decision can be made any longer without taking into account not only the world as it is, but the world as it will be. . . .*",[54] it is essential for there to be additions and modifications to the current legal system to address the issues relating to certification and liability when it comes to robots as surgeons, beginning with incorporating internationally harmonized standards. Some potential problems if the law fails to keep up with the pace of the technology include, failure to impose precautions and restrictions to control the risks of new technologies, uncertainty in the application of the current legal framework to new technologies and the

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[47] Shane O'Sullivan, Nathalie Nevejans, Colin Allen, Andrew Blyth, Simon Leonard, Ugo Pagallo, Katharina Holzinger, Andreas Holzinger, Mohammed Imran Sajid, Hutan Ashrafian, *Legal, regulatory and ethical framework for development of standards in artificial intelligence (AI) and autonomous robotic surgery*, 15(1) INT J MED ROBOTICS COMPUTER ASSIST SURG., (2018). https://doi.org/10.1002/rcs.1968

[48] Wendell Wallach, Colin Allen, Stan Franklin, *Consciousness and Ethics: Artificially conscious moral agents*, 3(1) INETERNATIONAL JOURNAL OF MEDICAL CONSCIOUSNESS, 177-192 (2011).

[49] THOMAS DAVENPORT, RAVI KALAKOTA *supra* note 41.

[50] Braden R. Allenby, *The Growing Gap Between Emerging Technologies and the Legal-Ethical Oversight, The Pacing Problem*, 19-33 (Gary E. Marchant, Braden R. Allenby, Joseph R. Herkert) (2011).

[51] BRADEN R. ALLENBY, *supra* note 50.

[52] Suzie Miles, *Does the law need to develop faster to keep up with the changes in technology?,* ASHFORDS (November 09, 2015) https://www.ashfords.co.uk/news-and-media/general/does-the-law-need-to-develop-faster-to-keep-up-with-changes-in-technology ; Hans Kelsen, *A "Dynamic" Theory of Natural Law*, 16 LA. L. REV. (1956) https://digitalcommons.law.lsu.edu/lalrev/vol16/iss4/2

[53] Lyria Bennett Moses, *Recurring Dilemmas: The Law's Race to Keep Up with Technological Change*, U. Ill. J. Law Tech. & Pol'y 239-285 (2007).

[54] Isaac Asimov, *Asimov on Science Fiction*.

possibility of the existing legal framework to under or over-regulate the new technologies, or the technology making the existing legal framework obsolete.[55]

III. SHOULD THE ROBOTIC SURGEON BE MADE PERSONALLY LIABLE?

The "pacing" problem requires adoption of an adequate legal framework to regulate robot surgeries, the manner in which they are adapted and executed and the identification of who would be held liable in case of any negligence leading to damage to the patient. To respond to this question, it is essential to understand the status of robots in our society and in the medical industry. Should they be given the status of medical devices or should they be granted "personhood" thereby being made personally liable for their actions? Some argue that robots should be granted 'personhood' and therefore, be accorded with the same rights and liabilities as humans, including making them liable in case of any damage due to any action or inaction of the robot.[56]

The European Union is another part of the world making strides in developing robotic surgeons with the intention of delivering superhuman performance.[57] The most recent robotic surgeon, granted approval beginning in January 2021 is Functionally Accurate Robotic Surgery (FAROS), which, as the name suggests, aims at improving functional accuracy through embedding physical intelligence in the surgical robotics.[58] FAROS explores venues to efficiently embody surgeon-like autonomous behaviour at different levels of granularity.[59] While autonomous robots with human-like all-encompassing capabilities are still decades away, European lawmakers, legal experts and manufacturers are already locked in a high-stakes debate about their legal status: whether it's these machines or human beings who should bear ultimate responsibility for their actions.[60] In 2017, the European Parliament in its report[61] recommended creating a specific legal status of 'electronic personality' for sophisticated autonomous robots. This status could allow robots to make good any damage that they may cause as an electric personality, insuring them individually and holding them liable for the damages if they go rogue and start hurting people or damaging property.[62]

While such recommendations of granting robots a 'legal personality' raises its own set of complexities and concerns as is also highlighted by many other legal AI experts,[63] like the questions about its ethical and normative implications as there are not just physical or monetary harms but also psychological harms associated with surgical errors, the recommendation of

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[55] BRADEN R. ALLENBY, *Supra* note 50.

[56] Alex Hern, *Give robots "Personhood" states, EU Committee argues*, THE GUARDIAN (Jan 12, 2017, 15:52 GMT) https://www.theguardian.com/technology/2017/jan/12/give-robots-personhood-status-eu-committee-argues

[57] CORDIS, *Functionally Accurate Robotic Surgery* https://cordis.europa.eu/project/id/101016985 (last accessed on May 20, 2021).

[58] *Id.*

[59] *Id.*

[60] Janonsch Delcker, *Europe divided over robot 'personhood'*, POLITICO (April 11, 2018). https://www.politico.eu/article/europe-divided-over-robot-ai-artificial-intelligence-personhood/

[61] European Parliament Report with recommendations to the Commission on Civil Law Rules on Robotics A8-0005/2017 Para. 59, (f) (Jan 27, 2017) https://www.europarl.europa.eu/doceo/document/A-8-2017-0005_EN.html?redirect (last accessed on May 02, 2021).

[62] *Id.*

[63] "By adopting legal personhood, we are going to erase the responsibility of manufacturers," said Nathalie Navejans, a French law professor at the Université d'Artois, who was the driving force behind the letter. Noel Sharkey, emeritus professor of artificial intelligence and robotics at the University of Sheffield, who also signed on, added that by seeking legal personhood for robots, manufacturers were merely trying to absolve themselves of responsibility for the actions of their machines.

individually insuring each robot such that they would not be expected to be morally conscious of their acts is something I agree with. Robots cannot stand analogous to humans capable of getting married or benefitting from human rights. Restricting them to be legally capable of making good for any damage they cause is reasonable because that liability would fall to other actors. As AI experts argue, granting legal personality to robots would act as a safe harbour for the manufacturers, absolving them of the actions of their machines. Simply insuring robots individually would be as good as medical devices, as the FDA treats robotic surgeons (example- AESOP[64]), still keeping them devoid of all rights and responsibilities.

Arguing for robotic rights has become a subject-matter of serious policy debates, however, many are skeptical to this thought, primarily because robots do not possess some of the qualities that are associated with human beings such as freedom of will, intentionality, self-consciousness, moral agency, or a sense of personal identity.[65] Granting rights and duties to a robotic surgeon would therefore not satisfy the question of liability in case of harm caused due to negligence. A robot can never be held culpable and subsequently punished for the same due to the notion of "culpability" which is dogmatically connected with the notions of free will and conscience, possession of which are essential for attribution of guilt. One may argue that there are other unnatural things that have been granted 'personhood' the same way one argues for robots, such as companies or even natural water bodies, which are considered to be separate legal entities.[66] However, in all these cases, there is always a natural person existing behind this legal person and the veil can always be lifted. This would not be the case if a robot surgeon is granted personhood. This argument was also upheld by the European Economic and Social Committee on AI of 31 May 2017 which considers "the comparison with the limited liability of companies is misplaced, because in that case a natural person is always ultimately responsible."[67] Therefore, granting robotic surgeons a legal personality would not resolve the issues relating to liability. Rather it would cause further damage by giving unreasonable immunity to the manufacturer, distributor, owner and operator in the event of damage caused by the robot surgeons.

Considering the benefits, a robot surgeon has to offer, be it from carrying out monotonous tasks, to diagnosing illnesses, to helping surgeons perform surgeries with utmost precision and in a minimally invasive manner, thereby assuring better performance and faster recovery of the patient, the intention is to continue with robotic surgeons while assuring a balance is maintained with respect to questions of accountability and liability between the various stakeholders and players involved in implementing the robot-assisted surgery. Hence it is reasonable to expect the robot to be treated as any other medical device for the purpose of assisting the surgeon, by either working autonomously or on the directions of the robotic surgeon. Robotic surgeons as medical devices should only be launched for medical use only after they meet the standards which are in compliance with assuring safety, efficacy and use of high quality medical devices. Further, even if personhood is granted to a robot, the veil of juristic identity should allowed to be lifted so that a patient who is wronged can claim adequate

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[64] NATHAN, *supra* note 34.

[65] World Commission on the Ethics of Scientific Knowledge and Technology, *Report of COMEST on robotics ethics 2017* https://unesdoc.unesco.org/ark:/48223/pf0000253952; Laura Voss, *More than Machines?: Attribution of (In)Animacy to Robot Technology* 145 (2021).

[66] Muhammad Waqas, Zahoor Rehman, *Separate legal entity of Corporation: the Corporate Veil*, 3(1) INTERNATIONAL JOURNAL OF SOCIAL SCIENCES AND MANAGEMENT 1-4, (2016).

[67] Office of Journal of European Union, *Opinion of the European Economic and Social Committee on 'Artificial intelligence — The consequences of artificial intelligence on the (digital) single market, production, consumption, employment and society'* OJ C 288, 31.8.2017, p. 1–9.

and reasonable damages for its losses even from an operator like hospital or doctor can be held liable for serious mishaps which causes physical, emotional and even psychological harms.

IV. THE NEED FOR AGILE AND COMPREHENSIVE GOVERNANCE FOR AI AND ROBOTICS IN THE MEDICAL INDUSTRY

The rapid developments of robotic technologies in the last decades have naturally fostered the use of robotic devices for medicine and health, e.g., for surgery, diagnosis, rehabilitation, prosthetics, and beyond.[68] These developments have given rise to various legal and ethical considerations where the current traditional regulations have proven to be insufficient. Be it issues surrounding the governance and liability of self-learning robotic surgeons or the question of accountability, liability and culpability, the current legal framework has not been able to resolve these complexities within its domain. Within their scope, which allows a doctor to perform live surgery from New York on a patient situated in Strasbourg,[69] emphasizes the need for appropriately tailored regulatory measures that are internationally harmonized, laying down the safety regulations before these robotic surgeons are launched for use on human patients. These standards are also required to answer the question of superiority between the human medical expert, whose opinions are grounded on experience and the robotic surgeon, who works on machine learning, basing all its actions and decisions on statistics collected from previous surgeries. This is essential in cases of conflict of opinion between the human surgeon and robotic surgeon. Further, the question of accountability and liability, which is extremely crucial in cases of robotic surgeons also needs to be effectively addressed under the regulatory provisions so that the manufacturers of these robotic surgeons do not use these machines as a shield to evade liability and the liability can be imposed in a balanced an just manner. However, with the cumbersome procedural and bureaucratic hindrances, it is rather likely that by the time a regulatory system does somehow manages to place new regulations for an emerging technology, they will likely be obsolete by the time the ink dries on the enactment, thereby further aggravating the 'pacing problem' instead of resolving it.[70] The need, hence, is for a method that is more flexible, agile, holistic, reflexive and inclusive.[71]

This method begins with setting up regulatory bodies on domestic/ regional and international levels, with members including experts from the medical and technical field, ethicists, lawyers and legislators. The sole objective of these regulatory bodies would be to regulate the involvement of AI and robotics in the medical industry, both autonomous and for assistance, by introducing periodical guidelines that continuously modify and address the safety, quality and efficacy needs of these robotic surgeons, similar to the FDA's standards for pharmaceuticals.[72] These bodies would be required to carry out continuous modifications in the guidelines as per the changing technology in order to address the successfully address pacing problem which essentially requires them be instilled with dynamism so that they can effectively and expeditiously respond of rapid technological changes. These guidelines can be

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[68] Shane O'Sullivan, Nathalie Nevejans, Colin Allen, Andrew Blyth, Simon Leonard, Ugo Pagallo, Katharina Holzinger, Andreas Holzinger, Mohammed Imran Sajid, Hutan Ashrafian, *Legal, regulatory and ethical framework for development of standards in artificial intelligence (AI) and autonomous robotic surgery*, 15(1) INTERNATIONAL JOURNAL OF MEDICAL ROBOTICS AND COMPUTER ASSISTED SURGERY (2018). https://doi.org/10.1002/rcs.1968

[69] *supra* note 36.

[70] Wendell Wallach, Gary Marchant (2019), *Toward the Agile and Comprehensive International Governance of AI and Robotics*, 107 PROCEEDINGS OF THE IEEE (2019). https://ieeexplore.ieee.org/document/8662741/authors#authors

[71] *Id.*

[72] *Supra.*

introduced as "soft law" into the system and once they have been tested by governments and judiciary, they can be incorporated in the traditional legal framework.[73] For example, the Future of Life Institute promulgated its Asilomar principles as a soft law tool for AI governance, but now the State of California has adopted those principles into its statutory law.[74]

These guidelines should incorporate standards that demonstrate the robotic surgeon's proficiency and safety in performing its claimed tasks. This can be determined based on a competency-based assessment, developed by this regulatory body, honouring the principle of "above all, do no harm". Analogous to clinical trials for pharmaceuticals, the competency-based assessment should be gleaned from the robotic surgeon's performance in virtual reality simulator systems,[75] where they can be trained and examined under different scenarios. The use of preliminary lab training in robotic skills is a good strategy for the rapid acquisition of further, standardized robotic skills.[76] These virtual reality simulators would also help pass other hurdles such as high costs, lack of availability of the surgical robot[77] and would allow approvals in different domestic jurisdictions thus allowing standardization of regulatory standards.

Further, in order to ensure adequate accountability for the steps pursued by the robotic surgeon, there needs to be a "black box," one similar to that on an airplane,[78] can be adopted which would record all the procedures undertaken by the robot along with the reasons and justifications for the same. This recording system must be installed in the medical device at the time of building the system. The intention behind the installation of this "black box" is to provide evidence and data that will assist in failure analysis[79] and identify dysfunctions[80] by learning the system's inputs, internal state and outputs.[81] A similar solution was proposed in a different context by Decker, [82] as he tries to keep track of the modifications of the robotics system related to the robot's learning of an algorithm.[83] This black box recorder would also be an effective tool for the question of accountability in legal disputes.[84] Once the robot passes these tests, and the regulatory body is confident about the robotic surgeon's safety, efficacy and quality, it should be allowed to be put to use, either for autonomous procedures or to assist human surgeons. Moreover, in the interest of further technological development and for patients to be able to make an informed decision while opting for robotic surgeons, the guidelines must mandate honest publication of the data produced during the competency-based assessment through the virtual reality simulators and during actual surgeries. In addition to

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[73] *Supra* note 70.
[74] ACR-215 23 Asilomar AI Principles. (2017-2018)**,** Assembly Current Resolution No. 215, Chapter 206 https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180ACR215
[75] The virtual simulator are being developed by the Italian BBZ srl that is currently commercialising Xron, a novel training system for robotic surgery that runs on common hardware platforms.
[76] Mangano A, Gheza F, Giulianotti PC. *Virtual Reality Simulator Systems in Robotic Surgical Training*. Surg Technol Int. 2018 Jun 1;32:19-23. PMID: 29689588.
[77] *Id.*
[78] George Wafula, *What is in a plane's black box?,* BBC NEWS (March 15, 2019). https://www.bbc.com/news/av/world-africa-47591211
[79] *Supra* note 68.
[80] Cooper MA, Ibrahim A, Lyu H, et al. *Underreporting of robotic surgery complications*. 37(2) J HEALTHC QUAL (2015).
[81] *Supra* note 68.
[82] Decker M., *Responsible innovation for adaptive robots.,* PISA UNIVERSITY PRESS 65-86 (2014).
[83] *Supra* note 68.
[84] *Supra* note 82 pp: 84.

patient safety, this would also allow insurance companies to understand what to include or not to include in their health coverage of patients undergoing surgery performed by robot surgeons.

Despite the permit to function independently, the guidelines must mandate the presence of a licensed and board certified surgeon in the operating room at all times, even if the robot is functioning autonomously. This is necessary in the interest of the patient, which should be of utmost priority. Look at this as a surgical parallel to autonomously driven vehicles. In this example, a human remains in the 'driving seat' as a 'doctor-in-the-loop' thereby safeguarding patients undergoing operations that are supported by surgical machines with autonomous capabilities.[85] This should not only be seen as a back-up option but also as an ethical obligation towards the patients. In case the robotic surgeon acts in an incorrect manner or against the understanding of the licensed surgeon in-charge or in case of any technical failures, instead of aborting the surgery altogether, the human surgeon must be obligated to step in and take charge because providing best medical care to the patient is top priority. Converting to another surgical modality would not only be in the best interest of the patient, but it is rather also an ethical obligation that the human surgeon is bound to fulfil in such cases. Thus, this alternative recourse must be adopted through the guidelines. Further, the guidelines must clearly and strictly draw a hierarchy amongst the robotic and human surgeons. An expert human surgeon must always be ranked above the robotic surgeon and a clause in this regard must necessarily be incorporated in these guidelines. It is further essential that a patient is apprised of such information pertaining to the surgery and of the possible complications that can arise so that the consent obtained from the patient to undergo surgery is sufficiently informed and so that the patient is empowered to adopt an effective recourse in case he feels that he has been harmed. Such regulatory determinations also further make it easier to make resolve claims where a harmed patient seeks damages.

In addition to the presence of the medical practitioner, there must also be present an industry representative in the hospital employing robotic surgeons, which can look into the machine in case of technical difficulties, troubleshoot the hardware, software and patient interface system. This industry representative must not necessarily be trained in terms of his/her surgical skills as he/she is onsite for equipment support and not operative care, thus not being analogous to the human surgeon. The presence of an actual human surgeon and industry representative during the surgery would also emphasize the healthcare provider's culture of safety. The guidelines must also mandate the criteria based on which cases can be referred for robotic surgery, keeping in mind the object of maximizing patient outcome and minimising the chances of preventable complications.

Further, partially agreeing with the European Parliament Report,[86] all robotic surgeons must be independently insured for the liability of acts/omissions committed by them, which can be tracked through the black box recording system, accounting for all the acts of the robotic surgeon. While on the one hand, this insurance and black box recording system would avoid blame shifting or the entire liability falling on one of the actors, which may lead to discouraging innovation in the medical industry, it would not leave the victim of this negligence empty handed as the insurance company would cover the damages. This insurance must be seen as analogous to medical malpractice insurance,[87] a specialized type of professional liability insurance that covers physician liability arising from disputed services that result in a patient's

[85] *Supra* note 68.
[86] *Supra* note 61.
[87] *Understanding medical malpractice insurance*, INSURANCE INFORMATION INSTITUTE, https://www.iii.org/article/understanding-medical-malpractice-insurance (last accessed June 03, 2021).

injury or death. Therefore, all robotic surgeons should be independently insured with equal contributions from all actors in the making of the machine, which would cover the damages, if and when necessary.

Finally, all members of the medical community who are availing themselves of the assistance of these robotic surgeons should undergo compulsory mentorship programs that should be supported by medical education institutions. This mentorship program could be in the form of certificate programs or fellowships or any other novel educational methods, which would train these medical experts on how to operate the robotic surgeons and assure safer outcomes. This would also assist in building patient trust and foster a culture of safety by building a supervised regulatory structure.

CONCLUSION

AI, robotics, in healthcare and medicine are integrating at an exponential rate, raising various questions about accountability and liability, where the traditional legal standards and doctrines are proving to be insufficient. These medical innovations are unprecedented, and they demand innovative solutions. Not only do these robotic surgeons have a significant impact on surgical practice, they are also challenging the legal regulatory framework and the ethics of medicine and health care.[88] Therefore in this paper I have identified a need for an internationally standardised curriculum for training, assessing and evaluating the robotic surgeons and certifying them based on their skillset.[89] Projects such as SAFROS,[90] an initiative of the European Commission to shape the digital future, are necessary to be adopted internationally to regulate the robotics industry in medicine and health care. SAFROS, i.e. Safety in robot surgeons' hands, is a research project adapting an existing framework to improve the level of patient safety currently achievable by traditional methods.[91]

Technology has been established as a key enabler for better healthcare throughout the COVID-19 crisis and beyond.[92] This integration of technology and healthcare is evolving through the needs of the world at large. Before human dependence on robotics increases, it is essential for the legal framework to address the disputes that may arise. This regulatory frame, through accelerated adoption of digital technologies and solutions, must focus on patient safety and high quality care. It is essential for there to be internationally harmonized standards regulating robotics in the healthcare industry, assuring the use of robotics only when they are proven to be safe, efficacious, and of high-end quality. Robotic surgeons must undergo a rigorous and reliable certification process for standardization and must be independently insured to account for the damages caused due to their actions or inactions. In addition, the patients must also be informed and prepared completely about their lives being given in the control of these electronic circuits, arms and fingers made of stainless steel, with full disclosure of their advantages as well as flaws. This would enable the patient to make an informed choice.

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[88] A Mavroforou, E Michalodimitrakis, C Hatzitheo-Filou, A Giannoukas, *Legal And Ethical Issues In Robotic Surgery*, 29(1) INTERNATIONAL ANGIOLOGY 79 (2010). https://read.qxmd.com/read/20224537/legal-and-ethical-issues-in-robotic-surgery

[89] Regina Faes Petersen, Fabiola Nuccio Giordano, Eduardo Villegas Tovar, Alejandro Díaz Girón Gidi, *The Road To Becoming A Certified Robotic Surgeon*, 7(1) WORLD JOURNAL OF ADVANCED RESEARCH AND REVIEWS 187-196 (2020).

[90] Patient Safety in Robotics Surgery (SAFROS), European Commission, https://ec.europa.eu/digital-single-market/en/content/safros-safe-robot-surgeons-hands .

[91] *Id.*

[92] Nitin Kumar, *Healthcare: Opportunity for a digital generation leap*, TATA CONSULTANCY SERVICES, https://www.tcs.com/healthcare-opportunity-for-a-digital-generation-leap (last accessed on June 20, 2021).

Lastly, these regulations must clearly draw a hierarchy between human surgeons and robots, holding the expertise of one over the other, to ensure that in situations of clash in opinions, the guidelines address how the situation is to be handled. Afterall, autonomous robots are designed to assist human surgeons, not outshine them.[93]

[93] Elizabeth Svoboda, *Your robot surgeon will see you now*, Outlook Nature 573, S110-S111 (2019). *https://doi.org/10.1038/d41586-019-02874-0*