A CRITICAL ANALYSIS OF ETHICAL AND LEGAL IMPLICATIONS IN ROBOTIC SURGERY

Dissertation submitted to the National University of Advanced Legal Studies, Kochi in partial fulfilment of the requirements for the award of LL.M. Degree in PUBLIC HEALTH LAW

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CERTIFICATE

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DECLARATION

I, Dr Ragesh R., do hereby declare that this LL.M. Dissertation titled "A CRITICAL ANALYSIS OF ETHICAL AND LEGAL IMPLICATIONS IN ROBOTIC SURGERY", researched and submitted by me to the National University of Advanced Legal Studies, Kochi in partial fulfilment of the requirement for the award of Degree "Master of Laws in Public Health Law", under the guidance and supervision of Dr. Sheeba S. Dhar, is an original, bona-fide and legitimate work and it has been pursued for an academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this University or any other University.

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PREFACE

The inspiration for this dissertation stemmed from a growing academic and professional interest in the ethical and legal questions posed by rapidly advancing medical technologies—particularly robotic surgery. As this mode of treatment becomes increasingly prevalent in Indian healthcare, it exposes significant gaps in the existing regulatory framework. This study was undertaken to examine whether the current legal and ethical standards are sufficient to address the complexities introduced by robotic-assisted surgical procedures.

The importance of this topic lies in its multidisciplinary relevance. Robotic surgery not only raises procedural and technical questions but also challenges core principles of patient rights, professional responsibility, and institutional accountability. The absence of specific statutory regulation, standardised training, or informed consent protocols in India makes this inquiry both timely and necessary.

This dissertation combines doctrinal and empirical methods to evaluate the regulatory adequacy of robotic surgery. It explores the historical development of the technology, analyses ethical and legal responsibilities of stakeholders, and includes insights from practising surgeons in Kerala. Based on the findings, the study concludes that the current framework is insufficient and calls for a dedicated statutory regime, structured credentialing, robotic-specific consent protocols, and clearer liability mechanisms. It also recommends that equity, ethical oversight, and patient safety be made central to any future reform.

This work aspires to contribute meaningfully to academic discourse and policy deliberation on regulating advanced medical technologies in India.

LIST OF ABBREVIATIONS

Abbreviation	Full Form
AI	Artificial Intelligence
AESOP	Automated Endoscopic System for Optimal Positioning
AMA	American Medical Association
ARTAS	Artas iX System (Advanced Robotic Technology for Automated Surgery)
BNS	Bharatiya Nyaya Sanhita
CDSCO	Central Drugs Standard Control Organisation
CEA	Clinical Establishments (Registration and Regulation) Act
CORI	Computer-Assisted Orthopaedic Robotic Interface
CT	Computed Tomography
CUVIS	Customised Vision Surgical System (by Meril Life)
D&C Act	Drugs and Cosmetics Act
DCGI	Drugs Controller General of India
DPDP Act	Digital Personal Data Protection Act
EMRB	Ethics and Medical Registration Board
FDA	Food and Drug Administration (United States)
GMP	Good Manufacturing Practices
HIV	Human Immunodeficiency Virus
ICMR	Indian Council of Medical Research
IMC	Indian Medical Council
IPC	Indian Penal Code
IT Act	Information Technology Act
JAMA	Journal of the American Medical Association

MD Rules	Medical Device Rules
MRI	Magnetic Resonance Imaging
NATHEALTH	Healthcare Federation of India
NHRC	National Human Rights Commission
NMC	National Medical Commission
NMC-RMP Regulations	National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023
NOTES	Natural Orifice Translumenal Endoscopic Surgery
OTTAVA	Proprietary robotic platform under development by Johnson & Johnson
PUMA	Programmable Universal Machine for Assembly
ROBIA	Robot Impact Assessment
RMP	Registered Medical Practitioner
ROSA	Robotic Surgical Assistant (Zimmer Biomet)
SSI	SS Innovations (Indian surgical robotics company)
TMINI	Compact robotic surgical system by Think Surgical
TSolution One	Robotic System by Think Surgical
UROBOT	Urological Robot
VR	Virtual Reality
WHO	World Health Organization
ZEUS / ZRSS	Zeus Robotic Surgical System

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4. Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972) (U.S.)
5. Donoghue v. Stevenson, [1932] AC 562 (HL) (Scotland)
6. Dr. (Mrs.) Chanda Rani Akhouri v. Dr. M.A. Methusethupathi, (2017) 11 SCC 805 (India)
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14. Martin F. D'Souza v. Mohd. Ishfaq, (2009) 3 SCC 1 (India)
15. Maynard v. West Midlands Reg'l Health Auth., [1985] 1 All ER 635 (HL) (UK)
16. M.C. Mehta v. Union of India, (1987) 1 SCC 395 (India)
17. Natanson v. Kline, 350 P.2d 1093 (Kan. 1960) (U.S.)
18. Prem Kishore v. Delhi Med. Council, W.P. (C) No. 5310 of 2017 (Del. HC 2023)
19. Prem Kishore v. Indraprastha Apollo Hosp., First Appeal No. 721 of 2017 (NCDRC Jan. 27, 2023) (India)
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22. Rogers v. Whitaker, (1992) 175 CLR 479 (Austl.)
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Chapter 1

Introduction

Surgery, as a core domain of medical science, has undergone an extraordinary transformation across centuries. From the rudimentary and often perilous procedures of the ancient world to today's highly specialised and minimally invasive interventions, the discipline has evolved in tandem with advancements in anatomical knowledge, instrumentation, and human dexterity. Early surgical attempts were crude and largely experimental, often performed without anaesthesia, antisepsis, or any structured understanding of the human body. However, with the advent of scientific medicine, landmark developments such as anaesthesia, aseptic techniques, radiology, and imaging technologies revolutionised surgical outcomes. The introduction of laparoscopy, followed by computer-assisted interventions, laid the foundation for a new era—robotic surgery—where technology and human skill converge to achieve unprecedented precision and control.

This progressive evolution of surgical techniques has not occurred in isolation. Legal principles, ethical frameworks, and regulatory mechanisms have historically mirrored these changes, expanding their scope to accommodate the increasing sophistication of medical practice. The field of medical jurisprudence has had to adapt to new questions of liability, patient consent, and standard of care with every technological leap. As surgical interventions became more complex and outcomes more dependent on systemic precision, the law responded with doctrines rooted in negligence, professional duty, and patient autonomy. At each stage of surgical advancement, corresponding legal and ethical reflections were required to ensure patient protection and professional accountability.

Among the most transformative advancements in recent decades is the development of robotic surgery, a field that employs robotic platforms—often powered by artificial intelligence—to assist or even perform surgical procedures. Initially designed as master-slave systems where surgeons directly controlled robotic arms, modern robotic surgery now increasingly integrates autonomous decision-making and machine learning. This raises an entirely new set of ethical and legal questions. How does one assign liability when an autonomous system errs? What are the implications of using

data-trained algorithms in life-critical settings? Should the informed consent process change when technology plays a quasi-independent role?

Global academic, medical, and regulatory communities have engaged in rich discussions around adapting ethical and legal frameworks to meet the demands of robotic surgery. Countries and institutions vary in their preparedness, but there is a growing consensus that conventional approaches may not suffice. In India, although robotic surgery is increasingly practised in leading healthcare institutions, there remains a lack of dedicated statutory or regulatory guidelines tailored to this domain.

This dissertation seeks to engage with these pressing concerns by critically analysing the adequacy of the existing legal and ethical framework governing surgery and medical practice in India. The study focuses on assessing whether the present regime sufficiently responds to the unique challenges posed by robotic surgical systems, especially those that incorporate AI and automation. In doing so, the research also aims to propose actionable recommendations for reforming and strengthening the current regulatory landscape, with a view to ensuring that it remains robust, forward-looking, and aligned with emerging medical technologies.

1.1. Scope of the Study

The study focuses on robotic-assisted surgical procedures, excluding broader applications of robotics in healthcare, such as diagnostics or rehabilitation. The research is limited to legal and ethical aspects and does not delve into technical development or operational efficiency. The study may face challenges in accessing comprehensive case law data and limited precedents on robotic surgeries in certain jurisdictions. Additionally, biases in interview responses could limit empirical findings.

1.2. Research Objectives

1. To understand the history and evolution of robotic surgery
2. To analyze the extent of responsibilities of stakeholders vis-à-vis the rights of the patients.
3. To suggest the necessary changes in regulatory framework to address the advancements in robotic surgery.

1.3. Research Questions

1. How is the history and evolution of robotic surgery?
2. What is the extent of responsibilities of stakeholders vis-à-vis the rights of the patients?
3. What are the necessary changes required in the regulatory framework to address the advancements in robotic surgery?

1.4. Hypothesis

The current regulatory frameworks are insufficient to address the complexities introduced by advancements in robotic surgeries.

1.5. Research Methodology

The primary method of research employed in this study is doctrinal. It is based on analysis of primary sources such as statutes, case laws, and regulations, along with secondary sources including scholarly articles, reports, and commentaries. In addition, the study incorporates an empirical component by collecting data from surgeons actively engaged in robotic surgery. The data was obtained through semi-structured interviews conducted with purposively selected participants to gain insights into practical challenges and regulatory expectations.

1.6. Review of Literature

Various scholars in India and abroad have investigated the ethical, legal, and regulatory aspects of robotic surgery, reflecting a growing academic interest in the challenges posed by this rapidly evolving medical technology. While Indian contributions primarily focus on medico-legal concerns within the existing healthcare framework, foreign studies offer broader perspectives on liability, consent, and the implications of artificial intelligence in surgical settings. This review categorises the available literature into Indian and foreign studies, with a view to identifying key contributions, assessing their relevance, and highlighting the lacunae that the present research seeks to address.

Vijayanath V. et al., in their article titled *"Consent and Medicolegal Aspects of Robotic Surgery"*, published in the *Journal of Indian Academy of Forensic Medicine* (2019), make one of the earliest Indian contributions to the legal discourse on robotic surgery. This article critically examines the medico-legal challenges surrounding the use of

robotic systems in surgical procedures, with a particular emphasis on the Indian context. The authors highlight that while robotic surgery is gaining traction in select Indian hospitals, there exists no dedicated legal or regulatory framework governing its use. The study underscores the lack of specific guidelines addressing the unique consent requirements, machine-dependence disclosures, or credentialing standards associated with robotic interventions. It further argues that the current consent procedures, designed around conventional surgery, fall short in addressing the complexities introduced by technology-mediated surgical decisions. The authors call for the establishment of robotic-specific informed consent protocols and regulatory oversight mechanisms, identifying a significant gap in the existing legal architecture that this dissertation also seeks to explore.[1]

M.B. Bagwan, in the article *"Liability in Robotic Surgery: Legal Frameworks and Case Studies"*, presents an in-depth analysis of the legal complexities surrounding liability in the context of robotic-assisted surgical procedures in India. The study discusses how the introduction of robotic platforms into the operating room complicates the traditional model of medical negligence, especially where errors may result from software malfunctions, interface failures, or ambiguous control-sharing between human and machine. Bagwan examines judicial reasoning in relevant Indian case law and contrasts it with emerging international discourse to highlight the lacunae in domestic jurisprudence. The article emphasises that current Indian legal provisions, primarily rooted in the Consumer Protection Act and the Indian Penal Code, do not adequately accommodate the nuances of shared liability involving surgeons, hospitals, manufacturers, and programmers. Furthermore, the study draws attention to the absence of any dedicated legal standard or statutory protocol for assessing liability in technologically mediated surgeries. Bagwan concludes that in the absence of a robotic-specific liability framework, courts and regulators are compelled to apply conventional legal doctrines, which may prove insufficient to address the intricacies of robotic error attribution.[2]

[1] Vijayanath V., Joel V., Priyadharsan S., & Kesavan Bharathi K.R. (2024). *Robotic surgery: Consent and medico-legal aspect*. *Indian Journal of Forensic and Community Medicine*, 11(2), 74–77. https://doi.org/10.18231/j.ijfcm.2024.018

[2] Bagwan, M.B., Joshi, T., Goswami, R.A., Patil, R.S., Sharma, V., & Wani, L.K. (2025). *Liability in Robotic Surgery: Legal Frameworks and Case Studies*. *Journal of Neonatal Surgery*, 14(2s), 70–77. https://doi.org/10.52783/jns.v14.1659

Satvik N. Pai et al., in their article *"In the Hands of a Robot: The Medicolegal Considerations of Robotic Surgery"*, published in the *Cureus Journal of Medical Science*, explore the evolving legal and ethical implications of robotic-assisted surgery from an Indian medical perspective. Though published in an international journal, the study is authored by Indian clinicians and addresses concerns relevant to the Indian healthcare setting. The authors discuss the inadequacy of existing legal standards in dealing with complex issues such as system failures, consent for robotic interventions, and multi-party liability involving programmers, manufacturers, and healthcare institutions. The article also highlights the potential medico-legal consequences of autonomous decision-making by surgical robots and the ambiguity surrounding accountability in such scenarios. It emphasises the need for defined credentialing protocols for robotic surgeons and robust consent frameworks that reflect the technological involvement in surgical outcomes. The study identifies that while robotic surgery is increasingly performed in high-end Indian hospitals, there is a conspicuous lack of institutional or legal preparedness to deal with its complications. The authors call for the development of India-specific regulatory responses to bridge this gap between clinical innovation and medico-legal oversight.[3]

George Chandy Vilanilam and Easwer Hariharan Venkat, in their editorial titled *"Ethical Nuances and Medicolegal Vulnerabilities in Robotic Neurosurgery"*, published in *Neurosurgical Focus*, delve into the complex ethical and legal challenges associated with the integration of robotic systems in neurosurgical procedures. The authors highlight that while robotic assistance offers enhanced precision and potential benefits in neurosurgery, it also introduces unique medicolegal vulnerabilities. They emphasize the absence of comprehensive regulatory frameworks specifically addressing robotic neurosurgery, leading to ambiguities in areas such as informed consent, surgeon training, and liability in cases of adverse outcomes. The editorial calls for the development of robust guidelines and policies to ensure patient safety and clarity

[3] Satvik N. Pai, Madhan Jeyaraman, Naveen Jeyaraman, Arulkumar Nallakumarasamy, and Sankalp Yadav, *In the Hands of a Robot, From the Operating Room to the Courtroom: The Medicolegal Considerations of Robotic Surgery*, 15(8) *Cureus* e43634 (2023), https://doi.org/10.7759/cureus.43634.

in legal responsibilities, advocating for a proactive approach to address the evolving ethical landscape in the era of advanced surgical technologies.[4]

Emma De Ravin et al., in their article titled *"Medical Malpractice in Robotic Surgery: A Westlaw Database Analysis"*, published in the *Journal of Robotic Surgery* (2022), present a comprehensive examination of malpractice claims associated with robot-assisted surgical procedures in the United States. The study analyzes 61 malpractice cases from 25 states, spanning from 2006 to 2021, and identifies a significant increase—over 250%—in such claims in the latter half of this period. The most common allegations include negligent surgery (82.2%), misdiagnosis or failure to diagnose (46.7%), delayed treatment (35.6%), and lack of informed consent (31.1%). Notably, hysterectomy procedures accounted for the highest number of litigated cases (42.2%), followed by prostatectomy and hernia repair. The authors highlight that while the majority of verdicts favored defendants (77.8%), the average indemnity payment in plaintiff-favored cases was substantial, averaging over $1.25 million. The study underscores the need for enhanced informed consent protocols, continuous medical education, and malpractice reform to mitigate future litigation risks in the evolving landscape of robotic surgery.[5]

Jake Young, in the article *"AMA Code of Medical Ethics' Opinions Related to Robotic Surgery"*, published in the *AMA Journal of Ethics* (2023), examines how existing ethical guidelines apply to the emerging field of robotic-assisted surgery. While the American Medical Association's Code of Medical Ethics does not explicitly address robotic surgery, Young identifies several relevant opinions that provide ethical guidance. Young emphasizes the importance of transparent communication with patients regarding the benefits, risks, and uncertainties associated with robotic procedures. He also highlights the necessity for continuous medical education to ensure that healthcare professionals remain competent in using advanced surgical technologies. The article underscores the ethical imperative for physicians to engage in open and honest discussions with patients about what is known and unknown

[4] Vilanilam, G. C., & Venkat, E. H. (2022). Ethical nuances and medicolegal vulnerabilities in robotic neurosurgery. Neurosurgical Focus, 52(1), E2. https://doi.org/10.3171/2021.10.FOCUS21533
[5] De Ravin, E., Sell, E. A., Newman, J. G., & Rajasekaran, K. (2022). Medical malpractice in robotic surgery: a Westlaw database analysis. Journal of Robotic Surgery, 17(1), 191–196. https://doi.org/10.1007/s11701-022-01417-6

concerning robotic-assisted surgeries, thereby fostering informed decision-making and maintaining trust in the patient-physician relationship.[6]

Victor Chang et al., in their conference paper titled *"Ethical Discussions for Autonomous Robotic Surgeries"*, presented at the 2nd International Conference on Industrial IoT, Big Data, and Supply Chain (2021), delve into the ethical considerations surrounding the increasing autonomy of robotic surgical systems. The authors conducted a mixed-method study, including a survey of 60 participants, to assess perceptions of fully autonomous surgical robots. The findings revealed that 77% of respondents were opposed to the idea of robots replacing surgeons entirely, and 75% recommended that surgeons should monitor interactions, suggesting a preference for collaborative rather than fully autonomous systems. The study emphasizes the ethical imperative of maintaining human oversight in robotic surgeries to ensure patient safety and accountability. It also highlights the need for updated training curricula that incorporate skills for managing and interacting with autonomous systems. The authors propose frameworks such as a Robot Impact Assessment (ROBIA) and standardized adverse event reporting mechanisms to address the ethical and legal challenges posed by autonomous surgical robots. This study underscores the importance of proactive ethical deliberation and regulatory development in tandem with technological advancements in surgical robotics.[7]

A.P. Rathnayake, in the article *"Legal and Ethical Facets of Robotic Surgery: A Suggestion for a Guideline"*, published in the *Sri Lanka Journal of Forensic Medicine, Science & Law* (2024), examines the legal and ethical implications of incorporating robotic systems into surgical procedures. The study highlights that while robotic surgery offers benefits such as increased efficiency and reduced invasiveness, it also introduces complex challenges concerning liability and ethical standards. Rathnayake discusses various scenarios where liability may arise: if a surgical error is due to the surgeon's fault, it constitutes medical malpractice; if an injury results from a malfunctioning robot, the manufacturer may be held liable under product liability laws; and if a hospital lacks adequate resources or expertise to support robotic surgery, it

[6] Jake Young, *AMA Code of Medical Ethics' Opinions Related to Robotic Surgery*, 25(8) *AMA Journal of Ethics* E605–E608 (2023), https://doi.org/10.1001/amajethics.2023.605.
[7] Chang, V., Kamanooru, M. R., & Darko, G. T. (2021). Ethical discussions for autonomous robotic surgeries. In Proceedings of the 2nd International Conference on Industrial IoT, Big Data, and Supply Chain.

could be deemed negligent. The article emphasizes the necessity for clear guidelines to delineate responsibilities among surgeons, manufacturers, and healthcare institutions. Ethically, the paper underscores the importance of informed consent, ensuring patients are fully aware of the risks and benefits associated with robotic surgery. It also calls for the development of comprehensive policies to address the unique challenges posed by robotic-assisted procedures, advocating for a proactive approach to safeguard patient rights and uphold ethical standards in the evolving landscape of surgical technology.[8]

Joschka Haltaufderheide et al., in their article *"The Ethical Landscape of Robot-Assisted Surgery: A Systematic Review"*, published in the *Journal of Robotic Surgery*, present a comprehensive analysis of the ethical considerations associated with robot-assisted surgical procedures. The study systematically reviews existing literature to identify and categorize ethical concerns arising from the integration of robotic systems into surgical practice. The authors delineate seven primary ethical themes: harms and benefits, responsibility and control, professional-patient relationships, ethical issues in surgical training and learning, justice, translational questions, and economic considerations. They emphasize that these themes are deeply interconnected and require careful deliberation within the surgical community. The review highlights the necessity for a proactive ethical framework that evolves alongside technological advancements, ensuring that patient welfare and professional integrity remain central to surgical innovation. The authors advocate for continuous ethical discourse and the development of guidelines that address the unique challenges posed by robotic surgery, particularly as automation and artificial intelligence become more prevalent in the operating room.[9]

The review of literature reveals a clear and consistent academic consensus: while robotic surgery represents a significant technological leap in modern medicine, the legal and ethical frameworks governing it—particularly in India—remain inadequate. Indian scholarship has begun to recognise the urgency of developing regulatory responses tailored to the complexities of robotic-assisted procedures, yet concrete policy or statutory development is still lacking. Foreign literature, on the other hand, offers

[8] Rathnayake, A.P. (2024). Legal and Ethical Facets of Robotic Surgery: A Suggestion for a Guideline. Sri Lanka Journal of Forensic Medicine, Science & Law, 15(1), 29–33. https://doi.org/10.4038/sljfmsl.v15i1.7947

[9] Joschka Haltaufderheide, Stefanie Pfisterer-Heise, Dawid Pieper, and Robert Ranisch, The Ethical Landscape of Robot-Assisted Surgery: A Systematic Review, 19(1) Journal of Robotic Surgery 102 (2025), https://doi.org/10.1007/s11701-025-02228-1.

broader and more mature discussions, especially in the areas of informed consent, liability attribution, and ethical oversight of autonomous surgical systems. However, these discussions remain fragmented across jurisdictions and are often speculative in the absence of robust empirical grounding. What is notably absent across both Indian and foreign studies is a holistic analysis that integrates doctrinal, ethical, and empirical perspectives within a jurisdictionally specific legal system. This gap underscores the need for the present study, which seeks to comprehensively evaluate the adequacy of India's existing legal framework in governing robotic surgery and proposes reforms to ensure patient safety, ethical integrity, and accountability in this rapidly evolving domain.

1.7. Chapterization

Chapter 1 – Introduction

Chapter 2 – Evolution and Scope of Robotic Surgery

Chapter 3 – Ethical Dimensions and Patient Rights

Chapter 4 – Fixing Liability in Robotic Surgery

Chapter 5 – Empirical Perspectives

Chapter 6 – Conclusion and Suggestions

Chapter 2

Evolution and Scope of robotic surgery

2.1. Introduction

Surgery, as an essential component of medical science, cherishes a long and intricate history that spans millennia, evolving alongside humanity's quest for knowledge and technological advancement. From the crude surgical techniques of ancient civilizations, where rudimentary tools were employed for lifesaving interventions, to the sophisticated robotic systems of the modern era, the journey of surgery reflects a remarkable trajectory of progress.[10] This evolution unfolded in stages, with open surgeries revolutionizing the field through enhanced precision and outcomes, followed by the advent of minimally invasive laparoscopic techniques, which redefined surgical practice in the 20th century. Robotic surgery represents the pinnacle of this historical continuum, merging the capabilities of artificial intelligence, precision mechanics, and human expertise to achieve outcomes previously unimaginable.[11] The history of surgical advancements mirrors humanity's broader achievements in fields like engineering, communication, and space exploration, demonstrating an unyielding commitment to innovation and improvement in the face of challenges. This chapter explores the historical milestones and the expanding scope of robotic surgery, situating it within the broader narrative of surgical and technological evolution.

The robotic surgery, or robot-assisted surgery, has become a part of day-to-day surgical practice only very recently. The number of years since its introduction can be counted on one's fingers. An increasing number of hospitals are now offering robotic surgeries across more and more specialties.[12] Even some government hospitals are offering robotic surgery and planning to introduce it in additional government facilities.[13] On one hand, it is undoubtedly a new technology in practice, but its research

[10] **Encyclopaedia Britannica,** *Surgery (Medicine)*, https://www.britannica.com/science/surgery-medicine (last visited Dec. 31, 2024).
[11] **Mayo Clinic,** *Robotic Surgery*, https://www.mayoclinic.org/tests-procedures/robotic-surgery/about/pac-20394974 (last visited Dec. 31, 2024).
[12] Rivero-Moreno, Yeisson, et al. "Robotic Surgery: A Comprehensive Review of the Literature and Current Trends." *Cureus*, vol. 15, no. 7, 2023, p. e42370, doi:10.7759/cureus.42370.
[13] **Healthcare IT News,** *Robotic Surgery Trickles Down to India's Public Health Sector*, https://www.healthcareitnews.com/news/asia/robotic-surgery-trickles-down-india-s-public-health-sector (last visited Dec. 31, 2024).

and development span more than three decades as of today. This chapter will explore the slow and step-by-step evolution of robotic surgery over these three decades.

2.2 The Concept of Robot

The term "robot" was coined by Karel Čapek in 1921. The term denoted a fictional humanoid character in his Czech-language play titled Rossumovi Univerzální Roboti (Rossum's Universal Robots).[14] He derived the term "robot" from the Czech word robota, meaning "forced labour."[15] The play was a science fiction work with a storyline centered around a factory that produced artificial workers from synthetic organic matter. The word "robot" gained popularity through the success of this play and its adaptation into other artworks. The definition of "robot" provided by the Robotics Institute of America in 1979 is: "a reprogrammable, multifunctional manipulator designed to move materials, parts, tools, or specialized devices through various programmed motions for the performance of a variety of tasks."[16] This definition remains relevant for the diverse functions performed by robots today.

2.3. Preprogrammed Robotic Arm

Robotic surgery was first attempted on a human patient in 1985 for performing neurosurgical biopsies. The robot, developed by Victor Scheinman, was named PUMA 200 (Programmable Universal Machine for Assembly 200).[17] Its accuracy and success led to its application in urology. Various modified versions of this system were developed for urological procedures, such as SARP (Surgeon Assistant Robot for Prostatectomy), PROBOT (Prostate Robot), and UROBOT (Urological Robot). The first two were specifically used for prostatic surgeries, while UROBOT was employed for general urological procedures.[18] The ease of designing and programming robots for

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[14] **Encyclopaedia Britannica,** *R.U.R.*, https://www.britannica.com/topic/RUR (last visited Jan. 21, 2025).

[15] **Robotics Academy,** *Who Invented the Word Robot and What Does It Mean?*, https://www.roboticsacademy.com.au/who-invented-the-word-robot-and-what-does-it-mean/ (last visited Jan. 21, 2025).

[16] Moran, Michael E. "Rossum's Universal Robots: Not the Machines." *Journal of Endourology*, vol. 21, no. 12, Dec. 2007, pp. 1399–1402, doi:10.1089/end.2007.0104.

[17] Shah, Jay, Arpita Vyas, and Dinesh Vyas. "The History of Robotics in Surgical Specialties." *American Journal of Robotic Surgery*, vol. 1, no. 1, 2014, pp. 12–20, doi:10.1166/ajrs.2014.1006.

[18] Badaan, Shadie R., and Dan Stoianovici. "Robotic Systems: Past, Present, and Future." In *Robotics in Genitourinary Surgery*, edited by A.K. Hemal and M. Menon, 657. Springer, 2011, doi:10.1007/978-1-84882-114-9_59.

urology was due to the availability of fixed anatomical landmarks, in contrast to other areas of the body, such as the abdomen.[19]

Programmable universal machine for assembly (PUMA) 200

2.4. Master-Slave Robotic Systems

Scientists progressed to developing master-slave robotic systems in the early 1990s. Before this, earlier robotic arms operated using preprogrammed procedures. For example, the PUMA 200 was used in neurosurgery to perform a stereotactic brain biopsy, where it was programmed to position a needle with high accuracy based on preoperative imaging data. In contrast, master-slave robotic systems are designed for teleoperation, where a human operator (master) controls the robot (slave) in real time.[20] In other words, the PUMA 200 functioned as an autonomous, preprogrammed industrial robot, while master-slave robots act as extensions of human operators, replicating their movements in real time to perform tasks that require human judgment and dexterity.[21]

[19] Thaly, Rahul, Ketul Shah, and Vipul R. Patel. "Applications of Robots in Urology." *Journal of Robotic Surgery*, vol. 1, 2007, p. 4, doi:10.1007/s11701-006-0003-9.
[20] Ashrafian, H., et al. "The Evolution of Robotic Surgery: Surgical and Anaesthetic Aspects." *British Journal of Anaesthesia*, vol. 119, no. S1, 2017, pp. i72–i84, https://academic.oup.com/bja/article/119/suppl_1/i72/4638479.
[21] Kawashima, Kenji, Takahiro Kanno, and Kotaro Tadano. "Robots in Laparoscopic Surgery: Current and Future Status." *BMC Biomedical Engineering*, vol. 1, no. 12, 2019, pp. 1–6, doi:10.1186/s42490-019-0012-1.

When used in surgery, master-slave robots consist of two essential parts: the surgeon's console and the robotic arms.[22]

2.4.1. First Master-Slave Robotic Arm

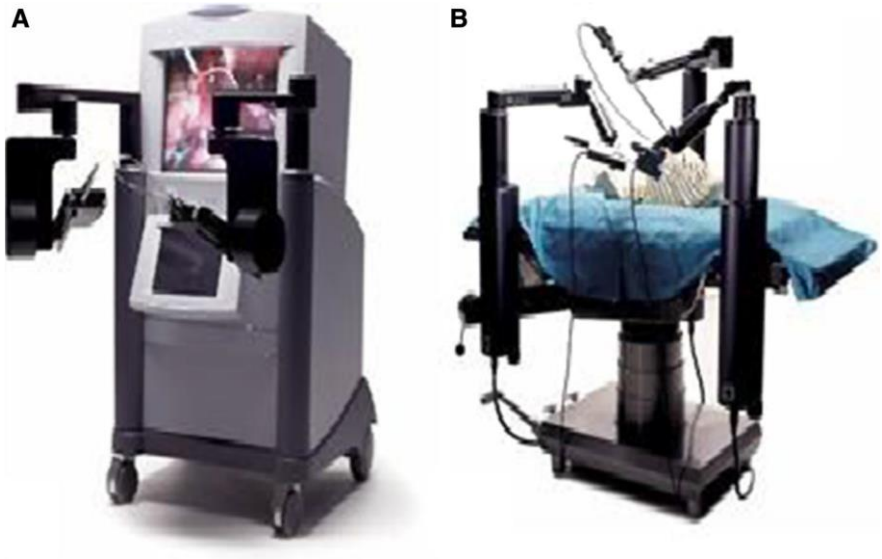
The first master-slave robotic system developed and used was AESOP (Automated Endoscopic System for Optimal Positioning). It was created in 1993 by Yulin Wang in California, USA. AESOP was capable of manipulating endoscopic cameras by responding to the surgeon's voice commands.[23] The U.S. Food and Drug Administration (FDA) approved AESOP as an endoscopic camera manipulator, though not specifically as a robotic surgery system.[24] This allowed AESOP to replace assistants who were traditionally assigned for this task. Despite being in its early stages, the robotic arm was utilized in various surgeries, including laparoscopic cholecystectomy, hernioplasty, fundoplication, and colectomy.[25]

Automated endoscopic system for optimal positioning (AESOP)

[22] Ghezzi, Tiago Leal, and Oly Campos Corleta. "30 Years of Robotic Surgery." *World Journal of Surgery*, 2016, doi:10.1007/s00268-016-3543-9.
[23] Pugin, F., P. Bucher, and P. Morel. "History of Robotic Surgery: From AESOP® and ZEUS® to da Vinci®." *Journal of Visceral Surgery*, vol. 148, no. e3–e8, 2011, doi:10.1016/j.jviscsurg.2011.04.007.
[24] Ghezzi, Tiago Leal, and Oly Campos Corleta. "30 Years of Robotic Surgery." *World Journal of Surgery*, 2016, doi:10.1007/s00268-016-3543-9.
[25] Baća, Ivo, Christian Schultz, Leszek Grzybowski, and Volker Götzen. "Voice-Controlled Robotic Arm in Laparoscopic Surgery." *Croatian Medical Journal*, vol. 40, no. 3, 1999, pp. 1–9.

2.5. Development of Full Fledged Robotic Surgical System

Since the robotic manipulation of the endoscopic camera alone was unsatisfactory, Yulin Wang advanced his research and developed a fully-fledged robotic surgical system named ZEUS. The ZEUS Robotic Surgical System was abbreviated as ZRSS.[26] It was tested on animals in 1995 and first used in humans for the anastomosis of the fallopian tube at the Cleveland Clinic in 1998.[27] The ZEUS robotic system was subsequently utilized for various other surgeries, including gastrointestinal, urologic, gynaecologic, and cardiac procedures.[28] The ZEUS system was also employed for telesurgery for the first time in 2001.[29] Telesurgery involves the surgeon remotely controlling the robotic system via a wireless network. Following a prolonged legal battle, Computer Motion Inc., the company founded by Yulin Wang that developed the AESOP and ZRSS robotic systems, merged with Intuitive Surgical Inc. and discontinued the ZEUS Robotic Surgical System.[30]



[26] Chitwood, W. Randolph Jr. "Historical Evolution of Robot-Assisted Cardiac Surgery: A 25-Year Journey." *Annals of Cardiothoracic Surgery*, vol. 11, no. 6, 2022, pp. 564–582, doi:10.21037/acs-2022-rmvs-26.

[27] Lawrie, Theresa A., et al. "Robot-Assisted Surgery in Gynaecology." *Cochrane Database of Systematic Reviews*, 2019, no. 4, Art. No. CD011422, doi:10.1002/14651858.CD011422.pub2.

[28] Marescaux, Jacques, and Francesco Rubino. "The ZEUS Robotic System: Experimental and Clinical Applications." *Surgical Clinics of North America*, vol. 83, no. 6, 2003, pp. 1305–1315, doi:10.1016/S0039-6109(03)00169-5.

[29] Gottlieb, Scott. "Surgeons Perform Transatlantic Operation Using Fibreoptics." *BMJ*, vol. 323, 29 Sept. 2001, p. 713, doi:10.1136/bmj.323.7313.713.

[30] **The New York Times,** *Acquisition Unites Rival Surgical Robot Manufacturers*, https://www.nytimes.com/2003/03/08/business/company-news-acquisition-unites-rival-surgical-robot-manufacturers.html (last visited Dec. 31, 2024).

ZEUS robotic surgical system with surgeon console (A) and robotic arms (B)

2.5.1. Development of da Vinci Robotic Systems

Before the merger, Intuitive Surgical Inc. developed the da Vinci Robotic System, which is currently the most widely used robotic system for surgeries worldwide. The first robot-assisted surgery using the da Vinci system was a cholecystectomy performed in 1997 by Jacques Himpens and Guy Cardiere in Brussels, Belgium. Following its success, the da Vinci system was used for a myocardial revascularization procedure at the University of Leipzig in Germany in 1998. However, the results in cardiovascular surgery were not satisfactory, despite the developers initially intending it for such procedures. Subsequently, the robotic system was employed for various abdominal surgeries, including cholecystectomy and fundoplication, across several European countries. Later, on July 17, 2000, the da Vinci system received FDA approval for human use. During that period, however, the da Vinci Robotic System was primarily utilized only for prostatectomy (removal of the prostate gland) for malignancy and hysterectomy (removal of the uterus) for benign conditions.

Da Vinci Robotic Surgical System with Surgeons' console, patient cart and vision cart.

2.5.2. Development of Other Surgical Robotic Systems

In addition to the da Vinci Robotic System, many other developers have introduced surgical robots to assist surgeons in performing robot-assisted surgeries. These include the ROSA® robotic systems by Zimmer Biomet, Mako SmartRobotics™ by Stryker, CORI and NAVIO Surgical Systems by Smith+Nephew, neuromate® by Renishaw, the Hugo™ RAS system and Mazor™ X Stealth Edition robotic guidance platform by Medtronic, the MONARCH™ Platform, VELYS™ Robotic-Assisted Solution, and OTTAVA Platform by Johnson & Johnson, as well as the Portico with FlexNav TAVI System and Prostar XL PVS System by Abbott.[31] Surgical robots are also manufactured in India. Examples of Indian surgical robots include the CUVIS Joint Robotic System by Meril Life and SSI Mantra by SS Innovations.[32,33] Although there are now numerous surgical robot manufacturers, the da Vinci system continues to dominate the field of surgical robotics.[34]

2.6. Advantages of Robotic Systems

Surgical robots can successfully overcome many of the disadvantages of laparoscopic surgery. Laparoscopic surgery provides a 2D vision on the screen for the surgeon, whereas robotic surgery offers a 3D view of the surgical field through the surgeon's console. Compared to open surgeries and laparoscopic surgeries, this 3D view is a high-definition magnified view, providing better visualization of the surgical field.[35] The fulcrum effect is another disadvantage of laparoscopic surgery. The fulcrum effect means that in laparoscopic surgeries, the abdominal wall acts as a pivot point. As a result, the tool endpoints inside the abdominal cavity move in the opposite direction to the surgeon's hands, making laparoscopic surgery a non-intuitive motor skill that is difficult to learn. This fulcrum effect can be effectively nullified in robotic surgery,

[31] **Roots Analysis,** *Top Surgical Robot Companies*, https://www.rootsanalysis.com/key-insights/top-surgical-robot-companies.html (last visited Dec. 31, 2024).
[32] **Meril Life Sciences,** *Robot-Assisted Surgery*, https://www.merillife.com/robot (last visited Dec. 31, 2024).
[33] **SS Innovations,** *SSI Mantra*, https://ssinnovations.com/ssi-mantra/ (last visited Dec. 31, 2024).
[34] Fortune Business Insights, Surgical Robots Market Report, https://www.fortunebusinessinsights.com/industry-reports/surgical-robots-market-100948 (last visited Dec. 31, 2024).
[35] Wong, Shing Wai, and Philip Crowe. "Visualisation Ergonomics and Robotic Surgery." *Journal of Robotic Surgery*, vol. 17, 2023, pp. 1873–1878, doi:10.1007/s11701-023-01618-7.

where the surgeon can control the tool's internal endpoints directly. Thus, the natural eye-hand-instrument alignment is preserved in robotic surgery.[36]

Laparoscopic surgery also uses non-articulated instrument arms, meaning straight instruments without joints. In contrast, robotic surgery utilizes EndoWrist instruments with seven degrees of freedom. The EndoWrist function replicates the human wrist's functionality.[37] In some robotic systems, elbow-like functionality is also integrated, offering an even better degree of freedom.[38] Another advantageous feature of robot-assisted surgery is physiological tremor filtering. Physiological tremor refers to the normal, slight shakes of human hands in the absence of disease. Laparoscopic instruments not only transmit this tremor into the surgical field but can also magnify its effects. On the other hand, robotic surgery filters out physiological tremors, preventing them from being transmitted to the surgical field.[39]

2.7. Advancements in Robotic Systems

Successive generations of robotic systems have introduced many advancements that significantly facilitate the work of surgeons. The Da Vinci Single-Site system restored instrument triangulation. Single-site surgery often causes crowding of instrument shafts at the narrow port, leading to instrument clashes, which can result in surgeon fatigue and frustration. In contrast, the three-port system avoids this clash by inserting each instrument through a separate port, with the handles of each instrument equidistantly placed, forming a triangle. This triangulation enables surgeons to operate instruments without interference. When robotic systems were introduced into single-site surgery, they restored instrument triangulation as in three-port surgery.[40]

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[36] Gruijthuijsen, Caspar, et al. "Leveraging the Fulcrum Point in Robotic Minimally Invasive Surgery." *IEEE Robotics and Automation Letters*, vol. 3, no. 3, 2018, pp. 2071–2078, doi:10.1109/LRA.2018.2809495.

[37] Longmore, Sally Kathryn, et al. "Laparoscopic Robotic Surgery: Current Perspective and Future Directions." *Robotics*, vol. 9, no. 2, 2020, p. 15, doi:10.3390/robotics9020042.

[38] Hwang, Minho, et al. "A Single-Port Surgical Robot System with Novel Elbow Joint Mechanism for High Force Transmission." *International Journal of Medical Robotics and Computer-Assisted Surgery*, vol. 13, no. 2, 2017, e1808, doi:10.1002/rcs.1808.

[39] Veluvolu, K. C., and W. T. Ang. "Estimation and Filtering of Physiological Tremor for Real-Time Compensation in Surgical Robotics Applications." *International Journal of Medical Robotics and Computer-Assisted Surgery*, vol. 6, 2010, pp. 334–342, doi:10.1002/rcs.340.

[40] Kroh, Matthew, et al. "First Human Surgery with a Novel Single-Port Robotic System: Cholecystectomy Using the da Vinci Single-Site Platform." *Surgical Endoscopy*, vol. 25, no. 11, 2011, pp. 3572–3573, doi:10.1007/s00464-011-1759-1.

Another improvement is the Da Vinci Firefly system, which incorporates a special video camera and a fluorescent dye injection mechanism. This mechanism allows surgeons to visualize blood vessels and ducts in detail during surgeries such as partial nephrectomy and cholecystectomy.[41] The Da Vinci dual console system features two consoles—one for the operating surgeon and another for a trainee surgeon—thereby reducing the learning curve for new surgeons in robotic surgery.[42] An advanced version of the Da Vinci system, the three-dimensional surgical navigation model, includes the TilePro display, enabling surgeons to view two images simultaneously. Surgeons can visualize the surgical field in real time and, if needed, simultaneously view imaging studies like CT scans, ultrasounds, or angiograms. This feature allows for accurate comparisons between the surgical field and imaging studies, improving surgical precision. For instance, during tumor resections, surgeons can accurately determine malignant areas by comparing real-time and imaging data.[43]

Another advancement in robotic surgical systems is Natural Orifice Translumenal Endoscopic Surgery (NOTES). In NOTES, the endoscope is inserted through natural orifices like the mouth, anus, vagina, or urethra to perform surgeries. For example, during a gastrectomy, the robotic endoscope is inserted through the mouth, and surgery is conducted within the lumen.[44] These advancements in robot-assisted surgical systems have significantly improved various surgical procedures.

2.7.1. Tele-Surgery

The development of Master-Slave surgical robotic systems has also made telesurgeries possible. Telesurgery refers to surgical procedures performed by a surgeon on a patient when the surgeon is not physically present near the patient. In this setup, the surgeon's console and the patient cart are connected via wireless and fiber-optic networks. The first telesurgery was performed in 2001 using the ZEUS system. This transatlantic procedure involved a laparoscopic cholecystectomy, with the patient in

[41] Hellan, Minia, et al. "The Influence of Fluorescence Imaging on the Location of Bowel Transection During Robotic Left-Sided Colorectal Surgery." *Surgical Endoscopy*, vol. 28, no. 12, 2014, pp. 3562–3574, doi:10.1007/s00464-013-3377-6.
[42] Smith, Ashlee L., et al. "Dual-Console Robotic Surgery: A New Teaching Paradigm." *Journal of Robotic Surgery*, vol. 7, 2013, pp. 113–118, doi:10.1007/s11701-012-0348-1.
[43] Bhayani, Sam B., and Devon C. Snow. "Novel Dynamic Information Integration During da Vinci Robotic Partial Nephrectomy and Radical Nephrectomy." *Journal of Robotic Surgery*, vol. 2, 2008, pp. 67–69, doi:10.1007/s11701-008-0083-9.
[44] Atallah, S., et al. "Robotic Transanal Total Mesorectal Excision: A Pilot Study." *Techniques in Coloproctology*, vol. 18, 2014, pp. 113–118, doi:10.1007/s10151-014-1181-5.

Strasbourg, France, and the surgeon, Dr. Jacques Marescaux, in New York, USA.[45] With high-speed data transfer, telesurgery enables high-quality surgeries in medically underserved areas such as rural regions, battlefields, and even spacecraft. Moreover, a single telesurgery event may involve multiple jurisdictions or, in rare cases, fall outside any jurisdiction.[46]

2.7.2. Microsurgery

Microsurgery means the area of surgery where the surgery is done under a microscope utilising various precision tools.[47] Robot-assisted microscopic surgery enables surgeons to perform surgery involving microscopic structures. The robot assistance in microscopic surgery has the potential to improve the surgery by scaling the surgeon's motions and eliminating natural tremors, enabling more precise manoeuvres in hard-to-reach locations.[48]

2.7.3. Micro Robots

Microrobots are miniature robots, typically having a size of less than 1 mm, that are mobile and capable of performing tasks. Microrobots can be utilised in medicine both diagnostically and therapeutically.[49] Microrobots can enter the body and perform surgical procedures inside the body. While this happens inside the body, the microrobots are controlled from outside the body.[50] Microrobots, or microbots, can move through blood vessels and remove clots inside the blood vessels. Thus, though microbots are in the experimental stage, they have the potential to treat diseases caused by clots in blood vessels, such as heart attack and stroke.[51]

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[45] Choi, Paul J., Rod J. Oskouian, and R. Shane Tubbs. "Telesurgery: Past, Present, and Future." *Cureus*, vol. 10, no. 5, 2018, e2716, doi:10.7759/cureus.2716.
[46] Mohan, Anmol, et al. "Telesurgery and Robotics: An Improved and Efficient Era." *Cureus*, vol. 13, no. 3, 2021, e14124, doi:10.7759/cureus.14124.
[47] **Washington University School of Medicine,** *What Is Microsurgery?*, https://surgery.wustl.edu/what-is-microsurgery/ (last visited Jan. 21, 2025).
[48] Gudeloglu, Ahmet, Jamin V. Brahmbhatt, and Sijo J. Parekattil. "Robotic-Assisted Microsurgery for an Elective Microsurgical Practice." *Seminars in Plastic Surgery*, vol. 28, no. 1, 2014, pp. 11–19, doi:10.1055/s-0034-1368162.
[49] Nauber, Richard, et al. "Medical Microrobots in Reproductive Medicine: From the Bench to the Clinic." *Nature Communications*, vol. 14, no. 728, 2023, doi:10.1038/s41467-023-36215-7.
[50] Ornes, Stephen. "Inner Workings: Medical Microrobots Have Potential in Surgery, Therapy, Imaging, and Diagnostics." *Proceedings of the National Academy of Sciences*, vol. 114, no. 47, 2017, pp. 12356–12358, doi:10.1073/pnas.1716034114.
[51] Soto, Fernando, Jie Wang, Rajib Ahmed, and Utkan Demirci. "Medical Micro/Nanorobots in Precision Medicine." *Advanced Science*, vol. 7, no. 2002203, 2020, pp. 1–34, doi:10.1002/advs.202002203.

2.7.4. Way forward to completely autonomous robotic surgery

Robotic surgery also paves the way for more and more degrees of autonomy in surgical procedures. The degree of autonomy in robotic surgical systems is classified into 5 levels generally.[52] Among these 5 levels of autonomy, level 0 means no autonomy, where the surgical procedure is equivalent to a non-robotic surgery or manual surgery. Level 1 means there is the task autonomy of the robotic system, where the robot assists the surgeon in performing the surgery, and the support is a passive support here. The passive support provides physiological tremor filtering, haptic feedback, etc. Other than this, the robot performs no autonomous tasks with this level of autonomy.

In level 2, the robot is able to perform some autonomous tasks, but the task to perform is decided and chosen by the surgeon. Thus, when the task is chosen, the robotic system performs that task autonomously. In the next level of autonomy, that is level 3 autonomy, the system is able to generate strategies for the patient in surgery. From among the probable strategies, the surgeon chooses the strategy. The strategy once chosen will be executed by the robotic system autonomously. By this way, it is called a level 3 autonomous robotic system.

In level 4 of autonomy of Robotic Surgical System, the system independently decides the best surgical plan for the patient, and the plan can be independently executed by it. But before execution, the surgeon needs to review the plan and give approval for this. In contrast to this, level 5 autonomy means complete autonomy, where the robotic surgical system itself determines the best surgical plan for the patient and executes the procedure without approval from a human master.[53]

Most of the robotic surgical systems currently in use are of autonomy at level 1. That means the surgical procedures done with them are robot-assisted surgeries. Very few surgical robotic systems have reached up to level 2 and 3. No robotic systems have been marketed after FDA approval at level 4 or 5 of autonomy.[54] Examples for level 2

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[52] Attanasio, Aleks, et al. "Autonomy in Surgical Robotics." *Annual Review of Control, Robotics, and Autonomous Systems*, vol. 4, 2021, pp. 651–679, doi:10.1146/annurev-control-062420-090543.
[53] Lee, Audrey, et al. "Levels of Autonomy in FDA-Cleared Surgical Robots: A Systematic Review." *NPJ Digital Medicine*, vol. 7, no. 103, 2024, doi:10.1038/s41746-024-01102-y.
[54] Jamjoom, Aimun A.B., et al. "Autonomous Surgical Robotic Systems and the Liability Dilemma." *Frontiers in Surgery*, vol. 9, 2022, doi:10.3389/fsurg.2022.1015367.

robotic systems are CorPath GRX by Siemens Healthineers, AquaBeam Robotic System by Procept Biorobotics, and TMINI by Think Surgical. Some examples for level 3 robotic systems are iSR'obot Mona Lisa 2.0 by Biobot, TSolution One by Think Surgical, and ARTAS iX System by Venus Concept. Among these robotic systems, iSR'obot Mona Lisa 2.0 is used for biopsy in urology, and ARTAS iX System is used for hair transplant in plastic surgery. TSolution One is used for total knee replacement surgery. These procedures are much less complicated compared to gastrointestinal surgeries. That is why these could offer autonomy of level 3 in these procedures. Higher levels of autonomy of robotic surgical systems, including fully autonomous robots, are in the experimental stage.[55]

2.7.5. Artificial Intelligence in Robotic Surgery

As in any other field, artificial intelligence is integrated with robotic surgical systems nowadays. The utilisation of artificial intelligence increases with increasing levels of autonomy in the robotic surgical system.[56] At level 0, the basic programming without artificial intelligence is sufficient as the robotic surgical system has no autonomy. When advancing to level 1, still the utilisation of artificial intelligence is minimal. Examples for utilisation of artificial intelligence in level 1 are filtration of physiological tremor and haptic feedback. These functions require basic artificial intelligence only.[57] On the other hand, the advanced levels of autonomy can be achieved only through the integration of artificial intelligence more and more. This progression should lead to an extent where artificial intelligence can completely take over the entire surgical procedure from the assessment of the patient and planning of surgery to the actual implementation of surgery without human assistance.[58]

2.8. Conclusion

This chapter examined the history and evolution of robotic surgery, tracing its origins from early programmable robotic arms to the present-day AI-integrated surgical

[55] Lee et al., supra note 44, at p.3.
[56] Knudsen, J. Everett, et al. "Clinical Applications of Artificial Intelligence in Robotic Surgery." *Journal of Robotic Surgery*, vol. 18, 2024, p. 102, doi:10.1007/s11701-024-01867-0.
[57] Gumbs, Andrew A., et al. "White Paper: Definitions of Artificial Intelligence and Autonomous Actions in Clinical Surgery." *Artificial Intelligence Surgery*, vol. 2, 2022, pp. 93–100, doi:10.20517/ais.2022.10.
[58] **Ahmad Guni et al.,** *Artificial Intelligence in Surgery: The Future Is Now*, 65 Eur. Surg. Res. 22, 22–39 (2024). DOI: 10.1159/000536393.

systems with progressive levels of autonomy. It detailed the technological milestones that have shaped the scope of robotic surgery and highlighted its integration of engineering innovations with surgical precision. The next chapter will turn to the ethical challenges posed by robotic surgery and explore the framework of patient rights in the context of this advancing medical technology.

Chapter 3

Ethical Dimensions and Patient Rights in Robotic Surgery

3.1. Introduction

This chapter addresses the second objective of the study, which is to analyse the extent of responsibilities of stakeholders vis-à-vis the rights of patients in the context of robotic-assisted surgery. As robotic systems increasingly mediate surgical interventions, the ethical and legal expectations placed upon healthcare providers require critical re-evaluation. The chapter begins by examining the framework of patient rights in India and internationally, and assesses how these established standards apply within the technologically complex landscape of robotic surgery. It then turns to foundational principles of medical ethics and the evolving professional codes that govern robotic surgical practice. In doing so, the chapter explores the ethical challenges posed by diminished human oversight, opaque decision-making processes, and compromised patient autonomy. The concluding part of the chapter identifies the key ethical and legal issues arising from this analysis—issues that form the basis of liability attribution and regulatory gaps discussed in the next chapter.

3.2 Patient Rights Framework

The rights of patients, as understood today, are the result of a long historical evolution rooted in the broader recognition of human dignity and personal autonomy. Over centuries, the interaction between medical professionals and patients has transformed from one of paternalism to one increasingly defined by respect for individual agency and participatory decision-making. The concept of patient rights draws its normative foundation from various international human rights instruments, which affirm the inherent dignity, equality, and autonomy of every individual. These universal human rights principles have, over time, been translated into the specific context of healthcare, giving rise to enforceable entitlements for individuals undergoing medical treatment. Thus, patient rights can be seen as the application of general human rights within the unique framework of the doctor-patient relationship, ensuring that medical interventions are not only clinically sound but also ethically and legally justifiable.

3.2.1 International Instruments on Patient Rights

Various international bodies have issued comprehensive charters and declarations affirming patient rights as extensions of fundamental human rights within the healthcare context. These documents, while varying in emphasis and scope, collectively aim to uphold dignity, autonomy, safety, and equitable access in medical treatment. Three significant international instruments—the World Medical Association Declaration (1981), the European Charter (2002), and the WHO Patient Safety Charter (2024)—form the normative foundation for patient rights globally.

The World Medical Association (WMA) Declaration of Lisbon on the Rights of the Patient (1981) outlines eleven core rights that emphasise the ethical obligations of physicians and the autonomy of patients. Key rights include the right to medical care of good quality, the right to freedom of choice in selecting one's physician and health institution, the right to self-determination including informed consent and refusal of treatment, and the right to confidentiality. The declaration also affirms the right to health education, the right to dignity in terminal care, and the right to religious assistance. It stands as one of the earliest professional documents articulating patient rights in a global medical ethics framework.[59]

The European Charter of Patients' Rights (2002) sets forth fourteen rights, each grounded in the EU Charter of Fundamental Rights and various WHO and Council of Europe documents. These include the right to preventive measures, access to healthcare, information, informed consent, free choice, privacy and confidentiality, respect for patient time, observance of quality standards, safety, innovation, personalised treatment, and the right to complain and receive compensation. It highlights the need for harmonisation of these rights across national health systems in the EU and calls for civic participation in healthcare reform, monitoring, and accountability.[60]

[59] *World Med. Ass'n, Declaration of Lisbon on the Rights of the Patient (1981, rev. 2005)*, https://www.wma.net/policies-post/wma-declaration-of-lisbon-on-the-rights-of-the-patient/.
[60] *Active Citizenship Network, European Charter of Patients' Rights (2002)*, https://www.activecitizenship.net/files/patients_rights/charter.pdf.

The most recent framework, the World Health Organization's Patient Safety Rights Charter (2024), proclaims ten patient safety rights with a specific focus on minimising harm in healthcare. These include the right to timely, effective and appropriate care; safe medical practices and facilities; qualified health workers; information and informed decision-making; and privacy, dignity, and non-discrimination. The Charter also stresses patients' rights to access medical records, be heard in the event of harm, and participate in shaping safety policies. It is grounded in the WHO's Global Patient Safety Action Plan (2021–2030) and links patient safety directly to the broader right to health under international human rights law.[61]

3.2.2 Recognition of Patient Rights in India

In India, patient rights are increasingly being recognised through a combination of judicial pronouncements, evolving regulatory mechanisms, and legislative actions. The courts have progressively interpreted the right to health as an integral part of the right to life under Article 21 of the Constitution.[62] Simultaneously, regulatory bodies and professional councils have emphasised ethical conduct and patient dignity. Over time, this evolving jurisprudence has been supported and consolidated by specific statutory enactments addressing various health conditions and medical practices.

Various healthcare statutes in India explicitly acknowledge and protect patient rights. For instance, the Medical Termination of Pregnancy Act, 1971 mandates that no termination of pregnancy shall be carried out without the informed consent of the woman and further protects her identity and confidentiality under Section 5A.[63] The HIV and AIDS (Prevention and Control) Act, 2017 recognises multiple patient rights, including the right to informed consent before testing, treatment, and disclosure (Sections 5–6), the right to confidentiality of HIV status (Sections 8–11), the right against discrimination (Section 3), and the right to access treatment (Section 14).[64] The Mental Healthcare Act, 2017 goes further in scope by codifying ten patient rights under Chapter V (Sections 18–28). These include the right to access mental healthcare, the

[61] *World Health Org., WHO Patient Safety Rights Charter (2024)*, https://www.who.int/publications/i/item/9789240091254.
[62] *Bandhua Mukti Morcha v. Union of India*, (1984) 3 SCC 161
[63] *The Medical Termination of Pregnancy Act*, No. 34 of 1971, § 3, § 5A.
[64] *The Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act*, No. 16 of 2017, §§ 3, 5–6, 8–11, 14.

right to community living, protection from inhuman treatment, non-discrimination, confidentiality, access to medical records, and legal aid.[65]

The Charter of Patients' Rights, issued by the National Human Rights Commission (NHRC) and endorsed by the Ministry of Health and Family Welfare, offers a comprehensive list of patient rights recognised or implied under the existing legal framework in India. It consolidates rights derived from constitutional guarantees, judicial decisions, statutory provisions, and professional codes of ethics. The Charter enumerates seventeen rights, including the right to information, right to records and reports, right to emergency medical care, right to informed consent, right to confidentiality and privacy, right to second opinion, and the right to non-discrimination. It also includes the right to safety and quality care, right to choose alternative treatment options, right to proper referral and transfer, right to protection during clinical trials, right to protection from commercial exploitation, right to discharge and receive care, and the right to be heard and seek redressal. Though the Charter is not legally binding, it functions as a normative instrument for healthcare providers and serves as a reference for policy and judicial interpretation of patient rights in India.[66]

3.2.3. Patient Rights in the Context of Robotic Surgery

The deficiencies in service in the context of robotic surgery can result in violations of recognised patient rights. Specific areas where such deficiencies may arise include failure to maintain the required standard of care, inadequacies in obtaining informed consent, dereliction in the duty of disclosure, malfunctioning of robotic systems, and failure to respect the dignity of the patient. Each of these shortcomings may lead to the infringement of more than one patient right as enumerated in the NHRC Charter of Patients' Rights. These potential deficiencies and their corresponding breaches of patient rights may be outlined as follows.

i. Failure to maintain the required standard of care or negligence

    a. Right to safety and quality of care according to standards

    b. Right to emergency medical care

[65] *The Mental Healthcare Act*, No. 10 of 2017, ch. V, §§ 18–28.
[66] Ministry of Health & Family Welfare, *Charter of Patients' Rights*, Nat'l Hum. Rts. Comm'n (2018), https://main.mohfw.gov.in/sites/default/files/PatientCharterforWebsite.pdf.

c. Right to choose alternative treatment options if available

d. Right to non-discrimination

ii. Inadequacies in obtaining informed consent

a. Right to information

b. Right to informed consent

c. Right to second opinion

d. Right to records and reports

e. Right to choose alternative treatment options

f. Right to patient education

iii. Dereliction in the duty of disclosure

a. Right to information

b. Right to informed consent

c. Right to medical records

d. Right to patient education

e. Right to be heard and seek redressal

iv. Malfunctioning of robotic systems

a. Right to safety and quality of care according to standard care

v. Failure to respect the dignity of the patient

a. Right to confidentiality, dignity, and privacy

b. Right to non-discrimination

The probable deficiencies in service associated with robotic surgery can also be examined through the lens of medical ethics. Each lapse—whether in consent, disclosure, or standard of care—not only constitutes a violation of patient rights but also implicates fundamental ethical principles that govern medical practice. Viewed from this perspective, deficiencies in robotic surgical procedures are not merely

procedural shortcomings but ethical transgressions that warrant critical scrutiny within the established framework of medical ethics.

3.3 Ethical Dimensions in Robotic Surgery

Medical ethics refers to the set of voluntarily accepted principles that guide conduct within the medical profession. These principles are operationalised through regulatory frameworks established by professional bodies such as medical councils and associations, which oversee adherence and accountability. In the context of robotic surgery, any deficiency in service—whether related to consent, disclosure, or standard of care—not only infringes upon the legally recognised rights of patients but also constitutes a deviation from the foundational principles of medical ethics. Accordingly, an ethical appraisal of robotic surgical practices becomes essential to ensure that technological advancement does not come at the cost of professional integrity or patient welfare.

3.3.1. Core Principles of Medical Ethics in the Context of Robotic Surgery

The ethical framework that governs clinical medicine is traditionally grounded in four cardinal principles:

1. Autonomy – right of patients to make informed decisions
2. Beneficence –obligation of healthcare providers to act in the best interest of the patient.
3. Non-maleficence – the duty to avoid causing harm to the patient.
4. Justice – the fair and equitable distribution of healthcare resources.

In the context of robotic surgery, these principles remain foundational but demand renewed interpretation. The principle of autonomy requires that patients be thoroughly informed about the nature and limitations of robotic-assisted procedures, yet the complexity of such technologies can hinder comprehension and compromise genuine informed decision-making. Beneficence is often invoked to promote robotic surgery due to its potential benefits—such as precision, smaller incisions, and reduced recovery time—but these advantages must be critically balanced against non-maleficence, especially where risks arise from machine malfunction, loss of tactile sensitivity, or inadequate surgical training. Meanwhile, justice becomes particularly relevant in

considering the accessibility and affordability of robotic surgery, as its availability is typically confined to well-equipped urban centers and private institutions, potentially widening existing disparities in healthcare access. Thus, robotic surgery calls for an ethically vigilant application of these principles to ensure that innovation does not outpace patient-centered care.

3.3.2. Principles of Medical Ethics in Regulatory Framework

The four core principles of medical ethics—beneficence, nonmaleficence, autonomy, and justice—have evolved through centuries of moral thought, professional practice, and societal expectations. While beneficence and nonmaleficence trace their roots to the Hippocratic tradition, the principles of autonomy and justice gained prominence in response to historical abuses and the expanding recognition of patient rights in modern healthcare. Today, these principles are universally accepted across medical professions worldwide as foundational ethical obligations that guide clinical decision-making, shape professional codes of conduct, and support patient-centered care in all settings.[67]

The core principles of medical ethics—autonomy, beneficence, non-maleficence, and justice—are not only globally recognized but have also been firmly integrated into the Indian medical regulatory landscape. This incorporation is reflected in both statutory regulations and voluntary codes of conduct. The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, currently in force, explicitly embed these ethical principles, laying down the duties of physicians towards patients, society, and the profession itself.[68] The more recent National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023—although currently placed in abeyance—represent an ambitious attempt to modernize the ethical framework, providing detailed normative and procedural guidelines to reinforce ethical conduct and professional accountability.[69] This shift was, however, paused via notification, reinstating the 2002 IMC Regulations until further notice.[70] Complementing these regulatory instruments, the IMA–NATHEALTH Code of Ethics,

[67] Basil Varkey, Principles of Clinical Ethics and Their Application to Practice, 30 Med. Princ. Pract. 17 (2021), https://www.karger.com/Article/FullText/509119.
[68] Indian Med. Council (Professional Conduct, Etiquette and Ethics) Reguls., 2002 (India).
[69] Nat'l Med. Comm'n Regd. Med. Practitioner (Professional Conduct) Reguls., 2023, Gazette of India, Aug. 2, 2023 (India).
[70] Nat'l Med. Comm'n Notification on Abeyance of Regd. Med. Practitioner (Professional Conduct) Reguls., Gazette of India, Aug. 24, 2023 (India).

issued jointly by the Indian Medical Association and the Healthcare Federation of India, reflects voluntary adherence to these ethical values by practitioners and institutional stakeholders.[71] Collectively, these documents illustrate that ethical principles are both codified by India's medical councils and endorsed by professional bodies, ensuring that ethical violations may lead to disciplinary action including censure, suspension, or removal from the professional registry, thereby reinforcing professional accountability and safeguarding patient rights.

Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002

The Indian Medical Council's Professional Conduct Regulations establish enforceable duties that reflect the core principles of medical ethics.

i. Autonomy is reflected in the regulatory provisions that mandate physicians to uphold the dignity and independence of patients by ensuring that they are fully informed about their medical condition, the proposed course of treatment, and possible alternatives. Patients are thus empowered to make voluntary and informed decisions, reinforcing the central role of patient agency in clinical practice.[72]

ii. Beneficence is embedded in the professional duty of doctors to serve humanity with devotion and competence, always prioritizing the welfare of the patient. The regulations oblige practitioners to perform their tasks with professional skill and ethical intent, aligning medical decisions with the best interests of the individual patient.[73]

iii. Non-maleficence is expressed through provisions that prohibit delegating medical duties to unqualified individuals and outlaw any engagement in unscientific or unethical practices. These safeguards aim to prevent harm to patients and ensure that medical care remains within the boundaries of professional responsibility and regulatory scrutiny.[74]

[71] Indian Med. Ass'n & NATHEALTH, Code of Ethics for Healthcare Professionals, (2022), https://www.ima-india.org/ima/pdf/IMA-NATHEALTH-COE.pdf.
[72] Indian Med. Council, Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, regs. 2.1.1, 2.3 (India).
[73] Id. regs. 1.1.2, 1.2.1.
[74] Id. regs. 1.6, 7.8.

iv. Justice is addressed through regulations that require equitable treatment of all patients, without discrimination based on caste, creed, or economic status. The mandate to promote public health and serve the wider community also reflects a commitment to fairness and social equity within the delivery of healthcare.[75]

Together, these regulatory obligations embed ethical norms directly into the legal framework of medical practice in India, enabling accountability for ethical violations through disciplinary mechanisms.

National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023

The 2023 regulations issued by the National Medical Commission represent a significant revision and modernization of the ethical code governing medical practice in India. These regulations retain the foundational ethical spirit of the earlier Indian Medical Council norms while embedding more explicit standards aligned with the four core principles of medical ethics: autonomy, beneficence, non-maleficence, and justice.[76]

i. Autonomy is upheld by provisions requiring RMPs to obtain valid and informed consent before any medical intervention, to disclose their identity, qualifications, and nature of treatment, and to respect patient confidentiality and data protection.[77] These measures promote the patient's right to make independent and informed decisions about their own health.

ii. Beneficence is reflected in the duties imposed on practitioners to act in the best interests of patients by providing evidence-based care, issuing referrals where appropriate, and abstaining from unjustified procedures or interventions.[78] The regulations also expect RMPs to ensure continuity of care and provide accurate medical information, all of which contribute to patient welfare.

iii. Non-maleficence is addressed through explicit prohibitions against the use of unverified therapies, dishonest documentation, and harmful or unsafe

[75] Id. regs. 1.1.1, 2.1.1, 5.1.
[76] Nat'l Med. Comm'n, National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023, Preamble & ch. I (India).
[77] Id. regs. 4.2.1, 4.2.3, 5.1.2.
[78] Id. regs. 4.2.6, 5.1.1, 6.3.

treatment practices.[79] RMPs are also required to ensure safe withdrawal from treatment only after arranging for alternate care, thereby minimizing potential harm to patients.

iv. Justice is incorporated through mandates requiring fair and non-discriminatory treatment of patients, upholding professional cooperation in inquiries, and avoiding commercial conflicts of interest.[80] Furthermore, the regulations outline structured disciplinary processes to ensure accountability and equal application of ethical standards.

3.3.3. Ethical Implications of Deficiency in Service

The probable deficiencies in service associated with robotic surgery—previously discussed in the context of patient rights—include failure to maintain the required standard of care, inadequacies in obtaining informed consent, dereliction in the duty of disclosure, malfunctioning of robotic systems, and failure to respect the dignity of the patient. Each of these deficiencies carries significant ethical implications when assessed against the core principles of medical ethics. Inadequacies in securing informed consent, withholding or inadequately disclosing critical information, and failing to uphold patient dignity directly undermine the principle of **autonomy**, which requires that patients be empowered to make informed, voluntary decisions regarding their care. Similarly, a failure to maintain the expected standard of care or to prevent harm arising from malfunctioning robotic systems implicates the principles of **beneficence** and **non-maleficence**, as these lapses breach the ethical obligation to act in the patient's best interest and to avoid foreseeable harm. Thus, deficiencies in robotic surgical services are not merely technical or procedural lapses, but raise profound ethical concerns that challenge the integrity of clinical decision-making and professional responsibility.

3.4. Implications of Service Deficiencies in Robotic Surgery: Ethical & Legal Perspectives

Robotic surgery presents a unique set of service-related vulnerabilities that raise both ethical and legal concerns. Five areas of possible deficiencies—failure to maintain the required standard of care, inadequacies in obtaining informed consent, dereliction in the duty of disclosure, malfunctioning of robotic systems, and failure to respect the

[79] Id. regs. 4.2.4, 7.5, 6.1.
[80] Id. regs. 6.5, 7.2, 8.1, 8.2.

dignity of the patient—serve as focal points for assessing such implications. Each of these deficiencies engages not only core ethical principles such as autonomy, beneficence, and non-maleficence, but also attracts liability under various legal frameworks, necessitating a dual-perspective analysis.

3.4.1. Maintenance of Required Standard of Care

When the standard of care is compromised in the context of robotic surgery, it can lead to a cascading infringement of multiple patient rights. The highly technical nature of robotic procedures demands strict adherence to institutional protocols, device-specific competencies, and evolving clinical benchmarks. A deviation from these standards may directly compromise the right to safety and quality care according to standards, which is central to patient trust and legal protection. Further, in emergency contexts, any delay or technical failure in robotic interventions may obstruct the patient's right to emergency medical care, particularly if human override is inadequate or unavailable. Similarly, unequal access to trained personnel or advanced systems may result in the right to non-discrimination being undermined, especially for patients in under-resourced settings. Finally, if alternative treatment options such as conventional or laparoscopic surgery are not adequately disclosed or made available, the patient's right to choose alternative treatment options if available also stands violated.[81]

3.4.2. Informed Consent in Robotic Practice

Informed consent stands as a cornerstone of ethical medical practice and a fundamental mechanism for safeguarding patient autonomy and rights. It not only reflects respect for individual decision-making but also functions as a legal shield for both patients and practitioners. However, in real-world clinical settings—especially within the emerging domain of robotic surgery—this principle often encounters multifaceted challenges. The complexity of technology, asymmetry of knowledge between surgeon and patient, and evolving medico-legal standards raise significant concerns about the adequacy and authenticity of consent obtained in such procedures.

Various scholars have highlighted distinct elements that can significantly affect the quality of the informed consent process, particularly in the context of robotic surgery.

[81] Ministry of Health and Family Welfare, *Charter of Patients' Rights*, NAT'L HUM. RTS. COMM'N (2019), (Rights 3, 8, 9, 10).

Ferrarese et al. underscore the inadequacy of traditional consent models in addressing the complexities introduced by robotic procedures. They propose that informed consent in such cases must include details about the surgeon's experience, the institution's procedural volume, and the regional distribution of surgical expertise. The same study emphasizes the legal importance of disclosing the roles and responsibilities of proctors, preceptors, and assistants involved in robotic operations, especially given their differing degrees of accountability.[82] Vilanilam and Hariharan further elaborate on the ethical and medicolegal vulnerabilities unique to robotic neurosurgery. They point out that the allure of technological superiority may distort autonomous decision-making, and they call attention to the lack of robust data supporting long-term safety and outcomes. Their discussion also reveals concerns about accountability in cases of device malfunction, advocating for transparency and open-access reporting mechanisms.[83] The AMA Code of Medical Ethics, as interpreted by Jake Young, reinforces the physician's duty to ensure that patients are fully informed of all treatment options, including comparative risks, costs, and benefits of robotic versus traditional surgery. It cautions against conflicts of interest and mandates that robotic surgery be offered only by those with adequate training and continuing education.[84] Vijayanath et al. further emphasize that patient comprehension may be compromised by both technical complexity and inconsistent disclosure practices among providers. They advocate for robust communication strategies that clearly explain technological risks, device dependencies, and failure contingencies to ensure valid consent.[85] Collectively, these studies affirm that robotic surgery presents a distinct set of ethical, educational, and legal challenges that must be addressed to uphold the integrity of the informed consent process.

The doctrine of informed consent has been progressively absorbed into the Indian legal framework through a series of judicial pronouncements, most significantly the Supreme Court's decision in *Samira Kohli v. Dr. Prabha Manchanda*, which marked a watershed moment in Indian medical jurisprudence by affirming that consent must not only be

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[82] Alessia Ferrarese et al., *Informed Consent in Robotic Surgery: Quality of Information and Patient Perception*, 11 OPEN MED. 279 (2016), https://doi.org/10.1515/med-2016-0054.
[83] George Chandy Vilanilam & Easwer Hariharan Venkat, *Ethical Nuances and Medicolegal Vulnerabilities in Robotic Neurosurgery*, 52 NEUROSURGICAL FOCUS E2 (2022), https://doi.org/10.3171/2021.10.FOCUS21533.
[84] Jake Young, *AMA Code of Medical Ethics' Opinions Related to Robotic Surgery*, 25 AMA J. ETHICS E605 (2023), https://doi.org/10.1001/amajethics.2023.605.
[85] Vijayanath V. et al., *Consent and Medicolegal Aspects of Robotic Surgery*, J. INDIAN ACAD. FORENSIC MED. (2019), https://www.researchgate.net/publication/338819458.

informed but also specific and prior, barring life-threatening emergencies.[86] It underscored that a broad or generic consent for diagnostic surgery cannot be construed as authorization for an entirely different therapeutic procedure. As discussed by Nandimath, the apex court explicitly rejected the paternalistic view long held by sections of the medical fraternity and emphasized the centrality of patient autonomy under Article 21 of the Constitution.[87] The court's insistence on prior informed consent places a legal and ethical duty upon the treating physician to disclose all relevant information regarding the nature, risks, alternatives, and consequences of the proposed treatment in a language comprehensible to the patient. The judgment, along with allied decisions, shifted the focus from doctor-centric discretion to patient-centric autonomy, thereby aligning Indian consent jurisprudence with the globally recognized 'prudent patient' standard. This evolution affirms that any medical intervention performed without such consent may expose the practitioner to liability under both tort and criminal law.

3.4.3. Upholding the duty of disclosure

A critical foundation of ethical and lawful medical practice is the obligation to ensure that patients are fully and meaningfully informed about the nature of the treatment they receive. In the context of robotic surgery, this duty becomes more complex due to the highly technical nature of the procedures, the involvement of automated systems, and the reduced opportunity for direct interpersonal communication. When healthcare professionals or institutions fail to uphold this duty of disclosure, several patient rights enshrined in the NHRC Charter stand compromised.

Foremost among these is the right to information, which mandates that patients be informed of the nature, benefits, risks, and alternatives of the proposed surgical procedure in a language they understand. The absence of such disclosure also renders the right to informed consent ineffective, as consent obtained without full comprehension of relevant facts cannot be considered valid in law. Similarly, denying access to or withholding clinical records impairs the right to medical records, which is essential for obtaining second opinions or pursuing accountability. The right to patient education is also infringed when patients are not guided or oriented about the robotic

[86] *Samira Kohli v. Dr. Prabha Manchanda*, (2008) 2 SCC 1.
[87] Omprakash V. Nandimath, *Consent and Medical Treatment—The Legal Paradigm in India*, 25 INDIAN J. UROLOGY 343 (2009).

system, its limitations, or expected outcomes. Lastly, without sufficient information, patients are often unable to articulate grievances or pursue remedy, thereby diluting the right to be heard and seek redressal.[88]

3.4.4. Technical limitations of robotic systems

Robotic surgery, while technologically advanced, remains susceptible to system malfunctions arising from software errors, mechanical defects, or communication failures between components. Such malfunctions, even if rare, can lead to unintended surgical movements, intraoperative delays, or procedural interruptions, posing significant risks to patient safety. These events compromise the right to safety and quality of care according to standard care, particularly when the surgical outcome is affected due to technical errors unrelated to the surgeon's competence.[89] The complexity of robotic platforms demands rigorous preoperative system checks and real-time monitoring to ensure functional reliability throughout the procedure. Failure to detect or mitigate such malfunctions not only undermines clinical standards but also erodes patient trust in technologically mediated care.

3.4.5. Safeguarding the dignity of the patient

The principle of respecting the dignity of the patient lies at the heart of ethical and legal healthcare delivery. In robotic surgery, this principle gains further relevance due to the involvement of sensitive personal data, intimate procedural settings, and the potential for reduced human interaction. If adequate safeguards are not maintained, the patient's right to confidentiality, dignity, and privacy may be compromised—whether through inadvertent exposure of medical records, data misuse, or impersonal communication during technology-mediated procedures. Additionally, failure to uphold patient dignity can lead to discriminatory practices, especially where access to robotic procedures is selectively offered based on socio-economic status, insurance coverage, or institutional biases. This infringes the right to non-discrimination, which mandates equal respect and

[88] Ministry of Health and Family Welfare, *Charter of Patients' Rights*, NAT'L HUM. RTS. COMM'N (2019), (Rights 1, 2, 4, 16, 17).
[89] Ministry of Health and Family Welfare, *Charter of Patients' Rights*, NAT'L HUM. RTS. COMM'N (2019), (Right 9).

access for all patients regardless of background.[90] Thus, ensuring patient dignity in robotic surgery requires both technical and humanistic vigilance in every stage of care.

Robotic surgery, by its very nature, demands elevated standards of disclosure. Failing to meet these standards erodes trust and exposes the patient to uninformed risks, ultimately undermining the legal and ethical integrity of the consent process too.

3.5. Conclusion

This chapter undertook a detailed examination of the ethical and patient rights dimensions of robotic surgery, thereby addressing the second core objective of the study: to analyse the responsibilities of stakeholders in relation to the rights of patients. Beginning with the conceptual evolution of patient rights, the chapter explored their codification in various international instruments and Indian legal frameworks, particularly the NHRC Charter. It then contextualised these rights within the domain of robotic surgery, identifying key areas where service deficiencies—such as inadequate consent, poor disclosure, system malfunction, or failure to uphold patient dignity—may result in violations.

The analysis proceeded to critically assess these deficiencies through the lens of medical ethics, reaffirming that ethical principles such as autonomy, beneficence, non-maleficence, and justice remain foundational in the robotic era, albeit requiring nuanced application. These principles are embedded not only in global ethical discourse but also in India's regulatory frameworks, including the IMC Regulations, 2002 and the more recent NMC-RMP Regulations, 2023. Each principle was shown to be engaged, and at times challenged, by the procedural and technological complexities unique to robotic interventions.

The chapter concluded that service-related lapses in robotic surgery are not merely technical or procedural irregularities, but also raise serious legal and ethical implications. These issues—ranging from consent and disclosure to system safety and patient dignity—create overlapping zones of liability involving multiple actors, including surgeons, hospitals, programmers, and manufacturers. Accordingly, the next chapter turns to a legal analysis of these implications by exploring how responsibility

[90] Ministry of Health and Family Welfare, *Charter of Patients' Rights*, NAT'L HUM. RTS. COMM'N (2019), (Rights 5, 8).

is currently apportioned among stakeholders, and whether the existing legal framework is sufficient to address the challenges posed by robotic surgical systems.

Chapter 4

Fixing Liability and Remedies in Robotic Surgery

4.1. Introduction

The previous chapter examined the ethical challenges and potential infringements of patient rights arising in the context of robotic surgery. It highlighted how core principles—such as informed consent, standard of care, privacy, and access to information—may be compromised when robotic systems are introduced without adequate safeguards. Building upon that foundation, the present chapter shifts focus from identifying ethical lapses to exploring how the law responds when such rights are violated. In other words, it attempts to map the framework of legal accountability in the context of robotic-assisted surgical procedures.

The intersection of law and robotic surgery introduces novel complications in the attribution of liability. Unlike traditional clinical contexts where the chain of responsibility is clearer, robotic surgery involves an expanded ecosystem of actors, including not only surgeons and hospitals but also programmers, software developers, manufacturers, and regulatory institutions. Questions therefore arise as to who should bear liability when harm results—especially in situations involving technical malfunction, algorithmic error, or system-based failure.

This chapter begins by evaluating the possibility of granting legal personality to artificial intelligence, and whether such an approach is viable or desirable within the Indian legal context. It then proceeds to affirm the human-centric model of accountability, which remains the prevailing legal position both in India and globally. Against this backdrop, the chapter develops a structured framework of liability by classifying legal consequences into three broad categories: civil liability, criminal liability, and disciplinary proceedings. Each of these will be applied across the key actors involved in robotic surgery—namely, the surgeon, the hospital, the manufacturer, and the programmer—so as to examine both the reach and the limitations of current Indian legal mechanisms in fixing responsibility and offering remedies.

4.2. Artificial Legal Personality and the Question of AI

In cases where an operator employs a machine, the liability for any errors arising during its operation is ordinarily attributed to the operator. This is because conventional

machines do not exercise independent decision-making. However, with the integration of artificial intelligence (AI) into operational processes—whether partially or fully—decision-making functions are increasingly delegated to the AI system itself. The extent to which AI participates in clinical decision-making and executes tasks beyond pre-programmed instructions raises fundamental questions of legal attribution. To the degree that an AI system functions autonomously, it may be argued that it should bear a proportionate share of liability, thereby diminishing the operator's direct accountability. Consequently, determining whether AI qualifies as a juristic or legal person becomes a matter of critical legal significance, as it directly impacts the identification of stakeholders upon whom liability may be imposed.

The attribution of legal responsibility in robotic surgery raises a foundational jurisprudential challenge: can an artificial intelligence system be recognised as a legal person under law? This inquiry is not merely academic; it determines the very basis on which accountability is to be distributed between human actors and the autonomous technologies they deploy. As robotic surgical systems increasingly incorporate adaptive AI—capable of learning from data, responding to intraoperative stimuli, and making quasi-autonomous decisions—the traditional liability models premised on human agency face strain. In such a context, analysing the possibility of legal personhood for AI becomes imperative. If AI could be treated as a juristic person, it might open the door to direct attribution of liability to the system itself, thereby relieving some burden from surgeons, hospitals, or manufacturers. Conversely, if AI is deemed incapable of legal personhood, responsibility must remain anchored in the conduct and decisions of the human stakeholders.

Therefore, this section explores the essential characteristics of legal persons, evaluates whether AI systems satisfy these requirements, and assesses comparative positions from jurisdictions like the European Union and France. This analysis sets the stage for affirming or rejecting AI's capacity to bear legal consequences in the realm of robotic surgery.

4.2.1. Concept of 'Person' and 'Legal personality'

In jurisprudence, the term "legal person" refers to any subject—natural or artificial—that is recognised by law as capable of possessing rights and duties. According to classical definitions, a legal person is not limited to human beings but includes any

entity that the law treats as a person for the purpose of conferring legal capacity. As noted by Salmond, "a legal person is any subject-matter other than a human being to which the law attributes personality."[91] This attribution is not grounded in sentience or consciousness but in the legal system's decision to assign an entity the ability to hold rights and duties and participate in legal relations.

This construct allows the legal system to impose obligations, recognise capacities, and allocate responsibilities to entities other than natural persons. Such recognition, however, depends entirely on normative considerations rather than biological or cognitive attributes. The legal personality of artificial persons, therefore, arises not from their inherent qualities but from their functional suitability to serve as units of accountability under the law.[92]

Legal personhood encompasses a diverse range of subjects recognized by law as capable of holding rights and bearing duties. The orthodox jurisprudential view, as articulated by Salmond and adopted in judicial reasoning such as in *People ex rel. Nonhuman Rights Project, Inc. v Lavery*, defines a legal person as "any subject-matter other than a human being to which the law attributes personality."[93] This includes natural persons (living human beings with legal capacity) and artificial or juristic persons, such as corporations, associations, trusts, states, municipalities, and even nonhuman entities like rivers and temples, in specific legal contexts.[94] The scope of legal personhood has historically evolved to include institutions capable of owning property, entering contracts, and bearing legal responsibility in their own name. Visa Kurki further expands this by explaining that legal personhood can consist of passive incidents (like the capacity to be protected by law or own property) and active incidents (like the ability to enter into contracts or bear criminal responsibility).[95] Hence, entities may be legal persons for certain purposes while not enjoying full legal agency. Contemporary legal systems also demonstrate increasing flexibility by recognizing foetuses, idols, or even nature as legal persons in limited domains, illustrating the functional and normative diversity of the concept.

[91] P.J. Fitzgerald, *Salmond on Jurisprudence* 61 (12th ed. 1966).
[92] Dr. Avtar Singh & Dr. Harpreet Kaur, *Introduction to Jurisprudence* 358–59 (4th ed. 2013).
[93] People ex rel. Nonhuman Rights Project, Inc. v. Lavery, 124 A.D.3d 148 (N.Y. App. Div. 2014).
[94] Dr. Avtar Singh & Dr. Harpreet Kaur, *Introduction to Jurisprudence* 358–59 (4th ed. 2013).
[95] Visa A.J. Kurki, *A Theory of Legal Personhood* 1–22 (Oxford Univ. Press 2019).

4.2.2. Arguments in Favour of Granting Legal Personality to Artificial Intelligence

There is growing academic and policy discussion advocating for the recognition of legal personality in artificial intelligence (AI). The arguments advanced in favour of this proposition are rooted in practical governance challenges as well as theoretical and economic considerations. These can be summarized under the following themes:

i. **Filling Responsibility Gaps:** As AI systems grow more autonomous, fixing liability becomes more complex. Scholars argue that assigning legal personality to AI helps close accountability gaps, especially where human actors are too far removed from the AI's decision-making processes.[96]

ii. **Instrumental Legal Recognition**: Like corporations, which were granted legal personhood to facilitate legal and commercial functions despite lacking human characteristics, AI could be similarly recognised as a legal person based on its functional social role.[97]

iii. **Economic and Commercial Necessity:** AI now performs tasks such as automated stock trading, financial management, and digital content creation. To engage in these activities independently and be held legally accountable, AI may require recognition as a legal person.[98]

iv. **Evolution of Legal Personhood**: Legal personality has historically extended to non-human entities, such as corporations, religious idols, and natural features like rivers. This demonstrates that personhood is a flexible legal construct, which could evolve to include AI.[99]

v. **AI as a Derivative Legal Subject:** Some scholars propose that AI could be treated as a derivative legal subject, possessing limited legal recognition in contexts where it operates with substantial autonomy and public impact.[100]

vi. **Autonomy and Decision-Making Capability**: AI systems, especially in fields like medical diagnostics and autonomous vehicles, make independent

[96] Simon Chesterman, *Artificial Intelligence and the Limits of Legal Personality*, 69 Int'l & Comp. L.Q. 819 (2020).
[97] Jasper Doomen, *The Artificial Intelligence Entity as a Legal Person*, 31 Artif. Intell. & L. 1 (2023).
[98] Irina A. Filipova, *Future of the Artificial Intelligence: Object of Law or Legal Personality*, 12 Russ. L.J. 45 (2024).
[99] Claudio Novelli et al., *AI as Legal Persons – Past, Patterns, and Prospects* (2024).
[100] Zhifeng Wen & Deyi Tong, *Analysis of the Legal Subject Status of Artificial Intelligence*, 14 Beijing L. Rev. 74 (2023).

decisions in real time. This growing decision-making power supports the argument for AI's formal legal recognition.[101]

vii. **Electronic Personhood as a Regulatory Solution:** The European Parliament's 2017 resolution on robotics proposed the category of "electronic personhood" for highly autonomous AI systems, aimed at improving legal clarity and liability allocation.[102]

4.2.3. Arguments Against Granting Legal Personality to Artificial Intelligence

Despite such proposals, there is a strong and coherent line of reasoning opposing the grant of legal personality to AI. These arguments are grounded in legal theory, ethics, practicality, and accountability principles:

i. **Lack of Moral and Social Responsibility**: AI lacks moral agency, emotional understanding, and societal integration—features foundational to legal responsibility. It is designed to be controlled by humans and does not possess the volitional or ethical reasoning needed for personhood.[103]

ii. **AI is Merely an Advanced Tool**: No matter how sophisticated, AI remains a human-made instrument. It does not have an independent will or consciousness, and should thus be treated as an object of law, not a legal person.[104]

iii. **Risk of Legal Evasion and Manipulation**: Granting AI legal status could be exploited by developers and operators to avoid liability. They may deflect blame onto the AI system, leading to diluted or misplaced legal accountability.[105]

iv. **No Legal Precedent Exists**: To date, no jurisdiction has officially recognised AI as a legal person. The absence of precedent raises significant

[101] Laylo Sultonova, Vitalii Vasyukov & Elena Kirillova, *Concepts of Legal Personality of Artificial Intelligence*, 15 Lex Humana 3 (2023).
[102] Visa A.J. Kurki, *The Legal Personhood of Artificial Intelligences*, in *A Theory of Legal Personhood* 175, 176–77 (Oxford Univ. Press 2019).
[103] Brandeis Marshall, *No Legal Personhood for AI*, 4 Patterns 100861 (2023).
[104] Irina A. Filipova & Vadim D. Koroteev, *Future of the Artificial Intelligence: Object of Law or Legal Personality?*, 1 J. Dig. Tech. & L. 359 (2023).
[105] Claudio Novelli et al., *AI as Legal Persons: Past, Patterns, and Prospects*, in *The Legal Status of AI: Personhood, Agency and Liability* (Andrea Bertolini ed., forthcoming 2024).

concerns about doctrinal consistency and the untested nature of such a legal innovation.[106]

v. **Existing Legal Frameworks Are Sufficient:** Current legal doctrines—such as product liability, vicarious liability, and corporate responsibility—already provide adequate means to assign accountability for harm caused by AI systems.[107]

vi. **AI Lacks Free Will and Consciousness:** Legal personhood is premised on the ability to intend, understand, and respond. Since AI lacks free will, subjective understanding, and conscious choice, it cannot be entrusted with legal obligations or rights.[108]

vii. **AI Cannot Bear Legal Consequences:** Unlike humans or corporations, AI cannot be deterred, punished, or reformed. This renders legal personality ineffective for ensuring real-world accountability.[109]

viii. **Potential for Unregulated Power and Autonomy:** Some scholars warn that recognising AI as a legal person could eventually enable it to accumulate economic and legal power, potentially disrupting existing institutional and human-centric frameworks.[110]

4.2.4. Essential Characteristics of Legal Personhood

In order to assess the viability of attributing legal personality to artificial intelligence, it is imperative first to examine the essential characteristics that constitute legal personhood. Only then can one meaningfully evaluate whether AI systems satisfy these foundational criteria. Legal personhood is a foundational concept in jurisprudence, denoting entities—natural or artificial—that the law recognizes as capable of bearing rights and duties. While traditional views emphasize a binary distinction between persons and things, contemporary scholarship presents a more nuanced understanding.

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[106] Simon Chesterman, *Artificial Intelligence and the Limits of Legal Personality*, 69 Int'l & Comp. L.Q. 819 (2020).

[107] Piotr Staszkiewicz et al., *Artificial Intelligence Legal Personality and Accountability: Auditors' Accounts of Capabilities and Challenges for Instrument Boundary*, 32 Meditari Acct. Res. 120 (2024).

[108] Zhifeng Wen & Deyi Tong, *Analysis of the Legal Subject Status of Artificial Intelligence*, 14 Beijing L. Rev. 74 (2023).

[109] Laylo Sultonova, Vitalii Vasyukov & Elena Kirillova, *Concepts of Legal Personality of Artificial Intelligence*, 15 Lex Humana 3 (2023).

[110] Jasper Doomen, *The Artificial Intelligence Entity as a Legal Person*, 31 Artif. Intell. & L. 1 (2023).

The following characteristics are widely acknowledged as essential attributes of legal personhood:

i. **Capacity to Hold Rights and Duties**: At the core of legal personhood is the capacity to possess rights and bear duties. This principle is echoed in various legal definitions. For instance, Black's Law Dictionary defines a legal person as an entity "given certain legal rights and duties of a human being; a being, real or imaginary, who for the purpose of legal reasoning is treated more or less as a human being."[111] This capacity is not limited to natural persons; corporations and other juridical entities are also endowed with rights and obligations under the law.

ii. **Recognition as a Subject in Legal Relations**: Legal persons are recognized as subjects capable of participating in legal relations. This includes the ability to own property, enter into contracts, and be held accountable for actions. The law treats these entities as distinct from their members or constituents, allowing for independent legal existence.

iii. **Capacity to Sue and Be Sued**: An essential attribute of legal personhood is the ability to initiate legal proceedings and be subject to them. This capacity ensures that legal persons can enforce their rights and be held accountable for their obligations. It is a critical mechanism for upholding the rule of law and ensuring justice.[112]

iv. **Continuity of Existence**: Legal persons, particularly artificial entities like corporations, possess continuity of existence. This means they maintain their legal identity despite changes in membership or leadership. Such continuity allows for stability in legal and commercial affairs, enabling entities to enter long-term contracts and obligations.

v. **Distinct Legal Identity**: Legal persons have a distinct legal identity separate from their members. This separation ensures that the rights and obligations of the entity do not directly impact the personal rights and obligations of its

[111] *Black's Law Dictionary* 791 (9th ed. 2009).
[112] Bryant Smith, *Legal Personality*, 37 Yale L.J. 283 (1928).

members, and vice versa. It provides a framework for limited liability and organizational autonomy.[113]

4.2.5. Legal Personhood in Corporations

Corporations have long been recognized as archetypal legal persons—despite being intangible and artificial—because they fulfill the essential characteristics of legal personhood through structured legal mechanisms. They can own property, enter contracts, sue and be sued, and maintain continuity of existence, all of which are administered through accountable human agents. Their personality is not intrinsic but conferred as a legal fiction to serve functional, economic, and governance purposes. The U.S. Supreme Court has repeatedly affirmed the personhood of corporations for specific legal ends, including constitutional protections and liability.[114] The organizational model of corporate personhood further explains this recognition by analogizing corporate decision-making to that of collective human reasoning.[115] Importantly, corporations have always operated with clear legal separateness, identifiable agents, and institutional frameworks, unlike AI systems, which lack genuine autonomy and legal accountability.[116]

4.2.6. Limitations of AI in Fulfilling Legal Personhood Conditions

The proposition that artificial intelligence (AI) could qualify as a legal person has generated considerable academic and policy debate. However, many scholars strongly argue that despite rapid advancements, current AI systems fail to meet the essential conditions of legal personhood. This section evaluates how AI falls short when examined against the five core characteristics previously discussed.

i. **Capacity to Hold Rights and Duties**: AI lacks independent moral agency and subjective interests, both of which are foundational to the attribution of legal rights and duties. As Brandeis Marshall argues, AI is merely a pattern recognition system, docile and mutable, with no moral compass, contextual awareness, or critical reasoning capacity. It operates only under human-

[113] *Salomon v. A Salomon & Co. Ltd.*, [1897] A.C. 22 (H.L.); see also Alexis Dyschkant, *Legal Personhood: How We Are Getting It Wrong*, 2015 U. Ill. L. Rev. 2075.
[114] *Trustees of Dartmouth Coll. v. Woodward*, 17 U.S. (4 Wheat.) 518, 636 (1819); see also *Citizens United v. FEC*, 558 U.S. 310, 342–43 (2010).
[115] Alexis Dyschkant, *Legal Personhood: How We Are Getting It Wrong*, 2015 U. Ill. L. Rev. 2075, 2085–86.
[116] Bryant Smith, *Legal Personality*, 37 Yale L.J. 283, 289–93 (1928).

defined objectives and cannot assert or understand rights in any meaningful way.[117] Similarly, Rafael Dean Brown distinguishes between weak AI (which may operate under delegated authority) and strong AI, which would require an inherent will—a criterion AI currently fails to meet.[118]

ii. **Recognition as a Subject in Legal Relations**: Legal personality presupposes that the entity can act as a participant in legal relations, such as entering into contracts or holding liability. But Jasper Doomen emphasizes that AI cannot meet this criterion since its supposed intentionality and autonomy are simulated rather than real, and such simulated behavior cannot substitute for genuine legal agency.[119] Furthermore, AI does not experience harm, cannot comprehend rights, and has no intrinsic or institutional reason to be a rights-holder.

iii. **Capacity to Sue and Be Sued:** Though AI can be used to automate legal tasks or manage contracts, it cannot initiate or defend legal proceedings independently. As Rafael Dean Brown notes, even in jurisdictions considering property ownership or liability delegation to AI, the lack of legal standing and procedural capacity to sue or be sued remains a fundamental limitation.[120] In U.S. law, legal standing is linked to the capacity to suffer injury in fact, which AI categorically lacks.

iv. **Continuity of Existence**: While AI software can be persistently deployed, its identity is often tied to specific servers, ownership licenses, or algorithmic updates. It lacks legal continuity that is distinct from the entities that create, own, or operate it. The ATARC White Paper cautions that even the most autonomous AI remains ultimately replaceable, upgradable, and terminable by human actors.[121] Its legal existence is not continuous or independent.

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[117] Brandeis Marshall, *No Legal Personhood for AI*, 4 Patterns 100861 (2023), https://doi.org/10.1016/j.patter.2023.100861.

[118] Rafael Dean Brown, *Property Ownership and the Legal Personhood of Artificial Intelligence*, 30 Info. & Commc'ns Tech. L. 208, 222–25 (2021).

[119] Jasper Doomen, *The Artificial Intelligence Entity as a Legal Person*, 32 Info. & Commc'ns Tech. L. 277, 283 (2023).

[120] Rafael Dean Brown, *Property Ownership and the Legal Personhood of Artificial Intelligence*, 30 Info. & Commc'ns Tech. L. 208, 222–25 (2021).

[121] ATARC Artificial Intelligence & Data Policy Working Group, *The Ghost in the Machine: Exploring AI Personhood and Policy* 8–9 (Feb. 2023), https://www.atarc.org.

v. **Distinct Legal Identity**: AI lacks a distinct identity separable from its creators, users, or owners. It cannot own itself, control its governance, or make irrevocable legal commitments. Hon. Katherine B. Forrest warns that granting full personhood would risk diffusing accountability, enabling "responsibility laundering" by shifting blame from humans to non-sentient tools.[122] This lack of separateness means AI is better understood as a tool within existing legal frameworks rather than a freestanding legal actor.

Given that AI systems do not fulfil the essential conditions required for legal personhood—such as independent moral agency, legal standing, continuity, and distinct identity—it is evident that the attribution of legal personhood to AI lacks both functional and jurisprudential justification. However, beyond the theoretical analysis, it is also important to examine how different jurisdictions are currently responding to this challenge. A comparative understanding of the global perspective—including recent EU debates—and the Indian legal position provides valuable insight into the normative and policy choices shaping this domain.

4.2.7. Comparative Legal Approaches to AI Personhood

While academic discourse has long entertained the possibility of granting legal personality to artificial intelligence (AI), very few governmental or supra-governmental bodies have taken concrete steps toward such recognition. However, among the jurisdictions that have addressed the issue, the European Union and France provide significant and instructive perspectives. Their approaches reveal a shift away from speculative notions like "electronic personality" toward more grounded, human-centric legal accountability.

In 2017, the European Parliament passed a landmark resolution concerning civil law rules on robotics, which included an open-ended suggestion to consider the creation of a new category of “electronic personality” for highly autonomous AI systems. The resolution acknowledged that modern AI systems—particularly those integrated with robotics—exhibit features such as learning from experience, making quasi-independent decisions, and interacting dynamically with their environment. Given this degree of operational autonomy, the Parliament noted the growing difficulty of assigning

[122] Hon. Katherine B. Forrest, The Ethics and Challenges of Legal Personhood for AI, 133 Yale L.J.F. 1175, 1177–78 (2024).

responsibility solely to human agents such as manufacturers, operators, or programmers. It was in this context that the concept of electronic personhood was proposed as a regulatory mechanism for certain categories of intelligent robots.[123]

However, this initial position underwent a substantial revision. In its February 12, 2019 resolution on a comprehensive European industrial policy on AI and robotics, the European Parliament consciously abstained from supporting the attribution of legal personality to AI. Instead, the resolution emphasized that legal responsibility and accountability must remain anchored in human actors. It argued that both legally and ethically, autonomy is a status that can only be attributed to human beings. The text flagged serious ethical, legal, and psychological concerns with delegating such status to machines—especially in sensitive domains like healthcare, where loss of human control could lead to grave consequences. Rather than endorsing a generalised legal personality for AI, the European Parliament called for sector-specific regulation, well-defined liability regimes, and strong ethical safeguards, thus reaffirming human agency and control as foundational principles of AI governance within the EU.[124]

The French legal system takes an even firmer position. Rooted in a robust philosophical and legal tradition that equates legal personality with human moral agency, France explicitly denies AI any form of legal or electronic personhood. Although France has invested heavily in AI innovation—most notably through the "France 2030" initiative and its National Strategy for Artificial Intelligence—its legal stance on personhood remains conservative. In 2023, an ethical charter was debated proposing a constitutional principle that AI cannot be granted legal personality. While this proposal was not ultimately incorporated into the French Constitution, it crystallised France's institutional posture. The charter defined AI as "an algorithm that changes in structure over time and learns by going beyond its original programming," and affirmed that AI must remain subordinate to human command.

This approach reflects France's long-standing commitment to human-centered legal governance, informed by concerns over privacy violations, algorithmic bias, and erosion of judicial responsibility. The latter was a point of contention during critiques

[123] Laylo Sultonova, Vitalii Vasyukov & Elena Kirillova, *Concepts of Legal Personality of Artificial Intelligence*, 15 Lex Humana 2596 (2023), https://doi.org/10.32426/2596-2830.2023.15.3.2596.
[124] Jasper Doomen, *The Artificial Intelligence Entity as a Legal Person*, 32 Info. & Comm. Tech. L. 277 (2023), https://doi.org/10.1080/13600834.2023.2196827.

of the algorithmic surveillance tools employed at the 2024 Paris Olympics. By maintaining that AI is a tool—not an entity—France assigns responsibility and culpability exclusively to human actors such as developers, deployers, and institutions. In doing so, it underscores the prevailing European view that granting legal personality to AI poses more risks than regulatory benefits, especially when traditional legal doctrines already provide mechanisms to hold human stakeholders accountable.

4.2.8. Indian Legal Position on AI Personhood

In the Indian legal system, artificial intelligence is not recognised as a legal person, either under statutory law or judicial interpretation. Indian jurisprudence traditionally reserves legal personhood for entities that are capable of holding rights and bearing liabilities. This includes natural persons (human beings) and certain legal or juristic persons such as corporations, trusts, and even religious idols, all of which operate through human agents and institutional structures. AI systems, despite their growing autonomy and sophisticated decision-making capabilities, lack essential attributes such as free will, moral agency, and the capacity to understand or discharge legal obligations.

Legal accountability in India is fundamentally tied to the concept of mens rea, or culpable mental state—a principle that presupposes conscious human intent. As AI does not possess consciousness or intentionality in any legally meaningful sense, it cannot be held criminally or civilly liable under prevailing doctrines. Consequently, both Indian courts and legislators have refrained from extending legal personhood to AI systems. Instead, legal responsibility is imposed on human actors—such as developers, manufacturers, and operators—who create, deploy, or control AI. This reflects the Indian legal system's commitment to a human-centric model of accountability, aligned with both ethical principles and practical enforcement mechanisms.

4.3. Human-Centric Liability of Robotic Surgery

Given that artificial intelligence systems used in robotic surgery do not qualify as legal persons, the question of liability necessarily reverts to the human actors involved in their deployment and operation. In the absence of legal personhood for AI, it becomes essential to determine how liability is to be distributed among individuals and entities such as surgeons, hospitals, manufacturers, and programmers.

To facilitate a structured analysis of such human-centric liability in robotic surgery, this study identifies five principal categories of actors involved in the use and implementation of these systems:

i. Surgeons
ii. Hospitals
iii. Manufacturers
iv. Programmers or software developers, and
v. Supply chain actors.

Each of these stakeholders engages with the robotic system at different stages—ranging from design and manufacturing to clinical application—and thereby assumes varying degrees of legal responsibility. Their potential liability is examined under three distinct but interrelated domains:

a. Civil liability, arising from breaches of duty of care or consumer protection norms;
b. Criminal liability, for conduct amounting to gross negligence or culpable acts; and
c. Regulatory actions, encompassing professional, administrative, or statutory sanctions imposed by oversight bodies such as the Medical Council, CDSCO, or District Registering Authorities.

4.4. Civil Liability under Consumer Protection Law

Civil liability arising from robotic surgery, particularly in cases of medical negligence or deficiency in service, is primarily governed by the provisions of the Consumer Protection Act, 2019, as well as its predecessor, the Consumer Protection Act, 1986. The legal position that medical services fall within the ambit of "service" under consumer law was firmly established by the Supreme Court in Indian Medical Association v. V.P. Shantha, wherein it was held that patients are consumers and healthcare providers are service providers under the Act.[125] This interpretation has continued to apply under the 2019 statute. For clarity, Section 2(42) of the Consumer Protection Act, 2019 defines "service" to include services of any description made available to potential users and specifically includes healthcare services, except those

[125] *Indian Medical Ass'n v. V.P. Shantha*, (1995) 6 SCC 651.

rendered free of charge.[126] Accordingly, when harm results from negligence, lack of due care, or improper application of robotic surgical systems, affected patients may seek remedies under consumer law against relevant stakeholders, including the surgeon, hospital, manufacturer, or other associated parties.

4.4.1. Civil Liability of Surgeons

The civil liability of surgeons performing robotic surgery is primarily assessed within the framework of medical negligence under the Consumer Protection Act, 2019. Given the complex interface of human expertise and advanced surgical technology, several distinct legal dimensions emerge when evaluating liability in such cases. These include: (i) negligence and the applicable standard of care, particularly whether the surgeon's actions align with accepted medical practice; (ii) informed consent, which must be appropriately obtained and documented given the unique risks associated with robotic interventions; (iii) errors of clinical judgment, which must be distinguished from actionable negligence; (iv) adequacy of training and credentialing, especially in relation to the surgeon's preparedness to operate robotic systems; (v) the evidentiary value of video recordings, which may support or rebut allegations of negligence; and (vi) the role of the Consumer Protection Act as the principal forum for redress in such cases. Each of these areas will be examined in detail to delineate the contours of civil liability borne by the surgeon in the context of robotic surgery.

i. Negligence and the Applicable Standard of Care

In the context of civil liability for medical negligence, the essential elements that must be established are: duty, dereliction (breach of duty), direct causation, and damage. Among these, the determination of whether there has been a breach of duty hinges upon whether the medical professional adhered to the standard of care expected of a reasonably competent practitioner. This criterion forms the cornerstone in adjudicating allegations of negligence, especially in technologically advanced procedures such as robotic-assisted surgery.

In robotic-assisted surgery, although the procedure is mediated by advanced technology, the surgeon remains the principal decision-maker and operator. Consequently, the legal assessment of civil liability continues to centre on the conduct, competence, and

[126] Consumer Protection Act, No. 35 of 2019, § 2(42), Acts of Parliament, 2019 (India).

judgment of the surgeon, even in technologically augmented settings. A foundational principle in medical negligence law is that liability hinges on whether the doctor adhered to the expected standard of care exercised by a reasonably competent professional in similar circumstances. This principle was first laid down in *Bolam v. Friern Hospital Management Committee*, where it was held that a medical professional is not negligent if they act in accordance with a practice accepted as proper by a responsible body of medical opinion.[127] Indian courts have consistently adopted this standard in civil negligence jurisprudence. In *Dr. Suresh Gupta v. Govt. of NCT of Delhi*, the Supreme Court affirmed that for the purposes of civil liability, a doctor must exercise reasonable care, caution, and skill.[128] The Court in *Jacob Mathew v. State of Punjab* further clarified that civil negligence could be established merely by showing deviation from accepted standards, without requiring proof of grossness or recklessness.[129]

The Indian legal position is further supported by a robust line of judicial precedents that emphasise adherence to standard care. In *Indian Medical Association v. V.P. Shantha*, the Supreme Court recognised that hospitals and doctors are duty-bound to exercise reasonable care and skill, establishing civil liability under consumer law for any departure from this expectation.[130] Similarly, in *Achutrao Haribhau Khodwa v. State of Maharashtra*, the Court highlighted the duty of doctors to act with skill and caution to prevent foreseeable harm.[131] In *Dr. Laxman Balkrishna Joshi v. Dr. Trimbak Bapu Godbole*, the Court outlined a threefold duty on the part of doctors: to decide whether to undertake the case, to determine the appropriate treatment, and to administer that treatment with care.[132] Procedural lapses, as seen in *State of Haryana v. Santra*, were also held to attract liability when they violated standard care expectations.[133] Further, in *Martin F. D'Souza v. Mohd. Ishfaq*, the Court reiterated that deviation from recognised practice constitutes negligence, particularly when supported by expert opinion.[134] Finally, *V. Kishan Rao v. Nikhil Super Speciality Hospital* clarified that

[127] *Bolam v. Friern Hospital Management Committee*, (1957) 1 WLR 582 (Eng.).
[128] *Dr. Suresh Gupta v. Govt. of NCT of Delhi*, (2004) 6 SCC 422 (India).
[129] *Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1 (India).
[130] *Indian Medical Ass'n v. V.P. Shantha*, (1995) 6 SCC 651 (India).
[131] *Achutrao Haribhau Khodwa v. State of Maharashtra*, AIR 1996 SC 2377 (India).
[132] *Dr. Laxman Balkrishna Joshi v. Dr. Trimbak Bapu Godbole*, AIR 1969 SC 128 (India).
[133] *State of Haryana v. Santra*, (2000) 5 SCC 182 (India).
[134] *Martin F. D'Souza v. Mohd. Ishfaq*, (2009) 3 SCC 1 (India).

although expert opinion is typically necessary in complex cases, negligence can be directly inferred in cases of clear procedural deviation.[135] These precedents, though developed in conventional surgical settings, are broad enough to apply to robotic surgeries where the expectation remains that the surgeon must exercise reasonable diligence, caution, and conformity with accepted standards.

Parallel principles can be found in foreign jurisprudence. In *Rogers v. Whitaker* (Australia), the High Court held that it is ultimately for the court—not the medical profession—to decide what constitutes reasonable care, and emphasised that full disclosure of material risks forms part of the doctor's duty.[136] *Whitehouse v. Jordan* recognised the validity of clinical judgment, but stressed that it must fall within acceptable standards.[137] In *Maynard v. West Midlands Regional Health Authority*, the House of Lords reaffirmed that adherence to one of two responsible bodies of medical opinion suffices to meet the standard of care.[138] Similarly, in *Sidaway v. Board of Governors of the Bethlem Royal Hospital*, the Bolam test was applied to risk disclosure, maintaining that compliance with a responsible body of medical opinion shields a doctor from liability.[139] *Roe v. Minister of Health* underscored that negligence must be assessed in light of the knowledge available at the time, warning courts against applying hindsight.[140] These cases contribute significantly to the jurisprudential framework for evaluating standard of care in robotic surgical claims.

Emerging scholarship and empirical data also affirm that deviation from standard of care remains the dominant basis for civil liability in robotic surgeries. A 2023 study by De Ravin et al., using the Westlaw U.S. database, analysed 61 malpractice cases involving robotic surgeries between 2006 and 2021 and found a 250% increase in the latter half of that period.[141] Among these, 82.2% of cases involved allegations of negligent surgery, underscoring the centrality of the standard of care issue in robotic interventions. In the Indian context, however, Satvik N. Pai et al. point out the absence of a national-level database documenting robotic surgery-related adverse events, which

[135] *V. Kishan Rao v. Nikhil Super Speciality Hospital*, (2010) 5 SCC 513 (India).
[136] *Rogers v. Whitaker*, (1992) 175 CLR 479 (Austl.).
[137] *Whitehouse v. Jordan*, [1981] 1 WLR 246 (UK).
[138] *Maynard v. West Midlands Reg'l Health Auth.*, [1985] 1 All ER 635 (UK).
[139] *Sidaway v. Bd. of Governors of the Bethlem Royal Hosp.*, [1985] AC 871 (UK).
[140] *Roe v. Minister of Health*, (1954) 2 QB 66 (CA) (UK).
[141] Emma De Ravin et al., *Medical Malpractice in Robotic Surgery: A Westlaw Database Analysis* (2023).

presents a significant challenge to evidence-based litigation.[142] Similarly, Dr. M.B. Bagwan cautions that the growing complexity of responsibility shared among surgeons, hospitals, and manufacturers in robotic procedures necessitates a clearer liability framework and empirical documentation.[143] Despite technological mediation, the core issue in negligence litigation remains whether the surgeon exercised the degree of skill and diligence expected by medical peers under similar circumstances.

A landmark Indian case that significantly informs the legal understanding of standard of care in robotic-assisted surgery is *Prem Kishore v. Indraprastha Apollo Hospital and Others*. In this case, Mr. Prem Kishore, a patient diagnosed with a renal tumour suspected to be renal cell carcinoma, underwent a robotic-assisted laparoscopic partial nephrectomy at Indraprastha Apollo Hospital, New Delhi. The surgery was conducted by Dr. D.K. Sharma. During the procedure, the patient experienced profuse intraoperative bleeding, necessitating an urgent conversion from robotic-assisted to open surgery. Despite all clinical efforts, the patient developed multi-organ dysfunction and ultimately succumbed to postoperative complications.[144]

Following the adverse outcome, the patient's family initiated parallel legal proceedings—one before the Delhi Medical Council (DMC), later escalated to the Medical Council of India (MCI), and another before the Consumer Fora. The medical councils, after reviewing operative notes, hospital records, surgical video recordings, and obtaining expert medical opinions, concluded that there was no negligence on the part of the operating surgeon. These findings were subsequently upheld by the Delhi High Court.[145]

In the consumer litigation before the National Consumer Disputes Redressal Commission (NCDRC), the complaint was dismissed. The Commission applied the *Bolam* test and reaffirmed the principles laid down in *Jacob Mathew v. State of Punjab*, holding that negligence could not be imputed where the medical practitioner had acted in accordance with a responsible body of medical opinion and accepted professional standards.[146] The NCDRC took into account several evidentiary components: the real-

[142] Satvik N. Pai et al., *In the Hands of a Robot: The Medicolegal Considerations of Robotic Surgery* (2023).
[143] M.B. Bagwan, *Liability in Robotic Surgery: Legal Frameworks and Case Studies* (2025).
[144] *Prem Kishore v. Indraprastha Apollo Hosp. & Ors.*, Civil Appeal No. 7700 of 2023 (India).
[145] *Prem Kishore v. Delhi Med. Council*, W.P. (C) No. 5310 of 2017 (Del. HC 2023).
[146] *Prem Kishore v. Indraprastha Apollo Hosp.*, First Appeal No. 721 of 2017 (NCDRC Jan. 27, 2023).

time surgical video, operative notes detailing prompt intraoperative decision-making, expert reports affirming compliance with standard procedures, and the inherent surgical risk of intraoperative bleeding and conversion to open surgery. The Commission reiterated that complications alone do not amount to negligence unless the conduct of the surgeon demonstrably falls below the accepted standard of care.[147]

Upon further appeal, the Supreme Court of India upheld the NCDRC's findings. The Court stressed that judicial assessment of medical conduct must consider the circumstances prevailing at the time of surgery, and not with the advantage of hindsight.[148] It observed that the decision to convert to open surgery in response to massive bleeding was medically justified and within the realm of sound clinical judgment. Moreover, the Supreme Court lent weight to the assessments provided by the DMC and MCI, which had independently found no deviation from accepted medical protocols.[149]

A particularly notable feature of the *Prem Kishore* case is its reliance on video recordings of the robotic procedure—a facility rarely available in conventional surgeries. This introduced a new dimension in evidentiary standards. The ability to review the actual operative technique, surgeon movements, and decision points in real time, allowed for a transparent and objective evaluation of whether standard care was maintained. This technological tool not only strengthens the adjudicatory process but also underscores the surgeon's accountability in robotic environments.

Importantly, the Court emphasized that robotic surgery does not diminish the surgeon's duty of care. Even in technologically sophisticated procedures, the legal scrutiny of negligence remains grounded in the same jurisprudential principles: whether the surgeon acted with reasonable skill, prudence, and conformity to accepted professional practices. The *Prem Kishore* case therefore serves as a key precedent in establishing that robotic surgical errors must be evaluated holistically—incorporating surgical risks, available evidence, clinical judgment, and expert evaluations—before arriving at conclusions of liability.

[147] *Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1 (India).
[148] *Bolam v. Friern Hosp. Mgmt. Comm.*, (1957) 1 W.L.R. 582 (Eng.).
[149] Indian Med. Ass'n v. V.P. Shantha, (1995) 6 SCC 651 (India).

ii. Distinguishing Negligence from Error of Judgment

In the legal assessment of civil liability, distinguishing between a culpable act of negligence and a permissible error of clinical judgment is of critical importance. Medical decisions often involve complex evaluations under time-sensitive and uncertain circumstances. Therefore, the mere occurrence of an adverse outcome does not, by itself, establish negligence. This distinction is especially crucial in the context of robotic-assisted surgeries, where the interface between human judgment and technological mediation may introduce unforeseen complications.

Judicial authorities, both in India and abroad, have firmly upheld that an error of judgment does not amount to negligence unless it clearly deviates from the expected standard of care. The Supreme Court of India in *Jacob Mathew v. State of Punjab* observed that decisions taken during medical emergencies must not be scrutinised with hindsight, and an error of judgment under such conditions may still conform to the conduct expected of a reasonably competent medical professional.[150] Similarly, in *S.K. Jhunjhunwala v. Dhanwanti Kaur*, the Court clarified that procedural deterioration during surgery, in itself, does not imply negligence unless accompanied by reckless or gross conduct.[151]

The case of *Dr. (Mrs.) Chanda Rani Akhouri v. Dr. M.A. Methusethupathi* reiterated that selection among various accepted medical treatments does not amount to negligence simply because the outcome was unsatisfactory. Rather, the exercise of reasonable clinical discretion must be respected.[152] Most notably, in *Martin F. D'Souza v. Mohd. Ishfaq*, the Court emphasised that a doctor is not to be held liable for an honest error of judgment made in good faith, especially where complex considerations are involved.[153] The principle was again echoed in *Malay Kumar Ganguli v. Dr. Sukumar Mukherjee*, where it was held that bona fide clinical decisions in difficult therapeutic scenarios are protected from liability.[154]

Indian jurisprudence is in accord with established international standards. For instance, in *Whitehouse v. Jordan*, the House of Lords held that an honest error in the use of

[150] *Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1 (India).
[151] *S.K. Jhunjhunwala v. Dhanwanti Kaur*, (2019) 2 SCC 282 (India).
[152] *Dr. (Mrs.) Chanda Rani Akhouri v. Dr. M.A. Methusethupathi*, (2017) 11 SCC 805 (India).
[153] *Martin F. D'Souza v. Mohd. Ishfaq*, (2009) 3 SCC 1 (India).
[154] *Malay Kumar Ganguli v. Dr. Sukumar Mukherjee*, (2010) 2 SCC 213 (India).

forceps during childbirth could not be construed as negligence unless it clearly fell below the accepted standard.[155] Likewise, in *Maynard v. West Midlands Regional Health Authority*, the court noted that differences in medical opinion are natural and courts must refrain from penalising decisions merely because an alternate course existed.[156] The Scottish case of *Hunter v. Hanley* and the English decision in *Roe v. Ministry of Health* have further reinforced that clinical errors must be judged contextually, not retrospectively.[157,158]

In the specific setting of robotic surgery, the doctrine of error of judgment becomes especially salient due to the inherent complexity of human-machine interactions. Empirical studies affirm that intraoperative errors during robotic procedures may arise from limitations in tactile feedback, altered decision-making processes, and procedural adjustments required by the robotic interface. A 2021 study by Kay Hutchinson et al. identified both executional and procedural errors in dry-lab robotic experiments, attributing many to human cognitive misjudgment in motor execution and task sequencing.[159] Similarly, Rebecca Randell et al. highlighted that robotic systems impact surgeon behavior and decision-making in ways that may inadvertently result in reasonable clinical deviations.[160]

These observations were judicially affirmed in *Prem Kishore v. Indraprastha Apollo Hospital*, the only reported Indian case on robotic surgery negligence. The National Consumer Disputes Redressal Commission (NCDRC), while dealing with a claim of intraoperative bleeding, held that the surgeon's decision to delay conversion from robotic to open surgery constituted an error of clinical judgment, not negligence.[161] The Commission stressed that intraoperative decisions must be judged within the boundaries of professional prudence, and unless proven to be grossly unreasonable, they fall within the protected domain of clinical discretion. On appeal, the Supreme Court upheld this reasoning and reiterated that poor outcomes alone do not imply breach

[155] *Whitehouse v. Jordan*, [1981] 1 All ER 267 (HL).
[156] *Maynard v. West Midlands Reg'l Health Auth.*, [1985] 1 All ER 635 (HL).
[157] *Hunter v. Hanley*, 1955 SLT 213 (Scotland).
[158] *Roe v. Minister of Health*, [1954] 2 All ER 131 (CA).
[159] Kay Hutchinson et al., *Analysis of Executional and Procedural Errors in Dry-lab Robotic Surgery Experiments*, arXiv:2106.11962v2 (2021), https://arxiv.org/abs/2106.11962.
[160] Rebecca Randell et al., *Impact of Robotic Surgery on Decision Making: Perspectives of Surgical Teams*, 19 J. Evaluation Clinical Practice 689 (2014), https://doi.org/10.1111/jep.12195.
[161] *Prem Kishore v. Indraprastha Apollo Hosp.*, First Appeal No. 721 of 2017, NCDRC (Aug. 7, 2023).

of duty, and courts must examine the real-time judgment exercised by the practitioner.[162]

In sum, while robotic systems introduce enhanced capabilities and objective feedback mechanisms, they do not eliminate the cognitive and situational aspects of surgical decision-making. Courts continue to recognise that intraoperative clinical judgment, even when flawed in hindsight, is not actionable as negligence unless it reflects a breach of the expected standard. The doctrine of error of judgment thus remains a vital safeguard in balancing legal accountability with the realities of medical practice—particularly in the technologically advanced realm of robotic-assisted surgery.

iii. Informed Consent in Robotic Surgery

Informed consent is a foundational doctrine in medical law, encapsulating the patient's right to autonomy and bodily integrity. It is not only a procedural formality but a substantive legal requirement that ensures medical interventions are carried out with the patient's voluntary and well-informed agreement. In the context of robotic surgery, informed consent assumes heightened importance due to the complex nature of the technology, layered clinical decisions, and increased procedural uncertainties. Hence, the duty of disclosure on the part of the medical practitioner becomes more stringent.[163]

A landmark exposition on the concept of informed consent was provided by the Supreme Court of India in Samira Kohli v. Dr. Prabha Manchanda, where the Court emphasised the centrality of real and informed consent in all surgical interventions.[164]

In Samira Kohli, the patient was admitted for diagnostic laparoscopy to investigate menstrual disorders. However, during the procedure, the surgeon performed an unwarranted hysterectomy and bilateral salpingo-oophorectomy without the patient's explicit consent. The Court ruled that such unilateral deviation constituted an invasion of bodily integrity and amounted to medical negligence. The decision outlined that

[162] *Prem Kishore v. Indraprastha Apollo Hosp. & Ors.*, Civil Appeal No. 7700 of 2023, Supreme Court of India (Dec. 5, 2023).
[163] Satvik N. Pai et al., *In the Hands of a Robot: The Medicolegal Considerations of Robotic Surgery*, 15 Cureus e43634 (2023).
[164] *Samira Kohli v. Dr. Prabha Manchanda*, (2008) 2 SCC 1 (India).

consent must be specific, voluntary, informed, and procedure-linked; broad authorisations or blanket consents do not suffice.

The Supreme Court, in paragraph 32 of its judgment in Samira Kohli, laid down five essential elements for valid informed consent:

a. the patient must be competent to decide;
b. consent must be voluntary and uncoerced;
c. adequate disclosure must be made regarding the procedure's nature, risks, benefits, and alternatives;
d. consent must be specific to the intended procedure; and
e. the consent must be a meaningful exercise in understanding rather than a mere signature ritual.[165]

These principles were further elaborated in Indian jurisprudence. In Malay Kumar Ganguli v. Dr. Sukumar Mukherjee, the Court noted that non-disclosure of material information could lead to post-operative litigation, even when the procedure itself is medically justified.[166] In Dr. Janaki S. Kumar v. Sarafunnisa, the Kerala State Commission held that consent obtained from an anaesthetised patient lacked legal validity.[167] The National Commission in Dr. Shailesh Shah v. Aphraim Jayanand Rathod ruled that repeat surgeries require renewed consent,[168] and in A.K. Mittal v. Rajkumar, performing surgery on a minor without specific parental consent was deemed negligent.[169]

Foreign legal systems also affirm the sanctity of informed consent. In Salgo v. Leland Stanford Jr. University, the U.S. courts first articulated the doctrine, establishing that non-disclosure of risks equates to legal trespass.[170] The Canterbury v. Spence ruling mandated disclosure based on a "reasonable patient" standard.[171] In Reibl v. Hughes, Canada's Supreme Court prioritised patient autonomy by shifting the standard from physician-centred to patient-centred disclosure.[172] In Rogers v. Whitaker, the Australian

[165] *Samira Kohli v. Dr. Prabha Manchanda*, (2008) 2 SCC 1 (India).
[166] *Malay Kumar Ganguli v. Dr. Sukumar Mukherjee*, (2009) 9 SCC 221 (India).
[167] *Dr. Janaki S. Kumar v. Sarafunnisa*, (1999) I CPJ 66 (Ker. SCDRC) (India).
[168] *Dr. Shailesh Shah v. Aphraim Jayanand Rathod*, FA No. 597/1995 (NCDRC) (India).
[169] *A.K. Mittal v. Rajkumar*, 2009 CTJ 606 (NCDRC) (India).
[170] *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560 (1957) (U.S.).
[171] *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972) (U.S.).
[172] *Reibl v. Hughes*, (1980) 114 DLR (3d) 1 (Can.).

High Court upheld a patient's right to be informed even about rare complications.[173] Similarly, Natanson v. Kline[174] and Roe v. Ministry of Health[175] underscored the need for clear communication regarding procedural risks and alternatives.

Robotic surgeries introduce further dimensions that necessitate comprehensive consent. According to scholarly commentary, the informed consent process in robotic interventions must include: (i) clear disclosure that a robotic system will be used and that it is not autonomous but surgeon-controlled; (ii) procedure-specific risks such as mechanical malfunction, loss of tactile feedback, and possibility of conversion to open surgery; (iii) disclosure of the surgeon's proficiency with robotic systems and institutional experience; (iv) viable alternative treatments with comparative outcomes; and (v) identification of all personnel involved, including trainers and proctors.

Studies by Satvik N. Pai et al.,[176] Alessia Ferrarese et al.,[177] and the MedPro Group[178] affirm that absence of such disclosures renders consent legally invalid and ethically compromised. Additionally, empirical research on robotic surgery underscores that while technology adds precision, it does not diminish the need for patient awareness and choice.

In total, the requirement of informed consent is both legally and ethically indispensable. Especially in robotic-assisted surgeries, where the complexity of the interface and associated risks are not easily comprehensible to lay patients, surgeons must ensure that consent is not only taken but is also meaningfully informed. Failure to obtain such consent can constitute actionable negligence, even if the surgery is technically sound and aligned with professional norms.

iv. Adherence to Training and Credentials

In the context of robotic surgery, where complex technologies are integrated into surgical decision-making and execution, training and credentialing become not only a

[173] *Rogers v. Whitaker*, (1992) 109 ALR 625 (Austl. H.C.).
[174] *Natanson v. Kline*, 186 Kan. 393, 350 P.2d 1093 (1960) (U.S.).
[175] *Roe v. Ministry of Health*, [1954] 2 QB 66 (CA) (U.K.).
[176] Satvik N. Pai et al., *In the Hands of a Robot: The Medicolegal Considerations of Robotic Surgery*, 15 Cureus e43634 (2023).
[177] Alessia Ferrarese et al., *Informed Consent in Robotic Surgery: A New Challenge*, 11 Open Med. 74 (2016).
[178] MedPro Group, *The Essential Role of Informed Consent in Robot-Assisted Surgery*, https://www.medpro.com/roboticsurgery-informedconsent.

matter of ensuring minimum proficiency but also a crucial element in determining liability or exoneration in medico-legal disputes. Unlike conventional surgeries where tactile and visual feedback dominate, robotic surgery requires mastery of robotic interfaces, haptic substitutes, and remote manipulation—all of which necessitate specialised learning curves. Consequently, whether or not a surgeon has undergone formal training in robotic systems can become a pivotal question in adjudicating negligence claims. Structured credentialing serves the dual purpose of enhancing surgical outcomes and evidencing adherence to accepted standards of care.

Scholarly studies consistently emphasize the centrality of formal training in robotic surgery to mitigate risk. Satvik N. Pai et al. argue that the absence of a nationally standardised credentialing framework in India creates variance in practice quality, thereby exposing patients and institutions to higher medico-legal risk.[179] They advocate for structured robotic training pathways, citing global best practices where performance-based progression models are the norm. Similarly, Dr. M.B. Bagwan underscores that in disputes concerning robotic surgical errors, courts often look for documentation of the surgeon's training to assess whether a departure from standard practice has occurred.[180] Gupta et al. also point out that although India now has a significant robotic surgery footprint, there remains a gap in uniform training, particularly among surgeons practising outside academic institutions.[181] All these studies converge on the idea that training is not optional but essential—both clinically and legally.

Importantly, the Indian legal framework already provides examples of statutorily mandated training and credentialing in advanced medical procedures. Under the Medical Termination of Pregnancy (MTP) Rules, a doctor must either have performed five terminations under supervision or hold a postgraduate degree in obstetrics and gynaecology to be eligible to carry out an MTP.[182] Similarly, the Assisted Reproductive Technology (Regulation) Rules, 2022 require that a gynaecologist performing ART must have completed 50 supervised oocyte retrievals or equivalent certified training.[183]

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[179] Satvik N. Pai et al., *In the Hands of a Robot: The Medicolegal Considerations of Robotic Surgery*, 15 Cureus J. Med. Sci. e43989 (2023).
[180] M.B. Bagwan, *Liability in Robotic Surgery: Legal Frameworks and Case Studies*, 10 Indian J. Forensic & Medico-Legal Sci. 201 (2025).
[181] Gupta et al., *Training and Credentialing in Robotic Surgery in India*, Int. J. Surg. (2021).
[182] Medical Termination of Pregnancy Amendment Rules, 2021, Rule 4.
[183] Assisted Reproductive Technology (Regulation) Rules, 2022, Rule 11.

The Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Rules mandate a six-month structured training, with assessment, for doctors intending to perform ultrasound diagnostics.[184] Even under the Surrogacy (Regulation) Rules, medical professionals must satisfy qualification and training thresholds before engaging in clinical surrogacy procedures.[185] These provisions show a clear legal recognition of training as a prerequisite to professional competence in high-stakes medical interventions.

On the international front, authoritative consensus documents such as the SAGES-MIRA Consensus Document[186] and the American Urological Association's Standard Operating Procedure (SOP) on Robotic Surgery[187] emphasize structured training as the cornerstone of safe robotic surgery. These documents recommend a phased approach that includes didactic instruction, simulation-based skill development, bedside assisting, proctored surgeries, and final competency assessments. They also call for integration of robotic surgery modules into postgraduate surgical curricula. Notably, the SAGES-MIRA document specifies that hospitals should not credential any surgeon for robotic surgery unless such benchmarks are demonstrably met. Similarly, the Joint Commission (USA) and the Royal College of Surgeons of England echo these standards, stressing that institutions must maintain formal records of credentialing, ongoing evaluations, and simulation-based proficiency.[188]

In India too, professional bodies have recognised the need for minimum training standards in robotic surgery. The CRSA India Chapter's 2022 Consensus Document on Surgical Management of Rectal Cancer indirectly addresses robotic surgical training by highlighting the need for trained personnel in complex colorectal interventions.[189] Other institutional publications and white papers advocate the establishment of

[184] Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996, as amended in 2014.
[185] Surrogacy (Regulation) Rules, 2022 (Read with ART Rules, 2022).
[186] SAGES-MIRA Consensus Document on Robotic Surgery (2007), Society of American Gastrointestinal and Endoscopic Surgeons (SAGES).
[187] American Urological Association, *Robotic Surgery (Urologic) Standard Operating Procedure*, AUA, 2022.
[188] Joint Commission, *Quick Safety Issue 3: Potential Risks of Robotic Surgery* (2014); Royal College of Surgeons of England, *Robotic-Assisted Surgery Guidance* (2020).
[189] Rakesh V. et al., *Consensus Statements on Management of Rectal Cancer in India*, Front. Oncol. 12:1002530 (2022).

credentialing protocols modelled after international standards, especially given India's increasing adoption of robotic systems in both public and private hospitals.

The training program offered by Intuitive Surgical, the manufacturer of the widely used da Vinci Surgical System, offers a concrete example of what constitutes comprehensive robotic surgical training. Their curriculum involves:

1. Didactic modules introducing robotic platforms and patient safety principles;
2. Simulator-based psychomotor skill training with target scores across increasing difficulty levels;
3. Observation of live surgeries;
4. Bedside assistance in at least 10 procedures;
5. Console participation in at least 20 surgeries under supervision, progressing toward independent surgery;
6. Proficiency assessments and final certification.[190]

   This phased training system ensures that a surgeon not only understands the mechanics of the robotic interface but also achieves functional expertise before independent practice. It closely mirrors the proficiency-based progression model advocated by FRS (Fundamentals of Robotic Surgery).

However, despite the availability of such detailed training guidelines and their endorsement by academic, industrial, and professional organisations, their enforceability remains questionable in India. Unlike in MTP, ART, or PCPNDT frameworks, where failure to meet prescribed training requirements may invite penal consequences, robotic surgery training remains largely institution-driven and discretionary. This regulatory vacuum creates inconsistency in patient safety and professional accountability. As robotic surgery becomes more prevalent, this gap necessitates urgent attention. It would be appropriate to incorporate minimum training and credentialing requirements into the existing legal and regulatory framework, either through the Clinical Establishments Act or via a dedicated statutory guideline. Doing

[190] Intuitive Surgical, *da Vinci Surgical System Resident & Fellows Training Guide*, 2023.

so would not only standardise practice but also shield compliant practitioners from undue legal exposure.

To sum up, the surgeon remains the central figure of accountability in robotic surgery, with liability hinging on adherence to the standard of care expected of a reasonably competent practitioner. Judicial precedents clarify that even in technologically complex procedures, civil liability arises when there is a clear deviation from accepted norms—be it through negligent conduct, lack of informed consent, or inadequate training. At the same time, courts continue to uphold the distinction between negligence and permissible clinical judgment, reinforcing that legal responsibility in robotic surgery remains guided by professional standards and context. In this evolving landscape, formalising minimum training and credentialing requirements through binding legal provisions would strengthen both patient protection and professional accountability.

4.4.2. Civil Liability of Hospitals/Clinical Establishments

Hospitals and clinical establishments play a pivotal role in robotic surgeries—not merely as facilitators but as essential service providers responsible for both infrastructure and human resources. Under the Consumer Protection Act, 2019, these establishments are recognised as "service providers" and may attract civil liability either directly or vicariously. Their liability becomes particularly significant in robotic surgery, where advanced equipment, skilled staff, and technology-dependent processes must all align for safe patient outcomes. Consequently, civil claims against hospitals may arise from vicarious liability for their staff, deficiency in service, or infrastructure-related failures, each of which falls within the consumer protection framework.

Vicarious Liability for Acts of Staff and Surgeons

The doctrine of vicarious liability holds a hospital liable for negligent acts committed by its employees—including surgeons, nurses, anaesthetists, and technicians—during the course of their employment. Indian courts have repeatedly affirmed that hospitals cannot evade responsibility by blaming individual practitioners when the service is delivered as an institutional whole. In *Spring Meadows Hospital v. Harjol Ahluwalia*, the Supreme Court held the hospital liable for the negligent administration of an

overdose by a nurse, establishing that institutions providing medical care are answerable for the actions of their staff.[191]

In *Savita Garg v. Director, National Heart Institute*, the Court reinforced the principle that the hospital bears the burden of proving that there was no negligence by its employees when a patient dies during treatment.[192] Similarly, in *Kusum Sharma v. Batra Hospital*, the Supreme Court clarified that hospitals must ensure that all procedures, staff conduct, and facilities conform to reasonable medical standards, else they risk vicarious liability.[193] In robotic surgery, such liability may arise where the support team fails to properly set up or assist during the operation, or where untrained staff are allowed to operate or manage the robotic system. If a surgeon acting within the scope of their engagement commits negligence, the hospital is answerable unless the surgeon was an independent consultant, a determination that courts assess based on control and supervision.

Service Deficiency under Consumer Protection Act, 2019

Section 2(11) of the Consumer Protection Act, 2019 defines "deficiency" to include any fault, imperfection, shortcoming or inadequacy in the quality, nature, and manner of performance that is required to be maintained under the law or as is claimed in any contract.[194] Hospitals are liable under this provision if there is a failure in providing standard services, even in the absence of direct negligence. This includes situations where:

- Robotic systems are not properly maintained or calibrated;
- Required surgical expertise or robotic technicians are unavailable;
- There is undue delay in initiating robotic intervention despite indication;
- Consent procedures are improperly handled or not institutionally verified.

In *Vinod Khanna v. R.G. Stone Urology & Laparoscopy Hospital*, the Delhi State Commission held that the hospital was liable for not maintaining its equipment in a

[191] Spring Meadows Hospital v. Harjol Ahluwalia, (1998) 4 SCC 39 (India).
[192] Savita Garg v. Director, National Heart Institute, (2004) 8 SCC 56 (India).
[193] Kusum Sharma v. Batra Hospital, (2010) 3 SCC 480 (India).
[194] Consumer Protection Act, 2019, § 2(11).

proper state, thus constituting deficiency in service.[195] Such reasoning extends naturally to robotic systems, where the hospital's control over infrastructure imposes a legal duty to maintain operative safety and technical functionality.

Equipment Failure and Infrastructure-Related Issues

Robotic-assisted surgery depends not only on human expertise but also on the optimal functioning of robotic systems. The hospital has an affirmative duty to ensure that the da Vinci system (or any other platform used) is routinely tested, maintained, and operated in conditions free from foreseeable risk. Failure of robotic arms, console misalignment, power interruptions, and even software glitches can have life-threatening implications. In *Kavita Narang v. Government of NCT of Delhi*, the Delhi High Court held the state hospital liable for causing brain damage to a patient due to alleged malfunctioning of the MRI machine, thereby reiterating that hospitals are custodians of safe infrastructure.[196]

In robotic surgery, the potential for liability extends even further. If a procedure fails due to malfunctioning or under-maintained robotic equipment, the hospital may be held liable regardless of the surgeon's individual diligence. Courts have held that such responsibility flows from the non-delegable duty of the hospital to provide a safe environment for treatment.

The civil liability of hospitals in robotic surgery is twofold: they are answerable both for their own acts or omissions—including equipment maintenance, personnel deployment, and consent oversight—and vicariously for the conduct of their employees. These liabilities are firmly situated within the scope of consumer law, as interpreted by Indian courts in a growing body of jurisprudence. As robotic surgery continues to expand, so too will the expectations placed on hospitals to ensure not just the presence of advanced technology but its safe, skilled, and accountable use.

4.4.3. Civil Liability of Programmers and Software Developers

Robotic surgery systems operate on software that translates surgical intent into machine execution. Software developers and programmers, although not medical professionals,

[195] Vinod Khanna v. R.G. Stone Urology & Laparoscopy Hospital, Complaint Case No. 22/2013, Delhi State Consumer Disputes Redressal Commission (2014).
[196] Kavita Narang v. Government of NCT of Delhi, W.P.(C) 7586/2002, Delhi High Court (2010).

directly influence surgical outcomes through the algorithms and logic they design. Their liability is distinct and complex—arising from the medical consequences of technological behaviour. Civil liability may be attracted when a flaw or error in the software contributes to patient harm, especially where such error results from negligent design, testing, inadequate safety mechanisms, or failure to update the software system.

Derivation from Legal Personhood Framework

As discussed earlier in Chapter 4, artificial intelligence and software systems—even when self-learning—lack legal personhood. Whether the robotic system is pre-programmed or trained through machine learning, the ultimate accountability lies with its human creator. This includes software developers who design the rules, input the training data, or build the architectures upon which the system learns. Therefore, when the algorithm behaves undesirably, and the system is not independently auditable or correctable by the end-user, liability flows upstream to the programmer, provided the criteria of negligence are met.[197]

Hidden Algorithmic Errors

Robotic surgical systems are deeply reliant on software-controlled functions such as instrument calibration, tissue recognition, force feedback modulation, and surgical path planning. Errors in any of these domains—such as targeting miscalculations, feedback loop anomalies, or instrument path prediction flaws—can remain undetected during standard testing and only emerge during live procedures. These are referred to as latent or hidden algorithmic errors, and they pose unique risks due to their unpredictable interaction with human oversight.

If such flaws are rooted in the software logic and directly lead to surgical mishap or injury, civil liability may arise for the programmer or software developer. This may be framed under the law of torts (negligent design or failure to warn), and potentially under product liability when the defect forms part of the marketed surgical system.[198]

Lack of Foreseeability and Safety Protocols

The imposition of liability does not extend to every software failure. A critical threshold lies in the foreseeability of risk and whether the developer breached the duty of care

[197] Visa A.J. Kurki, *A Theory of Legal Personhood* 168–69 (Oxford Univ. Press 2019).
[198] M.B. Bagwan, *Liability in Robotic Surgery: Legal Frameworks and Case Studies* (2025).

expected of professionals in high-risk environments. A robust defence exists where the developer adopted prevailing industry standards for safety and testing. However, when recognized protocols such as IEC 62304 (software lifecycle standards for medical devices) are ignored, or when:

- no mechanism for self-check or override is embedded,
- update patches are withheld despite identified bugs, or
- no disclosure of limitations is made to the clinical user,

then civil liability is more likely to attach, particularly when a causal link to patient harm can be demonstrated.[199]

Role under Consumer Protection Act, 2019

Programmers are not direct service providers to patients and hence may not always be liable under traditional service liability provisions. However, when embedded within the supply chain—e.g., as software engineers for manufacturers or vendors—their liability may be invoked through the product liability regime under Chapter VI of the Consumer Protection Act, 2019.

Specifically:

- Section 2(35) defines a "product manufacturer" to include those who design, assemble, produce, or label the product.
- Section 2(36) defines a "product liability action" as a claim for compensation for harm caused by a defective product.

If software, as part of a robotic surgery system, causes injury due to embedded flaws, then civil action may be maintainable under this provision, particularly against manufacturers who integrate software from third-party developers without adequate validation.[200]

In robotic surgery, where digital systems dictate physical execution, the role of the programmer or software developer becomes central to both surgical safety and legal scrutiny. Civil liability may arise when programming decisions, inadequate oversight,

[199] Satvik N. Pai et al., *In the Hands of a Robot: The Medicolegal Considerations of Robotic Surgery*, 15 Cureus J. Med. Sci. e43989 (2023).
[200] Consumer Protection Act, 2019, § 2(35)–(36) (India).

or omission of known risks cause harm to the patient. As robotic platforms grow more autonomous and complex, integrating mandatory compliance with safety protocols, periodic updates, and transparent documentation into software design becomes essential. Indian legal frameworks, including the Consumer Protection Act, 2019, provide a basis for such liability, and future legal standards must continue to evolve in alignment with the invisible yet impactful role of software in modern surgical practice.

4.4.4. Civil Liability of Manufacturers of Robotic Surgical Systems

Manufacturers of robotic surgical systems occupy a central position in the liability framework, as they are the originators of the physical and digital components that directly interface with patient care. Despite not being involved in clinical operations, their accountability arises from the design, manufacture, and quality control of the robotic systems that are deployed in surgical environments. Any failure in these aspects can result in direct harm to patients, thereby invoking civil liability through multiple legal avenues—tort law, statutory consumer protection mechanisms, and contractual provisions.

Product liability constitutes a foundational element of civil liability in the context of robotic surgery. Under Indian law, this encompasses negligence, strict liability, and, in exceptional cases, absolute liability. Negligence is attracted when the manufacturer fails to exercise reasonable care in the design, manufacture, assembly, or inspection of the surgical robot. For instance, a malfunction due to poor calibration of a robotic arm or a grip failure during surgery may constitute negligence if the harm could have been foreseen and prevented through ordinary engineering diligence.[201]

Strict liability arises when the defect exists despite the exercise of due care. The law imposes liability on the manufacturer simply upon proving that the product was defective and that the defect caused injury while being used in its intended manner.[202] This principle is particularly relevant in robotic surgery due to the high-risk, high-precision nature of the procedures.

Moreover, the doctrine of absolute liability, as laid down by the Indian Supreme Court in *M.C. Mehta v. Union of India*, extends to ultra-hazardous activities. Courts have

[201] M.B. Bagwan, *Liability in Robotic Surgery: Legal Frameworks and Case Studies* (2025).
[202] Emma De Ravin et al., *Medical Malpractice in Robotic Surgery: A Westlaw Database Analysis* (2023).

gradually begun applying this principle to advanced medical devices, including surgical robots, where the potential for irreversible harm due to system failure is high.[203]

On the statutory front, the Consumer Protection Act, 2019 provides a robust mechanism for product liability under Chapter VI. Section 83 permits consumers to initiate action for product liability against a manufacturer, product seller, or service provider. Section 84 elaborates the grounds, including manufacturing defects, design defects, failure to warn, and deviation from express warranties. The law, thus, ensures direct civil remedies for patients harmed by defective robotic surgical systems.[204]

Academic commentary supports this legal framework. Raghunath K.S. has noted that the 2019 Act marks a significant shift from *caveat emptor* (buyer beware) to *caveat venditor* (seller beware), reinforcing manufacturers' responsibilities, especially those dealing with high-risk products like surgical robots. He further argues that damages can now include not just physical injury but also mental agony, loss of consortium, and property damage—expanding the ambit of compensable harm.[205]

Additionally, contractual provisions under the Sale of Goods Act, 1930 and the Indian Contract Act, 1872 reinforce manufacturer liability. Under Sections 14 and 16 of the Sale of Goods Act, the seller implicitly warrants that the goods are fit for their intended use and of merchantable quality. If a robotic system fails during surgery due to a mechanical defect, the hospital or buyer may seek remedies for breach of contract. Section 73 of the Indian Contract Act allows recovery of consequential damages, including patient harm, when contractual warranties are violated.[206]

International studies further support the need for stringent manufacturer accountability. Andonian et al.'s review of MAUDE data identified failures like electrical arcing and mechanical detachment, directly leading to injuries such as burns and perforations. The FDA reported 1,914 malfunction events from 205,000 robotic procedures, with injury

[203] M.C. Mehta v. Union of India, (1987) 1 SCC 395 (India).
[204] Consumer Protection Act, 2019, §§ 83–84 (India).
[205] Raghunath K.S., *A Study of Product Liability with Special Reference to India*, VII VBCL L. Rev. 19, 22 (2022).
[206] Sale of Goods Act, 1930, §§ 14–16 (India); Indian Contract Act, 1872, § 73.

rates between 0.5% to 5.4%.[207] In a Japanese study, Ogihara et al. reported 15 intraoperative issues in 544 cases, with most traced to instrument or stapler failures.[208]

Given these findings, the manufacturer's duty to ensure faultless design, thorough testing, timely upgrades, and full disclosure of system risks becomes pivotal. Liability may also extend to failure to warn hospitals and users about known limitations or potential software vulnerabilities in the system. The absence of adequate safeguards or failure to recall defective models could strengthen civil claims.

To summarise, manufacturers are accountable under multiple heads: (i) negligence in engineering diligence; (ii) strict and absolute liability for device failure; (iii) statutory product liability under consumer law; and (iv) contractual liability through service or purchase agreements. These overlapping frameworks reinforce the legal expectation that manufacturers of robotic surgical systems must uphold the highest standards of product integrity, quality assurance, and patient safety.

4.4.5. Civil Liability of Supply Chain Actors (Distributors and Sellers)

In the context of robotic surgery systems, distributors and sellers typically have a limited role, primarily confined to marketing and delivering the products as received from the manufacturer. As such, civil liability generally does not attach to them unless their conduct independently contributes to the harm caused. Under the Consumer Protection Act, 2019, Section 86 provides that product sellers may be held liable only in specific circumstances—such as when they have exercised substantial control over the product, altered or modified it, failed to warn about known risks, or supplied a defective product despite having knowledge of its defect.[209]

Absent such conduct, the primary burden of civil liability for injury arising from robotic surgery equipment remains with the manufacturer or, in some cases, with the hospital or service provider. Thus, unless the distributor or seller engages in negligent or deceptive practices—such as misrepresenting the capabilities of the robotic system or

[207] Sero Andonian et al., *Device Failures Associated with Patient Injuries During Robot-assisted Laparoscopic Surgeries: A Review of FDA MAUDE Database*, Can J Urol. 2008 Feb;15(1):3954–3958.
[208] Akira Ogihara et al., *Intraoperative Robotic Surgical System-related Problems in Robot-assisted Thoracoscopic Surgery*, Gen Thorac Cardiovasc Surg (2024) 72:593–598.
[209] Consumer Protection Act, 2019, § 86 (India).

ignoring a recall notice—they are not ordinarily liable under civil negligence or product liability frameworks.

4.5. Criminal Liability in Robotic Surgery

While civil liability addresses compensation for harm, criminal liability is concerned with penal consequences for conduct that is grossly negligent or reckless. In the context of robotic surgery, criminal prosecution may arise when the actions or omissions of human actors—such as surgeons, hospitals, manufacturers, or programmers—result in grievous injury or death, and such conduct is shown to involve a culpable mental state. The framework for such liability primarily arises under provisions of the Indian Penal Code, 1860 (now subsumed by the Bharatiya Nyaya Sanhita, 2023), which penalise acts of gross negligence, rashness, or intentional harm. The application of criminal law requires a higher threshold of proof and focuses on the presence of *mens rea* in determining culpability.

4.5.1. Criminal Liability of Surgeons

In the Indian legal framework, criminal liability for acts committed during the course of medical treatment is distinguished from civil liability based on the gravity of the conduct and the requisite mental state. While civil negligence is grounded in failure to exercise reasonable care, criminal liability arises only when the negligence is gross, reckless, or manifestly indifferent to human life. This distinction is crucial when examining criminal charges against surgeons in the context of robotic surgery, where complex decision-making often interacts with high-risk procedures.

The seminal Supreme Court judgment in *Jacob Mathew v. State of Punjab* laid down the threshold for invoking criminal liability against medical professionals. The Court clarified that a medical practitioner can be held criminally liable only when their conduct falls so grossly below the accepted standard of care that it amounts to recklessness or gross negligence.[210] The judgment cautioned against prosecuting doctors for mere errors of judgment or adverse outcomes in good faith medical interventions. This remains the bedrock principle guiding criminal prosecutions in medical negligence.

[210] *Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1 (India).

Under the Indian Penal Code, 1860, and its updated counterpart, the Bharatiya Nyaya Sanhita, 2023, criminal charges may be attracted under:

- **Section 304A IPC / Section 106 BNS**: Causing death by negligence, when gross medical negligence directly results in the death of a patient.[211]
- **Section 337 IPC / Section 122(1) BNS**: Causing hurt by an act endangering life or personal safety.
- **Section 338 IPC / Section 122(2) BNS**: Causing grievous hurt by an act endangering life or personal safety.[212]

However, mere deviation from standard protocol or surgical complications are not sufficient for invoking these provisions unless the conduct is accompanied by reckless disregard for life or safety. For instance, in *Dr. Suresh Gupta v. Govt. of NCT of Delhi*, the Court held that failure to tie a bleeding artery during surgery, though serious, did not amount to gross negligence justifying criminal prosecution under Section 304A IPC.[213]

In robotic-assisted surgeries, determining criminal liability becomes even more intricate. These surgeries often involve human-machine collaboration, with the surgeon relying on sophisticated systems to execute movements and commands. However, the surgeon remains in full control of the console, and hence, any fatal error stemming from operational misjudgment or disregard of known system limitations may still attract penal liability—provided the recklessness threshold is met.

The presence of intraoperative video recordings in robotic surgery has added an evidentiary dimension to criminal cases. These recordings can either exonerate or implicate a surgeon by offering real-time insights into surgical conduct. In *Prem Kishore v. Indraprastha Apollo Hospital*, while the case was not one of criminal liability, the availability of surgical footage played a crucial role in demonstrating that the decision-making process was within acceptable professional standards, thereby ruling out even civil negligence.[214]

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[211] Indian Penal Code, 1860, § 304A; Bharatiya Nyaya Sanhita, 2023, § 106.
[212] Indian Penal Code, 1860, §§ 337, 338; Bharatiya Nyaya Sanhita, 2023, § 122.
[213] *Dr. Suresh Gupta v. Govt. of NCT of Delhi*, (2004) 6 SCC 422 (India).
[214] *Prem Kishore v. Indraprastha Apollo Hospital*, Civil Appeal No. 7700 of 2023, Supreme Court of India (Dec. 5, 2023).

Nonetheless, the general judicial approach remains cautious. Courts have consistently insisted on expert medical opinions before initiating criminal proceedings against surgeons. In *Martin F. D'Souza v. Mohd. Ishfaq*, the Court directed that no criminal complaint should be entertained against a doctor unless supported by credible expert opinion establishing prima facie evidence of gross negligence.[215]

To summarise, while the advent of robotic surgical technology does not alter the legal standards of criminal negligence, it introduces new complexities in assessing intent and recklessness. Surgeons may attract criminal liability under Sections 106, 122(1), or 122(2) of the Bharatiya Nyaya Sanhita, 2023, but only when there is a demonstrable breach amounting to gross negligence or wilful disregard for patient safety. Courts must continue to exercise restraint and adhere to the safeguards laid down in *Jacob Mathew* to prevent undue harassment of medical professionals acting in good faith.

4.5.2. Criminal Liability of Hospitals

Criminal liability, although generally centred on individuals, may extend to corporate or institutional entities under Indian law under specific circumstances. Indian courts recognise that a corporation acts through its directors and managers, whose intent and conduct may be attributed to the entity itself under the "alter ego" doctrine—where the controlling individuals are viewed as the mind and will of the corporation.[216] Thus, the foundational criminal law requirements of *mens rea* (guilty mind) and *actus reus* (guilty act) may be satisfied in institutional contexts where culpable conduct is traceable to responsible human actors.

In robotic surgery, if institutional lapses such as failure to maintain or calibrate robotic systems, or permitting unqualified staff to operate critical technology, result in grievous injury or death, criminal prosecution may follow under Section 304A IPC or its equivalent Section 106 of the Bharatiya Nyaya Sanhita, 2023.[217] Similarly, Sections

[215] *Martin F. D'Souza v. Mohd. Ishfaq*, (2009) 3 SCC 1 (India).
[216] *Tesco Supermarkets Ltd. v. Nattrass*, [1972] AC 153 (HL) (UK); also applied in *Iridium India Telecom Ltd. v. Motorola Inc.*, (2011) 1 SCC 74 (India).
[217] Indian Penal Code, 1860, § 304A; Bharatiya Nyaya Sanhita, 2023, § 106.

337 and 338 IPC, or Section 122 BNS, address cases involving hurt or grievous hurt caused by rash or negligent acts.[218]

The judicial position on corporate criminal liability has evolved to permit prosecution of juridical persons. In *Standard Chartered Bank v. Directorate of Enforcement*, the Supreme Court held that a corporation can be prosecuted and punished even where the statute prescribes mandatory imprisonment.[219] In *Iridium India Telecom Ltd. v. Motorola Inc.*, the Court reaffirmed that the mental state of responsible individuals can be imputed to the corporation, enabling the prosecution of companies for offences requiring intent.[220]

As custodians of critical medical equipment and organisers of robotic surgical procedures, hospitals may be held criminally liable for failing to act upon known risks or complaints, such as ignoring maintenance warnings or continuing usage after prior malfunctions.

In the context of robotic surgery, where sensitive electronic patient data—including operative videos, diagnostic records, and real-time physiological information—is digitally processed, the hospital bears the primary responsibility for ensuring data privacy and cybersecurity. Under the Digital Personal Data Protection Act, 2023, the hospital functions as the Data Fiduciary and is obligated to implement reasonable safeguards to prevent breaches, failing which it may incur financial penalties of up to ₹250 crore for non-compliance or failure to notify the Data Protection Board.[221] While the DPDP Act does not prescribe imprisonment, the Information Technology Act, 2000 imposes criminal liability for unauthorised access, disclosure, or breach of patient data. Sections 72, 72A, and 66E of the IT Act provide for imprisonment and fines in cases involving breach of confidentiality, violation of contractual obligations, or publication of private images, respectively.[222] Although individual surgeons may be held personally liable under these provisions if they disclose or misuse patient data intentionally—such as by sharing surgical videos without consent—such liability is typically secondary. The hospital, as the systemic data controller and custodian of electronic records,

[218] Indian Penal Code, 1860, §§ 337, 338; Bharatiya Nyaya Sanhita, 2023, § 122.
[219] *Standard Chartered Bank v. Directorate of Enforcement*, (2005) 4 SCC 530 (India).
[220] *Iridium India Telecom Ltd. v. Motorola Inc.*, (2011) 1 SCC 74 (India).
[221] Digital Personal Data Protection Act, 2023, §§ 8(5), 8(6), 15 (India).
[222] Information Technology Act, 2000, §§ 66E, 72, 72A (India).

remains the principal entity accountable for institutional data protection failures that result in criminal harm.[223]

To sum up, the attribution of criminal liability to hospitals in robotic surgery depends on the degree of institutional control and culpable inaction. Indian law recognises the criminal accountability of corporations when *mens rea* can be established through responsible individuals. In technologically advanced contexts like robotic surgery, hospitals are duty-bound to prevent institutional negligence from resulting in criminal harm.

4.5.4. Criminal Liability of Non-Clinical Technical and Commercial Actors

The criminal liability of non-clinical actors in robotic surgery—namely programmers, manufacturers, and supply chain actors (distributors and sellers)—arises only in exceptional cases where gross negligence or willful disregard for safety can be established. Under Indian law, Section 106 of the Bharatiya Nyaya Sanhita, 2023 (BNS) (equivalent to Section 304A of the IPC) penalises causing death by negligence, while Section 122 (equivalent to Sections 337 and 338 IPC) addresses harm or grievous hurt due to rash or negligent acts.[224]

In addition to general provisions under the Indian Penal Code and Bharatiya Nyaya Sanhita, the Drugs and Cosmetics Act, 1940 imposes criminal liability on manufacturers, importers, and sellers of medical devices—including robotic surgical systems—if found to be substandard or unsafe. Section 27 prescribes imprisonment up to 10 years and fines for manufacture or sale of adulterated or spurious medical devices likely to cause death or grievous hurt. Further, Section 27A extends penalties to other violations of medical device safety rules. These penal provisions apply even to non-clinical actors in the supply chain where gross negligence or reckless disregard for safety protocols can be established. Notably, under Section 32 of the Act, prosecutions may be initiated not only by CDSCO Inspectors but also by aggrieved persons or recognised consumer associations, thereby broadening the scope of enforcement beyond regulatory authorities.[225]

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[223] Id. § 2(1)(w), § 43A; "National Digital Health Blueprint," Ministry of Health & Family Welfare (India), 2019.
[224] Bharatiya Nyaya Sanhita, 2023, §§ 106, 122.
[225] Drugs and Cosmetics Act, 1940, §§ 27, 27A, 32, No. 23 of 1940 (India).

For software developers, criminal liability may attach if they knowingly deploy flawed algorithms, conceal safety risks, or fail to update known defects that foreseeably endanger patient life. Similarly, manufacturers may be prosecuted if they distribute robotic systems with known defects, bypass regulatory safety protocols, or suppress adverse findings. Distributors and sellers, being more remote, are rarely liable unless they consciously circulate hazardous systems despite warnings.

Indian courts have maintained a high bar for criminal prosecution in such contexts. In *Jacob Mathew v. State of Punjab*, the Supreme Court held that criminal liability in professional and technical domains arises only when negligence is gross or reckless, not merely inadvertent.[226] The threshold applies equally to non-clinical actors in the medical supply chain.

Thus, while technically possible, the attribution of criminal liability to programmers, manufacturers, and supply chain entities in robotic surgery remains rare and would require strong proof of culpable mental state, direct causation, and foreseeable harm.

4.6. Regulatory Actions in Robotic Surgery

In addition to civil and criminal liability, various regulatory bodies in India are empowered to take administrative or disciplinary action against stakeholders involved in robotic surgery. These regulatory actions are preventive and corrective in nature, and are typically invoked when there is a violation of statutory obligations, professional norms, or licensing conditions. Depending on the nature of the actor—clinical, institutional, or commercial—such oversight is exercised by medical councils, clinical establishment authorities, or the Central Drugs Standard Control Organisation (CDSCO).

4.6.1. Regulatory Oversight of Surgeons

Surgeons involved in robotic surgical procedures are subject to professional scrutiny under the National Medical Commission Act, 2019, and related ethical frameworks including the IMC (Professional Conduct, Etiquette and Ethics) Regulations, 2002 and the NMC Registered Medical Practitioner (Professional Conduct) Regulations, 2023. Regulatory liability arises where a surgeon fails to comply with ethical, professional,

[226] *Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1 (India).

or statutory duties—particularly in contexts requiring specialised training and adherence to informed consent, such as robotic surgery.[227]

Disciplinary authority rests with the Ethics and Medical Registration Board (EMRB) of the NMC and respective State Medical Councils. Offences such as performing robotic surgery without adequate training, failure to obtain valid informed consent, or engaging in experimental use of surgical robotics without ethical clearance may constitute professional misconduct.[228] These violations are actionable even if they do not rise to the level of civil or criminal liability.

Under the IMC Ethics Regulations, 2002, Chapter 7 provides an illustrative list of misconduct, including permitting unqualified persons to operate or perform procedures, while Chapter 8 authorises State Medical Councils to impose penalties including temporary or permanent removal from the medical register.[229] Similarly, the NMC RMP Conduct Regulations, 2023 (currently in abeyance) prescribe a five-tiered penalty framework ranging from advisory warnings to permanent debarment depending on the severity of the misconduct.[230] These include violations of informed consent, operating outside the scope of one's expertise, and refusal to comply with ongoing inquiries.[231]

Disciplinary actions available to State Medical Councils include:

- Issuing formal warnings or advisories.
- Imposing temporary suspension from medical practice.
- Mandating corrective training or skill certification.
- Censure in the professional register.
- Permanent removal from the State or National Medical Register in aggravated cases.

The significance of regulatory proceedings is illustrated in the Prem Kishore v. Indraprastha Apollo Hospital case. After the patient's death during a robotic-assisted nephrectomy, the family filed complaints before the Delhi Medical Council (DMC),

[227] National Medical Commission Act, 2019, §§ 27–30.
[228] NMC Registered Medical Practitioner (Professional Conduct) Regulations, 2023, cl. 37.
[229] Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, chs. 7–8.
[230] NMC RMP Conduct Regulations, 2023, cl. 40.
[231] NMC RMP Conduct Regulations, 2023, cls. 37–38.

which conducted a detailed inquiry—including review of operative notes and surgical video—and concluded that there was no professional misconduct. This finding was upheld by the Medical Council of India and later affirmed by the Delhi High Court, demonstrating the layered mechanism of professional regulation prior to civil litigation.[232]

Thus, in the context of robotic surgery, the surgeon's responsibility extends beyond clinical competence to include adherence to evolving ethical and regulatory standards, with failure inviting sanctions from professional regulators.

4.6.2. Regulatory Oversight of Hospitals

Hospitals and clinical institutions offering robotic surgery are subject to registration and regulation under the Clinical Establishments (Registration and Regulation) Act, 2010 (CEA)[233], or under State-specific laws such as the Kerala Clinical Establishments (Registration and Regulation) Act, 2018.[234] These statutes impose regulatory obligations concerning infrastructure, staffing, operational protocols, and patient safety standards.

The District Registering Authority (DRA) is empowered to monitor compliance and initiate action where hospitals fail to meet prescribed norms. In the context of robotic surgery, regulatory action may be warranted for:

- Allowing unqualified or untrained personnel to assist in robotic procedures.
- Breaches in standardised safety, maintenance, or infection control protocols.
- Violations of statutory obligations related to informed consent or patient grievance redressal.

Under Sections 11 and 12 of the CEA, 2010, a hospital's registration may be suspended or cancelled for non-compliance with minimum standards.[235] Similarly, the Kerala Clinical Establishments Act, 2018,[236] supported by its Rules, empowers the authority to take proportionate action, including sealing of premises or monetary penalties, for

[232] *Prem Kishore v. Indraprastha Apollo Hospital & Ors.*, First Appeal No. 721 of 2017, NCDRC (Aug. 7, 2023); affirmed in *Civil Appeal No. 7700 of 2023*, Supreme Court of India (Dec. 5, 2023).
[233] Clinical Establishments (Registration and Regulation) Act, 2010.
[234] Kerala Clinical Establishments (Registration and Regulation) Act, 2018.
[235] Clinical Establishments (Registration and Regulation) Act, 2010, §§ 11–12.
[236] Kerala Clinical Establishments (Registration and Regulation) Act, 2018, §§ 10–15.

regulatory breaches.[237] Inspections may be initiated suo motu or in response to specific complaints.

While a regulatory breach may not by itself constitute civil or criminal liability, it can serve as corroborative evidence in negligence claims. For example, if harm arises from a robotic procedure conducted without trained staff or adequate infrastructure, the hospital's failure to comply with regulatory mandates may support a civil claim for damages.

Thus, statutory regulation through clinical establishment laws ensures that hospitals delivering robotic surgical services are held to enforceable standards of care, transparency, and accountability.

4.6.3. Regulatory Actions against Non-Clinical Stakeholders

Robotic surgical systems, including their mechanical instrumentation and embedded software, are regulated as medical devices in India. The Central Drugs Standard Control Organisation (CDSCO) functions as the national regulatory authority, operating under the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017. These laws govern not only manufacturers, but also software developers, importers, and distributors, who form the non-clinical chain in robotic surgical interventions.[238]

Classification and Compliance Obligations

Robotic surgical systems fall within the scope of the term “medical device” as defined under Rule 3(zb) of the Medical Devices Rules, 2017, which includes instruments used for diagnosis, treatment, or mitigation of disease.[239] Most robotic systems are classified under Class C or D, based on risk levels associated with invasive procedures, as per Rule 4(iii)–(iv).[240]

Manufacturers and importers of such systems are required to obtain a central licence from the Drugs Controller General of India (DCGI) under Rules 20 to 25.[241] Post-licensing, they must maintain:

[237] Kerala Clinical Establishments (Registration and Regulation) Rules, 2018, rr. 12–17.
[238] Drugs and Cosmetics Act, 1940, Preamble (India).
[239] Medical Devices Rules, 2017, r. 3(zb), G.S.R. 78(E), Gazette of India, Jan. 31, 2017.
[240] Medical Devices Rules, 2017, r. 4(iii)–(iv)., G.S.R. 78(E), Gazette of India, Jan. 31, 2017.
[241] Medical Devices Rules, 2017, rr. 20–25., G.S.R. 78(E), Gazette of India, Jan. 31, 2017.

- A Device Master File with safety, performance, and design particulars;[242]
- Compliance with Good Manufacturing Practices (GMP) and quality standards under Rule 6(2);
- Post-market surveillance and adverse event reporting under Rule 26.

Software Developers and Embedded Systems

Software developers are also regulated under this framework, as Rule 3(za) explicitly includes software and firmware within the definition of a device's "component". Thus, negligence in algorithm design, absence of update mechanisms, or lack of validation protocols may attract scrutiny. These developers, although not direct licence-holders, are tied to regulatory submissions through the Device Master File and Plant Master File required during registration.

Inspection and Enforcement Mechanisms

The CDSCO, through appointed Medical Device Officers, is empowered under Section 22 of the Drugs and Cosmetics Act, 1940 to:

- Inspect manufacturing or distribution premises,
- Seize defective or non-compliant products under Section 22(c) of the Act,
- Issue prohibition or suspension orders under Rules 74–75 through Form MD-34,
- Order corrective actions such as recall or withdrawal under Rule 76(1).[243]

These actions may be taken suo motu or based on adverse event reports filed by hospitals, healthcare professionals, or patients.

Consequences of Non-Compliance

The consequences of regulatory failure are both procedural and operational. These include:

- Suspension or cancellation of manufacturing/import licence under Rule 29;

[242] Medical Devices Rules, 2017, r. 19(2), Sch. VI (Device Master File contents), G.S.R. 78(E), Gazette of India, Jan. 31, 2017.
[243] Drugs and Cosmetics Act, 1940, § 22(c); Medical Devices Rules, 2017, rr. 29, 74–76, Form MD-34.

- Seizure and prohibition of stock under Section 22(c) of the Act;
- Product recalls and public alerts issued through CDSCO channels under Rule 76(2);
- Blacklisting from future CDSCO approvals, typically as an administrative penalty for repeated or grievous breaches.[244]

Enforcement Challenges and Current Trends

Despite this framework, direct regulatory action against software developers or distributors remains rare in practice. Enforcement is primarily directed at manufacturers, who are accountable for overall system conformity. However, as software components are traceable through mandatory documentation, developers may face indirect consequences through licence suspension or recall actions affecting the associated system.

In summary, robotic surgical systems are subject to layered regulatory oversight. While manufacturers carry the principal burden, programmers and supply chain actors are obligated to ensure that every component—mechanical or digital—complies with prescribed safety, performance, and surveillance standards.

4.7. Conclusion

The complexities of robotic surgery demand a reimagined framework for legal accountability—one that recognises both the traditional norms of medical liability and the evolving realities introduced by algorithm-driven systems. This chapter has established that, under the current Indian legal framework, artificial intelligence systems do not possess legal personhood. Consequently, all liability—civil, criminal, or regulatory—must be attributed to the human and institutional stakeholders who develop, deploy, or operate these robotic surgical systems.

By categorising liability across civil, criminal, and regulatory domains, the chapter has mapped how different actors—surgeons, hospitals, programmers, manufacturers, and supply chain participants—may be held accountable when harm results from robotic surgery. Surgeons remain bound by the standard of care, with courts distinguishing between permissible errors of judgment and actionable negligence. Hospitals are

[244] Id.

responsible not only for the conduct of their personnel but also for maintaining infrastructure and upholding systemic standards of service. Programmers and manufacturers, though non-clinical, are not immune to liability, especially where design flaws or inadequate testing lead to patient harm. Even regulatory frameworks, ranging from the Medical Council to the CDSCO, impose distinct obligations and sanctions on these actors.

The chapter also highlights the significant gaps in existing legal and regulatory mechanisms—especially regarding minimum training, credentialing, and software compliance. While global and domestic consensus documents advocate high standards, enforceability remains weak in the absence of binding statutory mandates. The critical insight is that legal frameworks must evolve to keep pace with the technological frontier of medicine. In the context of robotic surgery, this includes formulating dedicated legal provisions for training requirements, software certification, institutional responsibilities, and data protection safeguards.

Ultimately, a future-ready liability framework must not only assign blame after harm occurs but must also function as a preventive mechanism that safeguards patients, supports professionals, and maintains trust in technology-enhanced care. Robotic surgery offers immense promise—but only when backed by a legal ecosystem capable of ensuring transparency, accountability, and justice.

Chapter 5

Empirical Perspectives

5.1. Introduction

This chapter presents the empirical component of the study, undertaken to supplement the doctrinal and normative analysis with grounded insights from the field. While legal texts, ethical principles, and regulatory frameworks provide a structural understanding, empirical inquiry enables observation of how these frameworks are experienced and interpreted in practice. Given that surgeons are the primary human actors in robotic surgical procedures, their experiences, opinions, and operational challenges form a crucial layer of evidence. Through this study, the actual state of robotic surgery as practised in Kerala is explored, providing valuable context on training practices, consent procedures, system usage, and professional observations. Such real-world insights help assess how ethical and legal principles translate into practice and highlight implementation-level implications that might otherwise remain unexamined in a purely doctrinal study.

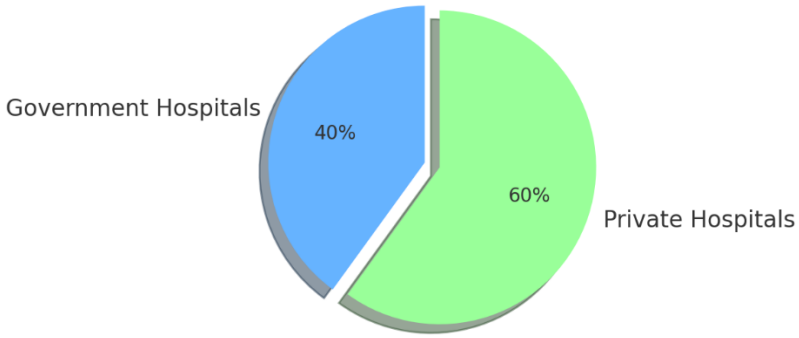
To gain practical insights into the ethical and legal dimensions of robotic surgery, interviews were conducted with five practising surgeons from across Kerala who are currently engaged in robotic-assisted surgical procedures. Among them, two represented government institutions—the Regional Cancer Center (RCC) and Malabar Cancer Center (MCC)—while the remaining three were affiliated with reputed private hospitals. A semi-structured questionnaire was used to explore key areas such as the surgeons' training and experience in robotic surgery, comparative preferences between conventional and robotic methods from both the surgeon's and the patient's perspective, and the availability of robotic systems in public healthcare settings. The interviews also probed into whether there has been a shift in the consent-taking process due to the introduction of robotic technology, the specific robotic platforms in use, the potential for telesurgery in current clinical environments, and the availability of intraoperative video recording features for post-operative verification. These empirical inputs enrich the normative analysis by offering real-world reflections from professionals directly involved in robotic surgical practice.

5.2. Analysis of Interview Responses

The following section presents an analysis of the responses obtained through semi-structured interviews conducted with surgeons actively performing robotic surgeries in various institutions across Kerala. The data collected was thematically organised to reflect patterns in surgical practice, training experiences, consent procedures, and broader observations on the integration of robotic systems in clinical settings. Each thematic category is based on direct practitioner insights and aims to highlight the current state of robotic surgery as experienced on the ground.

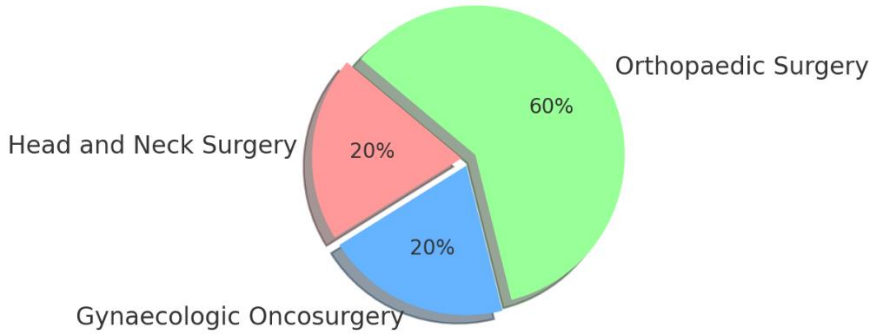
5.2.1. Institutional Background of Respondents

Among the five surgeons interviewed for this study, two were affiliated with government hospitals, while three were practising in private sector institutions. This institutional variation is relevant in understanding differences in access, infrastructure, training, and regulatory implementation across hospital types in Kerala.



5.2.2. Specialty-Wise Distribution of Respondents

The surgeons interviewed for this empirical study represented three distinct surgical specialisations. One respondent was a head and neck surgeon, one was a gynaecologic oncosurgeon, and three were orthopaedic surgeons. This distribution indicates a significant representation from the orthopaedic field, reflecting the increasing adoption of robotic systems in joint and spine procedures. The inclusion of respondents from oncological and head and neck surgical domains further illustrates the expanding applicability of robotic surgery across diverse clinical specialities in Kerala.



5.2.3. Surgical Robots in Practice

All five surgeons interviewed reported the use of da Vinci robotic surgical systems in their respective institutions. Although the specific models varied depending on institutional capacity and procurement timelines, the da Vinci platform was universally identified as the operative system of choice. This reflects the predominance of Intuitive Surgical's da Vinci systems in both government and private sector hospitals in Kerala, mirroring global trends in robotic-assisted surgery. The choice of system was largely influenced by institutional investment, procedural versatility, and familiarity developed through formal training. The responses also indicate that despite model variations, the core functionalities—such as high-definition 3D visualization, articulated instrument control, and ergonomic surgeon consoles—were consistent across all installations.

5.2.4. Special Training for Robotic Surgery

All five surgeons reported having undergone specialised training programmes before independently performing robotic-assisted surgeries. These training modules were conducted by the manufacturers of the da Vinci robotic surgical systems and followed a structured, multi-phase approach designed to ensure procedural safety and surgical competence. The training began with simulation-based exercises, progressing through hands-on practice using manikins, and subsequently included live animal (porcine) models. Once foundational proficiency was achieved, the surgeons participated in procedures by assisting in human surgeries, followed by performing surgeries under expert supervision. Only upon completion of these sequential stages were they allowed to operate independently.

The respondents uniformly noted that the learning curve in robotic surgery is relatively shorter when compared to traditional laparoscopic surgery. This was attributed to the

intuitive console controls, which allow for more natural instrument manipulation and ergonomic operation. Most surgeons felt confident to operate independently after completing at least five supervised robotic procedures, by which point the core competencies in system handling, tissue manipulation, and intraoperative decision-making were effectively developed. On average, this structured training process was completed within a period of approximately one month, demonstrating both the efficiency and intensity of the learning pathway required for robotic surgical competence.

5.2.5. Comparative Preferences: Robotic vs. Conventional Surgery

Despite being trained in and routinely performing robotic surgeries, the respondent surgeons unanimously emphasized that robotic surgery is not preferred indiscriminately for all procedures within their respective specialties. Their clinical approach remains grounded in evidence-based indications, and robotic surgery is chosen only where it offers a demonstrable advantage in terms of surgical precision, patient outcomes, or recovery time. For instance, in gynecologic oncological surgery, robotic systems are commonly used for endometrial carcinoma surgeries, where minimally invasive precision is beneficial. However, in cases of advanced ovarian carcinoma, open surgical methods continue to be preferred due to the extensive nature of the required dissection and lack of clear evidence supporting robotic superiority in such cases.

Interestingly, patient preferences also influence the selection of surgical modality. Surgeons reported that some patients, particularly those from urban centres such as Kochi, express a clear preference for robotic surgery. This preference is often attributed to their desire to access the latest medical technologies or as a mark of affluence. At the same time, there are patients who decline robotic surgery even when clinically advisable, primarily due to financial constraints, as robotic procedures are significantly costlier than conventional open or endoscopic surgeries. This divergence between clinical recommendation and patient choice underscores the complex interplay between medical judgment, technological access, and socioeconomic considerations in the adoption of robotic surgical practices.

5.2.6. Consent Process in Robotic Surgery

When asked about the consent-taking process specific to robotic surgery, all five surgeons indicated that there is no distinct or separate protocol followed in their

institutions for obtaining consent for robotic procedures. Instead, the existing consent forms and procedures used for endoscopic surgeries are generally adapted by substituting the term 'endoscopic' with 'robotic'. This approach, though administratively convenient, raises important ethical and legal questions, particularly given the technological complexity and distinct risk profiles associated with robotic-assisted surgeries. The respondents acknowledged that while basic procedural risks are explained, specific details related to the robotic system, its functioning, and its limitations are not always elaborated upon unless the patient expressly inquires. This uniformity in consent practices across robotic and endoscopic procedures suggests a gap in disclosure standards, which may undermine the patient's ability to make fully informed decisions tailored to the unique aspects of robotic surgical intervention.

5.2.7. Availability of Robotic Surgery in Government Hospitals

Among the five surgeons interviewed, only two were from government institutions—Malabar Cancer Center (MCC) and Regional Cancer Center (RCC)—which currently represent the only two government-run hospitals in Kerala equipped with robotic surgical systems. At present, government medical colleges across the state do not have such systems, although future expansion plans are underway, and robotic platforms are expected to be installed in the near future. In contrast, corporate hospitals in major cities and large towns in Kerala have already adopted robotic surgery across multiple specialties, driven by institutional capacity, private investment, and patient demand.

Despite this disparity in distribution, the presence of robotic systems in RCC and MCC serves as a significant milestone in ensuring equitable access to advanced surgical technology. These institutions cater to a large number of socioeconomically disadvantaged patients, thereby extending the benefits of robotic surgery to segments of the population who may otherwise be excluded due to financial constraints. While the overall public sector availability remains limited, these two centers demonstrate that robotic surgery in government settings is not only feasible but also essential for inclusive healthcare delivery.

5.2.8. Robotic Surgery in Postgraduate Surgical Training

At present, government medical colleges in Kerala have not integrated robotic surgical systems into their clinical or academic infrastructure. However, it is expected that these institutions will adopt robotic platforms in the near future as part of a broader effort to

modernize surgical education and align with national and international advancements. In contrast, certain other institutions—including the Regional Cancer Center (RCC), which conducts superspecialty (MCh) programs, and private teaching hospitals equipped with robotic systems—are already incorporating robotic surgery into their training modules. As a result, a divergence has emerged wherein two categories of surgical specialists are graduating: those who have had exposure to robotic systems during their training, and those who have not.

Nevertheless, this disparity is not insurmountable. The interviewed surgeons emphasized that specialized training in robotic surgery can be acquired post-residency through structured programs like those they personally completed. These short-term, stepwise training modules enable specialists who were not exposed to robotic platforms during formal education to attain the necessary competence to perform robotic surgeries independently. In this evolving landscape, supplementary hands-on training serves as a vital bridge, allowing equitable access to robotic surgical expertise irrespective of the institution of origin.

5.2.9. Video Recording in Robotic Surgery

One notable feature of robotic surgical systems is the automatic video recording of the entire surgical procedure. All interviewed surgeons confirmed that their robotic platforms enable high-quality intraoperative video capture, providing a continuous visual record from the surgeon's console. However, it was also pointed out that this feature is not unique to robotic surgery, as laparoscopic systems have long supported video documentation of operative procedures.

The surgeons noted that the video recordings serve multiple important functions, particularly in academic discussions, surgical audits, performance review, and skill improvement. They are also valuable for medico-legal purposes, offering an objective record that can support verification or accountability in case of post-operative complications or disputes. However, a practical limitation expressed by the surgeons is the length and volume of these recordings, which typically run for several hours—matching the duration of the surgery. This sheer size often poses challenges for storage, indexing, and retrieval, especially in high-volume centers. Despite these limitations, the availability of video documentation is seen as a progressive step toward transparency, education, and continuous improvement in surgical practice.

5.3. Limitations of the Study

While the empirical component of this study offers valuable insights into the practical dimensions of robotic surgery in Kerala, it is subject to certain limitations. First, the study focused exclusively on interviewing surgeons actively engaged in robotic surgical practice. Other key stakeholders—such as patients, hospital administrators, biomedical engineers, and regulatory officials—were not included, and no institutional records or case data were independently examined. This poses a possibility of respondent bias, as the perspectives gathered may reflect subjective experiences rather than a comprehensive institutional or systemic view. Secondly, the sample size was limited to five surgeons, which restricts the ability to generalise the findings to represent the full scope of robotic surgery practice across the state. Although the study aimed for diversity in institutional and disciplinary representation, the limited number of participants inevitably narrows the range of perspectives captured.

5.4 Conclusion

This chapter aimed to supplement the doctrinal and regulatory analysis by incorporating empirical insights from surgeons currently practising robotic surgery in Kerala. Based on semi-structured interviews with five surgeons across both government and private hospitals, the study captured practical observations relating to training, system usage, informed consent, and institutional variations. These responses offer a clearer picture of how robotic surgery is being implemented on the ground and how key ethical and procedural concerns are handled in actual clinical settings.

The findings from this empirical inquiry align with several of the concerns identified through the doctrinal study. For example, the absence of standardised consent procedures and variation in training practices support the previously discussed concerns regarding autonomy, safety, and professional accountability. Similarly, the predominance of robotic systems in the private sector affirms concerns about unequal access to advanced surgical care, engaging the ethical principle of justice. Thus, the empirical observations not only reinforce but also contextualise the theoretical issues discussed in the earlier chapters.

Despite its limitations in scope and sample size, this empirical component adds a valuable dimension to the study by providing practitioner perspectives. These findings help in assessing how far the existing ethical and legal principles are observed in

practice, and they form the basis for the concluding chapter, which will consolidate the outcomes of this research and propose concrete recommendations for reform.

Chapter 6

Conclusion and Suggestions

6.1. Introduction

This study on the ethical and legal implications of robotic surgery has undertaken a comprehensive analysis of various dimensions of this emerging surgical modality. It examined the historical development and technological evolution of robotic surgery, the ethical landscape governing its practice, and the implications for patient rights in the context of advanced machine-assisted interventions. The study also explored the framework for fixing legal liability in cases arising from robotic procedures and assessed the applicability of existing legal principles to such technologically mediated contexts. Through this multidimensional inquiry, the research critically evaluated the adequacy of India's current ethical and legal framework in addressing the novel issues posed by robotic surgery and identified the need for specific improvements and reforms in law and policy.

6.2. Conclusion

Chapter 1 laid the foundation for this study by tracing the technological evolution of surgical practice and situating robotic surgery within that continuum. It articulated the central concern of the dissertation—whether the current legal and ethical framework in India is adequate to address the complexities introduced by robotic-assisted surgeries. The chapter defined the scope of the research, framed the core objectives and research questions, and stated the hypothesis that existing regulations are insufficient to meet the challenges posed by robotic systems in clinical settings. It further outlined the research methodology, which combined doctrinal and empirical approaches, and presented a structured review of Indian and international literature on the subject. Finally, the chapter provided an overview of the dissertation's structure, setting the stage for a systematic analysis of the history, ethical concerns, stakeholder responsibilities, liability frameworks, and practical insights drawn from the field.

Chapter 2 analysed the first objective of the study, namely, to understand the history and evolution of robotic surgery. The chapter situated robotic surgery within the broader trajectory of surgical advancements, beginning from traditional open surgeries and progressing through laparoscopic techniques to the emergence of robotic-assisted

interventions. It detailed the progression from early robotic systems like the preprogrammed PUMA 200 to master-slave models such as AESOP and ZEUS, culminating in the development of the da Vinci system, which brought refined precision and limited AI integration into mainstream surgical practice. The chapter also noted the relatively recent adoption of robotic systems in India, highlighting the growing prevalence in both public and private healthcare sectors. The study observed that the rapidly evolving technological developments in surgery can outpace the corresponding legal and regulatory frameworks. The chapter concluded that while robotic surgery marks a significant innovation in surgical science, its rapid growth presents pressing challenges that necessitate urgent legal and policy attention.

Chapter 3 partly addressed the second objective of the study, which was to analyse the extent of responsibilities of stakeholders vis-à-vis the rights of patients. The chapter began by tracing the evolution and recognition of patient rights both internationally and within the Indian legal framework. It examined three major international instruments and several Indian statutes—including the Mental Healthcare Act, HIV Act, and NHRC's Charter of Patient Rights—to show how patient rights are formally codified. These were then analysed in the specific context of robotic surgery, identifying how technological complexities and procedural lapses can lead to infringement of rights such as informed consent, confidentiality, access to care, and dignity. The chapter further explored the ethical implications of these deficiencies through the lens of the four cardinal principles of medical ethics—autonomy, beneficence, non-maleficence, and justice. These principles were examined both in their classical form and as incorporated into Indian regulatory instruments like the IMC Regulations, 2002 and the NMC-RMP Regulations, 2023. The analysis established that robotic surgical environments require heightened ethical vigilance to ensure patient-centred care. Finally, the chapter identified key deficiencies—such as lack of standardised informed consent, inadequate disclosure, system malfunction, and insufficient respect for patient dignity—as raising overlapping ethical and legal implications. These emerging challenges necessitate closer examination of liability attribution and regulatory adequacy, which forms the subject of the next chapter.

Chapter 4 addressed the remaining portion of the second objective of the study, namely, to analyse the extent of responsibilities of stakeholders vis-à-vis the rights of the patients in the context of robotic surgery. The chapter began by examining the

jurisprudential question of whether artificial intelligence systems integrated into robotic surgery could be granted legal personhood. It concluded that, under Indian law and comparative jurisdictions like the EU and France, AI does not qualify for legal personality, reaffirming a human-centric liability model. Building on this, the chapter developed a structured analysis of liability distributed across key human stakeholders—surgeons, hospitals, programmers, manufacturers, and supply chain actors—across three distinct domains: civil liability, criminal liability, and regulatory sanctions. Through doctrinal interpretation and empirical insights from robotic surgeons in Kerala, the chapter explored how liability is currently assigned under Indian statutes including the Consumer Protection Act, the Information Technology Act, the Digital Personal Data Protection Act, and sectoral regulatory frameworks like the Medical Device Rules, 2017. The chapter also highlighted emerging challenges in apportioning liability where multiple actors jointly contribute to adverse outcomes. Particular emphasis was placed on the absence of statutory training and credentialing requirements, which not only impacts the standard of care but also weakens the legal basis for accountability. The analysis concluded that India's existing laws provide partial coverage but lack comprehensive and technology-specific provisions, thereby necessitating robust statutory and institutional reform to ensure legal clarity and patient protection in robotic surgery.

Chapter 5 added an empirical dimension to the study by capturing practitioner insights through semi-structured interviews with five surgeons actively engaged in robotic surgery across Kerala. These respondents, drawn from both government and private institutions and representing diverse surgical specialisations, offered first-hand accounts of training, consent practices, system use, and the operational challenges faced in robotic-assisted procedures. The interviews confirmed that while all surgeons had undergone structured multi-phase training programmes, consent-taking protocols remained underdeveloped and largely mirrored existing endoscopic templates. The study also highlighted disparities in access to robotic systems between public and private sectors, the practical utility of video recording features, and the lack of readiness for full-scale telesurgery in India. Importantly, it revealed that patients' socio-economic status significantly influences access and choice of surgical modality, raising concerns about justice and equity in healthcare delivery. The empirical findings served to reinforce and contextualise the doctrinal concerns raised in earlier chapters, particularly

with respect to informed consent, training standards, and distributive justice. While limited in scale, the empirical component confirmed that key ethical and legal principles—though present in theory—often remain inconsistently implemented in practice. These real-world observations thus provide essential grounding for the final chapter, which consolidates the conclusions of the study and offers actionable suggestions for reform.

The central hypothesis of this dissertation was that the current regulatory frameworks are insufficient to address the complexities introduced by advancements in robotic surgeries. This hypothesis has been affirmed through both doctrinal and empirical analysis. Chapter 2 demonstrated that the pace of technological evolution in surgical robotics has significantly outstripped the development of corresponding legal and regulatory mechanisms in India. Chapter 3 established that while ethical principles and patient rights are well-articulated in existing charters and codes, they require substantial reinterpretation and reinforcement in the context of robotic surgery, especially regarding informed consent, disclosure, and patient autonomy. Chapter 4 further confirmed that the allocation of legal responsibility among multiple stakeholders—including surgeons, hospitals, manufacturers, and programmers—is poorly defined under current laws, and that statutory training, credentialing, and data protection obligations remain fragmented. The empirical insights gathered from robotic surgeons also reinforced the practical deficiencies in legal oversight and standardisation. Taken together, the study conclusively establishes that India's existing medico-legal and regulatory frameworks are indeed inadequate to govern the complex, multi-actor, and technology-intensive domain of robotic surgery, thereby validating the hypothesis.

6.3. Suggestions

i. **Introduce a Dedicated Statutory Framework for Robotic Surgery:** A comprehensive law exclusively regulating robotic surgery should be enacted at the national level. This legislation may be modelled on the structure of the Clinical Establishments Act but tailored to address the specific ethical and legal issues posed by advanced robotic systems. It should include definitions of robotic surgical platforms, stakeholder responsibilities, device classification, data protocols, and patient rights in technology-mediated interventions.

ii. **Formulate Robotic Surgery Guidelines through National Medical Commission:** The National Medical Commission should issue binding guidelines under its regulatory authority for robotic surgery. These should detail eligibility criteria for performing robotic procedures, structured training modules, minimum case volume requirements, and periodic credentialing mandates. Such regulation will ensure uniform standards of competence and patient safety.

iii. Model Structure for Minimum Training Requirements in Robotic Surgery

Preclinical Phase: Knowledge Acquisition: This phase should begin with structured didactic instruction, delivered through online or in-person modules, covering the fundamentals of robotic surgical systems, instrumentation, ergonomics, console operations, patient selection criteria, procedural indications, and emergency protocols. Crucially, this phase should also address legal and ethical dimensions, such as informed consent in technologically mediated environments and compliance with data protection laws. Following this, the candidate must engage in simulation-based training. This includes dry lab exercises with inanimate models to develop hand–eye coordination and robotic dexterity, followed by virtual reality simulations to rehearse procedural steps and decision-making scenarios. Wet lab exposure using cadaveric or animal models may be optionally incorporated for realistic anatomical practice. Skill development at this stage should be assessed using validated tools such as the Robotic Objective Structured Assessment of Technical Skills.

Clinical Phase - Modular Training: In the clinical training phase, hands-on experience is gradually integrated through a modular structure. The candidate must first participate as a bedside assistant in at least 10 robotic surgical procedures, gaining familiarity with workflow, robotic docking, and intraoperative coordination. Thereafter, the candidate must progress to console operation, completing a minimum of 20 supervised robotic surgeries across varied clinical contexts. This case volume requirement reflects current global training protocols—including those of Intuitive Surgical—and ensures adequate exposure to different procedure types and complexities. Alternatively, the requirement may be fulfilled through a structured six-month training period in a recognised high-volume centre, subject to oversight and certification by an authorised credentialing body. Detailed case logs must be maintained to

document the level of participation and intraoperative responsibilities. Final assessment must confirm technical competence, patient safety awareness, and readiness for independent practice.

Non-Technical Skills Development: In addition to surgical proficiency, candidates must undergo training in non-technical domains. Participation in multidisciplinary team simulations is essential to build communication, leadership, and situational awareness skills during robotic procedures. Equally important is structured exposure to the ethical and legal dimensions of robotic surgery, including medico-legal risks, digital data handling, and patient rights. These topics may be covered through dedicated workshops or integrated modules within the clinical training period.

Credentialing and Maintenance: Upon successful completion of the preclinical, clinical, and non-technical components, the candidate shall be granted a credentialing certificate by the appropriate authority. This credential shall be valid for five years, subject to periodic audit and compliance verification. To maintain the credential, the surgeon must either continue performing a minimum number of robotic surgeries per year or undergo periodic revalidation through continuing education and skill demonstration. Surgeons who remain inactive in robotic procedures for a defined period (e.g., one year) must undergo refresher training prior to re-engagement. This dynamic, outcome-oriented system will ensure that robotic surgery in India is performed only by clinicians who are both technically competent and ethically accountable.

iv. **Incorporate Robotic-Specific Informed Consent Protocols:** Consent forms and preoperative counselling must explicitly address the unique aspects of robotic surgery. This includes disclosing the level of machine involvement, absence of tactile feedback, potential machine malfunction, and whether AI components are decision-supportive or autonomous. Model consent templates may be issued by medical regulatory authorities and made mandatory for institutional compliance.

v. **Mandate Data Protection Compliance under DPDP and IT Acts:** Hospitals and software vendors involved in robotic surgery must implement robust technical safeguards and data handling protocols in compliance with the Digital Personal Data Protection Act, 2023 and the Information Technology Act, 2000.

Real-time data logging, encryption of sensitive patient information, and patient access to their procedural data should be made standard practices.

vi. **Create a National Registry of Robotic Surgical Procedures:** A centralised registry documenting all robotic surgeries conducted across India should be maintained under the supervision of the Ministry of Health and Family Welfare. This will assist in tracking safety outcomes, identifying trends in malpractice, and promoting quality assurance.

vii. **Develop Liability Apportionment Guidelines:** The legislature or judiciary may issue interpretive guidelines or rules to address the apportionment of liability in robotic surgery involving multiple actors. This should cover scenarios where surgeons, hospitals, manufacturers, or programmers jointly contribute to adverse outcomes, including technical malfunction or protocol deviation.

viii. **Mandate Ethical Certification for Programmers and Non-Clinical Actors:** Developers and technicians involved in the creation or maintenance of robotic surgery software and systems should be required to complete basic certification in medical ethics, patient rights, and data protection laws. This measure would improve awareness of healthcare sensitivities among non-clinical stakeholders.

ix. **Strengthen Institutional Liability of Hospitals:** Hospitals must be held directly accountable for equipment maintenance, surgeon accreditation, consent protocols, and compliance with robotic surgery regulations. Institutional liability should be codified to ensure that hospitals are not shielded behind the individual liability of surgeons or device suppliers.

x. **Incorporate Robotic Surgery into Medical Education Curriculum:** A long-term measure would be to integrate basic knowledge of robotic surgery, medical technology law, and ethical frameworks into the undergraduate and postgraduate medical curriculum. This will prepare future healthcare professionals for the evolving demands of technology-intensive practice environments.

Robotic surgery epitomises the convergence of advanced engineering and clinical practice, promising unprecedented surgical precision while presenting novel ethical and legal challenges. By adopting the foregoing suggestions—ranging from a dedicated statutory framework to mandatory ethical certification and curricular

reform—India can move decisively toward a regulatory environment that both safeguards patient rights and fosters responsible innovation. These measures will complete the bridge between cutting-edge technology and a robust, patient-centred legal-ethical architecture, thereby fulfilling the ultimate objectives of this study.

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APPENDIX

Questionnaire

1. What was training process you underwent before doing robotic surgery independently?
2. How many supervised procedures did you perform before you felt confident to conduct robotic surgery independently?
3. Which robotic surgical system do you currently use in your practice?
4. How does the process of obtaining informed consent for robotic surgery differ from that of conventional surgical procedures?
5. What are the occasions where you still prefer conventional surgery over robotic surgery?
6. Have you had patients preferring conventional surgery where robotic surgery is clearly advantageous?
7. How much exposure to robotic surgery do resident doctors get during their MS/MCh course?
8. How much is the availability of robotic surgery in Government Hospitals in Kerala?
9. Is the video recording of the procedure retained in the robotic system after surgery for later verification?

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