Central University of Kashmir Law Review
Vol. 5 (2025)
eISSN: 2583-6935
pp. 93-107

Emergence of Robot-Assisted Surgery and the Evolving Legal Landscape in India

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Abstract

The emergence of robot-assisted surgery has brought about significant advancements in surgical techniques and improved patient outcomes. This technology, however, also raises several legal, ethical, and public policy concerns that must be addressed in order to ensure its responsible and equitable development and use in India. This article provides an overview of the current state of robot-assisted surgery in India, the legal framework governing medical devices, and the various legal and ethical issues surrounding the technology, including informed consent, liability, intellectual property rights, and accessibility. The legal framework governing medical devices in India primarily consists of the Medical Device Rules, 2017, and the Drugs and Cosmetics Act, 1940. These regulations, although providing a foundation for the regulation of robotic surgical systems, must be updated and expanded to accommodate the unique challenges posed by this technology. Key legal issues include obtaining informed consent from patients, determining liability in cases of medical malpractice, and protecting intellectual property rights. Ethical considerations and public policy concerns include the accessibility and affordability of robot-assisted surgery, training and certification of surgeons, the impact on traditional surgical practices, and balancing patient safety with medical innovation. To address these concerns, this article proposes a series of legal reforms and recommendations. By examining international perspectives and best practices from the United States and the European Union, India can draw valuable insights to inform the development of its legal framework for robot-assisted surgery.

Keywords: *Robot-assisted surgery, Technology, Ethics, Liability, Medical Devices*

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https://doi.org/10.66498/CUKLR.5.2025.93-107

1. Introduction

In recent years, the rapid advancements in technology have revolutionized various sectors, including the medical field. One such notable development is the emergence of robot-assisted surgery, which has brought a paradigm shift in the way surgical procedures are performed. Robot-assisted surgery involves the use of computer-controlled robots to assist surgeons in performing intricate surgical procedures with high precision, dexterity, and control. Robotic surgery assists doctors in performing complex operations and procedures with accuracy and precision. Robotic surgery also increases the flexibility and control of the procedures, which is difficult to achieve in traditional surgical procedures. Sometimes, this robotic surgery is coupled with conventional surgical procedures as per the convenience and requirements of the case. The Da Vinci Surgical System, introduced by Intuitive Surgical in 2000, is one of the most well-known robotic surgical systems that has gained widespread acceptance worldwide.[1]

Despite its increasing prominence in today's globe, artificial intelligence in India's healthcare industry is still in its infancy. The major force behind the development of new surgical technology at the moment is robotic surgical instruments. New disorders are continually being discovered in healthcare, and the therapeutic approach is gradually developing. However, it comes with dangers and terrible consequences that might perhaps cost more lives than they save. According to Article 21 of the Indian Constitution, the Supreme Court of India determined that protecting life is a basic right. Additionally, the government authorised the use of robotic equipment that are prone to malfunction and the use of these gadgets that were obtained illegally in surgical procedures. By failing to enact required rules to control robotic device accidents, the government has subtly infringed the patient's right to protection. In the modern world, people are so reliant on technology that it has permeated every aspect of their decision-making. Similar to how few surgeons rely on robotic tools that encourage major errors threatening patient lives.

[1] *Available at:* https://www.uchealth.com/services/robotic-surgery/patient-information/davinci-surgical-system/ (last visited on March 10,2023).

2. Development and Advancements in Robot-Assisted Surgery

The concept of robotic surgery dates back to the late 20th century, with the first robot-assisted surgical procedure performed in 1985 using the PUMA 560 robotic system. The field of robot-assisted surgery has since witnessed several advancements, including the development of the AESOP robotic system in 1994, the ZEUS Surgical System in 1998,[2] and the Da Vinci Surgical System in 2000. Surgeons can use robotic surgery to improve precision, reduce blood loss, and alleviate patient suffering.[3] Robotic surgery reduces the risk of tissue damage by allowing the surgeon to do the procedure from a distance and using reduced gripping forces made possible by tactile feedback.[4] Robots with AI capabilities can assist in minimizing surgeon variances that can impair patient recovery.

There are various robotic surgical systems available in the market, including:

- *Da Vinci Surgical System*: A multi-armed, teleoperated surgical system used for a wide range of surgical procedures, including urologic, gynecologic, and general surgeries.
- *Senhance Surgical System*: A laparoscopic surgical system that employs eye-tracking technology to control the movement of instruments.[5]
- *Mako Robotic-Arm Assisted Surgery*: A platform specifically designed for orthopedic procedures, such as joint replacement surgeries.[6]

Robot-assisted surgery offers numerous advantages over traditional surgical methods, such as:

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[2] *Available at*: https://thesurgicalclinics.com/history-of-robot-assisted-surgery/ (last visited on March 10,2023).

[3] K. Kakar , *AI trends that are disrupting healthcare industry*, *available at:* https://insights.daffodilsw.com/blog/4-ai-trends-that-are-disrupting-healthcare-industry (last visited on March 10,2023).

[4] CR Wottawa, B Genovese, BN Nowroozi, SD Hart, JW Bisley, WS Grundfest, EP Dutson, *"Evaluating tactile feedback in robotic surgery for potential clinical application using an animal model"* 30(8) Surgical Endoscopy 3198-3209 (2016).

[5] *Available at*: https://bowa-medical.co.uk/senhance-surgical-system/ (last visited on March 10,2023).

[6] *Available at:* https://www.docwirenews.com/future-of-medicine/top-5-robotic-surgery-systems/ (last visited on March 10,2023).

a) Enhanced precision and control: Robotic surgical systems provide surgeons with greater control and accuracy, reducing the risk of human error.
b) Minimally invasive procedures: Robot-assisted surgery allows for smaller incisions, resulting in less blood loss, reduced postoperative pain, and faster recovery times.
c) Improved visualization: The advanced imaging capabilities of robotic systems enable better visualization of the surgical site, leading to more precise decision-making and improved surgical outcomes.

The use of robotic surgery is quickly replacing traditional methods. These innovations, like many others in medicine and surgery, have seldom been used as a consequence of randomized prospective research.[7] There are now three major categories of surgical robotic systems. Master-slave, semi-active, and active systems. Active systems function independently (while still being controlled by the operational surgeon) and carry out predetermined objectives. Examples include the PROBOT and ROBODOC systems. With semi-active systems, surgeon input can supplement the robots' predetermined actions. The da Vinci and ZEUS platforms are precursors to formal master-slave systems, and these systems have no pre-programmed or autonomous components. They rely completely on surgical intervention. By transmitting the surgeon's hand movements to laparoscopic surgical instruments, these tools accurately recreate the surgeon's hand activity within the body.

The Indian medical landscape has evolved significantly over the past few decades, with an increasing number of hospitals and medical institutions adopting advanced surgical technologies to improve patient outcomes. Robot-assisted surgery is a relatively new phenomenon in India, with the first robotic surgical procedure performed in 2002. Since then, there has been a growing interest in and adoption of robotic surgical systems across the country.[8] The

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[7] Tim Lane, *"A short history of robotic surgery"* 100(6 sup) *Ann R Coll Surg Engl.* 5-7(2018), *available at:* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5956578/ (last visited on March 12,2023).

[8] *Available at:* https://www.healthcareradius.in/people/interviews/revolutionizing-robotic-surgery-in-india (last visited on March 12,2023).

surgical community's acceptance of robotic surgery has been unprecedented. This trend has been propelled in part by the quick pace of technological advancement and in part by the relative simplicity with which laparoscopic procedures and methods may be adapted to meet new needs. "Robot-assisted surgery" has seen increased adoption in India over the past two decades. The country now has over 70 robotic surgical systems across various hospitals, with the majority being the Da Vinci Surgical System. The increasing demand for minimally invasive surgical techniques, coupled with the availability of skilled surgeons, has led to a steady growth in the popularity of robot-assisted surgery in India.

3. Legal Framework Governing Medical Devices in India

The legal framework governing medical devices in India primarily consists of the "Medical Device Rules, 2017, and the Drugs and Cosmetics Act, 1940", along with various other rules and regulations.

(a) Medical Device Rules, 2017

The Medical Device Rules, 2017, provide the regulatory framework for medical devices in India. They were notified by the Central Government under the Drugs and Cosmetics Act, 1940, and came into effect on January 1, 2018.

Classification of medical devices: Under the Medical Device Rules, medical devices are classified into four categories based on their risk levels: Class A (low risk), Class B (low-moderate risk), Class C (moderate-high risk), and Class D (high risk).[9] Robotic surgical systems fall under Class C or Class D, depending on their intended use and associated risks.

Registration and licensing requirements: Manufacturers and importers of medical devices are required to obtain a license from the Central Licensing Authority (CLA) before they can market their products in India. The licensing process involves the submission of a comprehensive application, including details about the device, its intended use, and relevant clinical data.

[9] N. Radhadevi, V. Balamuralidhara, T. P. Kumar, V. Ravi, *"Regulatory guidelines for medical devices in India: An overview"* 6(1) *Asian Journal of Pharmaceutics* 10(2012).

(b) Drugs and Cosmetics Act, 1940

The Drugs and Cosmetics Act, 1940, is the primary legislation governing the manufacture, sale, and distribution of drugs and medical devices in India. The Act has been amended several times to incorporate provisions related to medical devices.

Amendments related to medical devices: The Drugs and Cosmetics (Amendment) Act, 2005, introduced the definition of "medical device" within the scope of the legislation. Subsequent amendments have brought about changes in the regulatory framework, leading to the formulation of the Medical Device Rules, 2017.

Responsibilities of Central Licensing Authority and State Licensing Authority: The CLA is responsible for granting licenses for the manufacture and import of medical devices in India, while the State Licensing Authority (SLA) oversees the sale and distribution of such devices within the state. Both authorities play a crucial role in ensuring the quality and safety of medical devices available in the Indian market.

(c) Clinical trials and regulations

Before a medical device can be marketed in India, it must undergo clinical trials to establish its safety and efficacy. The Indian Council of Medical Research (ICMR) and the Central Drugs Standard Control Organization (CDSCO) regulate clinical trials and their approval in India. Manufacturers of robotic surgical systems must adhere to these regulations and obtain necessary approvals before they can introduce their products to the Indian market.

4. Ethical Considerations, Legal Issues and Public Policy Concerns in Robot-Assisted Surgery

The introduction of robot-assisted surgery in India raises several legal issues, including informed consent, liability in case of malpractice, and intellectual property rights. As robot-assisted surgery continues to gain popularity in India, it raises several ethical and public policy concerns that must be addressed to ensure the responsible and equitable development and use of this technology.

(a) Informed consent

Informed consent is a fundamental principle in medical ethics and jurisprudence, ensuring that patients have the autonomy to make decisions about their medical treatment after being provided with all relevant information. Surgeons using robotic surgical systems must

disclose pertinent information to their patients, including the nature and purpose of the procedure, potential risks and benefits, and available alternatives. Patients must be given the opportunity to ask questions, understand the risks and benefits associated with robot-assisted surgery, and make informed decisions about their treatment.[10]

(b) Liability in case of malpractice

In the event of a mishap during a robot-assisted surgical procedure, determining liability can be a complex issue, given the involvement of multiple parties, including the surgeon, the hospital, and the manufacturer of the robotic surgical system. Hospitals can be held vicariously liable for the negligence of their employees, including surgeons. In the context of robot-assisted surgery, hospitals must ensure that the surgical team is adequately trained and skilled in using the robotic system and that all necessary safety precautions are in place. Surgeons may be held liable for medical negligence if they fail to exercise the required standard of care during a robot-assisted surgical procedure. Manufacturers of robotic surgical systems may also be held liable under product liability laws if defects in the design or functioning of the device lead to harm to the patient.

(c) Intellectual property rights

The development of robotic surgical systems involves significant investment in research and development, resulting in a range of intellectual property rights, including patents and trade secrets. Manufacturers of robotic surgical systems rely on patents and trade secrets to protect their innovations and maintain a competitive edge in the market. Hospitals and surgeons using these systems must be aware of the applicable intellectual property rights and ensure compliance with licensing agreements.

(d) Data privacy and protection

Robotic surgical systems often generate and store large amounts of data, including sensitive patient information. Ensuring the privacy and security of this data is crucial to maintaining patient trust and complying with data protection regulations, such as the Information

[10] Sean C. Wightman, Elizabeth A. David, Scott M. Atay, Anthony W. Kim, Peter Angelos, *"The ethics of robotic surgical systems is a conversation of informed consent" 5 Video-Assisted Thoracic Surgery* 24(2020).*Available at:* https://vats.amegroups.com/article/view/5469/html (last visited on March 12,2023).

Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, and the Personal Data Protection Act, 2023.

(e) Accessibility and affordability of robot-assisted surgery

One of the primary concerns surrounding robot-assisted surgery in India is the issue of accessibility and affordability. The high cost of robotic surgical systems and the associated expenses, such as maintenance and consumables, may result in increased treatment costs, potentially limiting access to the technology for economically disadvantaged patients.

(f) Training and certification of surgeons

The successful adoption of robot-assisted surgery in India depends on the availability of skilled and trained surgeons. There is a need for standardized training programs and certification mechanisms to ensure that surgeons have the necessary expertise to perform robotic surgical procedures safely and effectively.

(g) Impact on traditional surgical practices

The introduction of robot-assisted surgery may have implications for traditional surgical practices, with concerns that the technology could potentially replace human surgeons in the long run. It is essential to strike a balance between embracing technological advancements and preserving the skills and expertise of human surgeons.

(h) Balancing patient safety and medical innovation

While robot-assisted surgery offers numerous benefits in terms of improved surgical outcomes and patient safety, it also raises concerns about potential complications and unforeseen risks associated with the technology. Policymakers must balance the need to promote medical innovation with the responsibility to protect patient safety and well-being.

Possible future advances in surgical technique brought about by robotic surgery. The delivery of standard careful care and innovative therapy in robotic surgery, however, requires specialized training and skills in addition to high quality assessment. Litigation involving robotic surgery may be difficult to resolve, despite the fact that the legal basis for professional obligation is unchanged. The producer of the robotic technology, as well as the treating physician and healthcare facility, might be sued in the case of an unfavorable outcome. When it comes to ethical considerations in robotic surgery, patient safety, technological reliability, information availability, and

privacy are of the highest importance. Additionally, the expense of robotic surgery and the absence of such equipment in the majority of public institutions may prevent the majority from taking use of the advantages that the new technology offers. Surgical robots will significantly change surgical practice, but it also offers issues in the areas of law and ethics as well as in the fields of medicine and healthcare.[11]

5. Malfunction of the Robotic Device while Performing a Surgery

1391 injuries, 144 deaths, and 8061 instances of equipment failure were recorded by the US Food and Drug Administration. Additionally, the mechanical surgeon either spontaneously powered down mid-operation or made a mistake, according to reports from Rush University Medical Centre and the University of Illinois, resulting in two fatalities and fifty-two injuries. Overall, 10.5 percent of instances included faults such as electrical sparks that burnt patients, resulting in 193 injuries.[12]

As a developing nation, India has just lately begun to integrate technological innovation in healthcare. A failing artificial gadget finally cost an eleven-year-old victim his life in the case of *Kumar Mohammed Rafique V. Municipal Corporation*[13] of Greater Bombay, demonstrating how poorly controlled these advancements are. When transferred to the hospital, the man, identified as Mohamed Rafiq Haji Umar, was semi-conscious after falling off a bus. The victim was reportedly suffering from a disease known as a hematoma, and at the Bombay Hospital, a Ventriculoarterial Shunt was implanted to allow the movement of cerebrospinal fluid from the cerebral ventricular

[11] A. Mavroforou, E. Michalodimitrakis, C. Hatzitheo-Filou, & A. Giannoukas, *"Legal and ethical issues in robotic surgery" 29(1) International angiology: a journal of the International Union of Angiology* 75–79 (2010).

[12] Iain Thomson, Robot surgeons kill 144 patients, hurt 1,391, malfunction 8,061 times, *available at:* https://www.theregister.co.uk/2015/07/21/robot_surgery_kills_americans/ (last visited on March 12,2023).

[13] *Available at:* https://indiankanoon.org/doc/1154351/ (last visited on March 18, 2023).

system to the atrium of the heart.[14] The hospital reportedly had this shunt device fixed twice before, yet they still using it. Failure of this shunt led to hydrocephalus, which increased intracranial pressure and led to fatalities. By failing to stop a device that posed a probable danger of malfunctioning, the government indirectly violated Article 21, which guaranteed the protection of life. The lives of many innocent people might be lost if these medical robotic technologies used in surgery are not thoroughly evaluated. To evaluate the performance of artificial robotic devices, the government must enact stringent legislation. By enacting such legislation, hospitals will be able to frequently monitor robotic equipment.

Illegality in the Procurement of Artificial Intelligence- Medical devices are critical because their failure can result in patient harm. Improper regulation in the acquisition of medical equipment is the unavoidable cause of such robotic device failure. However, in India, the manufacturing, marketing, and distribution of these medical devices are protected and controlled by the Drug and Cosmetic Act of 1940 & Rules 1945.[15] Only fifteen devices are controlled by the government, while others might be imported from a corporation or an industry. The applicant brought the lawsuit, *Sanjay Shyamsundar Sharma vs State of Gujarat*[16], to challenge the illegalities and irregularities in the acquisition of the "Robotic Assistant Surgery Instrument" at Civil Hospital, Ahmedabad. Sanjay further asked the court to go through the process of changing the equipment in issue so that the general public might benefit from the modernized instrument for knee and hip replacement surgery. Mr. Majmudar alluded to several documents relevant to the matter and demonstrated that public funds totaling eleven crore rupees were spent on bidding for the instrument. Despite the procurement of such a pricey device, just three procedures were conducted during a six to seven-year span. As a result, the instrument was brought before the Additional Director of

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[14]Todd C Hankinson, *Ventriculoarterial Shunt Placement, available at*: https://emedicine.medscape.com/article/1895753-overview?form=fpf. (last visited on March 12, 2023).

[15] *Available at:* https://cdsa.thsti.in/medical-devices-regulations-faq/ (last visited on March 12,2023).

[16] *Available at:* https://www.casemine.com/judgement/in/5a9548f84a93260d852ce7c1 (last visited on March 14, 2023).

Medical Education and Research for examination. The instrument was discontinued since it did not correspond to any single brand of equipment. Many individuals may ignore these facts when they lose loved ones, assuming it was due to the severity of the patient's condition. This is one situation when such an incidence was brought to light. To promote greater safety, the government should require hospitals to notify patients not only about the technique of the operation but also about the legitimacy of the instruments used in the surgery.

Extreme Dependency on Robotic Surgery: In today's environment, people trust artificial intelligence more than they trust their own intelligence. While artificial intelligence has undoubtedly improved the efficiency and accuracy of diagnosis, it should not be used to replace the surgeon's discretion when doing surgery. Some scientists believe that artificial intelligence will augment physicians' roles.[17] Here is a case of severe reliance on robotic surgery that resulted in a loss of life. In the case *Prem Kishore vs. Union of India And Ors*[18], Urmila Devi underwent "Robotic Ureterolysis," a procedure done at Shri Ganga Ram Hospital to remove the ureter's fibroid. The patient's petitioner stated that during the patient's operation, the doctor accidentally damaged the external iliac artery. Rather than treating this promptly, the worried doctors allegedly applied hemoclips and sutures before continuing with the robotic surgery for a further three hours. It is alleged that the petitioner's wife experienced severe blood loss as a result of the afore-mentioned action of the involved doctors, which led to acute renal failure. Despite going into cardiac arrest twice, the patient survived. After a third cardiac arrest occurred after 30 minutes, she was subsequently pronounced dead. Due to the surgeon's excessive reliance on robotic surgery, he made a mistake by switching to open surgery later in the procedure, which resulted in severe blood loss and, ultimately, cardiac arrest. This example of medical carelessness may have been avoided by enacting rigorous rules that require physicians to undergo training and get licences

[17] Abhimanyu S Ahuja , *The impact of artificial intelligence in medicine on the future role of the physician*, PeerJ. Oct 4, 2019, available at: https://peerj.com/articles/7702/ (last visited on March 14,2023).

[18] *Available at*: https://indiankanoon.org/doc/82071084/ (last visited on March 14,2023).

before performing procedures, especially those involving robotic technology.[19]

6. International Perspectives and Best Practices

In order to develop a comprehensive legal framework for robot-assisted surgery in India, it is useful to examine international perspectives and best practices from other countries where this technology is more established.

(a) United States

The United States has been at the forefront of the development and adoption of robot-assisted surgery, with the Food and Drug Administration (FDA) playing a crucial role in regulating medical devices, including robotic surgical systems.

FDA regulatory framework: The FDA classifies medical devices into three classes based on their risk levels and imposes different regulatory requirements for each class. Robotic surgical systems generally fall under Class II or Class III, which require pre-market approval or clearance before they can be marketed in the United States.

Liability and malpractice: In the United States, medical malpractice claims involving robot-assisted surgery are primarily governed by state laws. These claims often involve allegations of negligence by the surgeon, the hospital, or the manufacturer of the robotic surgical system.[20] Successful claims may result in compensation for the patient, including damages for pain and suffering, medical expenses, and lost wages.

(b) European Union

The European Union (EU) has a well-established regulatory framework for medical devices, including robotic surgical systems. The Medical Devices Regulation (MDR), which came into force in May 2021, governs the safety and performance of medical devices in the EU.

Medical Devices Regulation: The MDR classifies medical devices into four risk-based classes, similar to the Indian Medical Device Rules. Robotic surgical systems usually fall under Class IIb or Class III, which

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[19] *Available at*: https://lawbhoomi.com/legal-system-and-implementation-of-artificial-intelligence-into-healthcare/ (last visited on March 14,2023).

[20] B. Sonny Bal, *"An introduction to medical malpractice in the United States"* 467(2) *Clinical Orthopaedics and Related Research* 339-347 (2009).

require a conformity assessment by a notified body before they can be placed on the EU market.[21]

Liability and malpractice: In the EU, medical malpractice claims involving robot-assisted surgery are subject to national laws of the member states. The EU's Product Liability Directive provides a framework for determining liability in cases of defective products, which can be applied to robotic surgical systems in the event of a malfunction or design defect.

By examining international perspectives and best practices, India can draw valuable insights and lessons to inform the development of its legal framework for robot-assisted surgery. Some key takeaways include:

- Risk-based classification of medical devices: Adopting a risk-based classification system for medical devices, as seen in the United States and the European Union, can help ensure that robotic surgical systems are subject to appropriate regulatory scrutiny and oversight.
- Clear liability rules and dispute resolution mechanisms: Establishing clear liability rules and specialized dispute resolution mechanisms for medical malpractice claims involving robot-assisted surgery can provide legal certainty for patients, surgeons, hospitals, and manufacturers.
- Harmonization with international standards: Aligning India's regulatory framework for robotic surgical systems with international standards can facilitate the global exchange of knowledge and technology, as well as promote the adoption of best practices in the field of robot-assisted surgery.

7. Conclusion and Recommendations

The emergence of robot-assisted surgery in India has brought about significant advancements in surgical techniques and improved patient outcomes. However, this technology also raises several legal and ethical issues, including informed consent, liability, intellectual property rights, and public policy concerns. Addressing these issues requires a dynamic legal framework that keeps pace with

[21] Ksenija Vasiljeva, Bernard H van Duren , Hemant Pandit , "Changing Device Regulations in the European Union: Impact on Research, Innovation and Clinical Practice" 54(2) *Indian Journal of Orthopaedics* 123-129(2020).

technological advancements and ensures the responsible and equitable development and use of robot-assisted surgery in India. The future of robot-assisted surgery in India appears promising, with increasing adoption of the technology and growing interest in its potential applications. As the country continues to invest in the development and implementation of robotic surgical systems, it is crucial to establish a robust legal framework that balances the need for medical innovation with patient safety, ethical considerations, and public policy concerns. A dynamic legal framework is essential for fostering innovation and ensuring the responsible and equitable development and use of robot-assisted surgery in India. By addressing the various legal and ethical issues surrounding this technology and adapting to the rapidly evolving medical landscape, India can continue to make strides in improving patient outcomes and advancing the field of surgery. The following measures are required to address concerns relating to robot assisted surgery:

(a) Development of a comprehensive legal framework for robot-assisted surgery

There is a need for a comprehensive legal framework that specifically addresses the unique aspects of robot-assisted surgery. This framework should cover various aspects such as licensing, training and certification of surgeons, patient rights, data privacy, and liability issues. The existing regulations under the Medical Device Rules, 2017, and the Drugs and Cosmetics Act, 1940, can serve as a foundation for this new framework, but they must be updated and expanded to accommodate the unique challenges posed by robotic surgical systems.

(b) Strengthening patient rights and informed consent

Patient rights, particularly in the context of informed consent, must be strengthened to ensure that patients have access to all relevant information about robot-assisted surgery and can make informed decisions about their treatment. This may include the development of standardized informed consent forms for robot-assisted surgical procedures, as well as increased emphasis on patient education and awareness about the risks and benefits of the technology.

(c) Establishing clear liability rules

Liability rules in the context of robot-assisted surgery must be clarified to provide legal certainty for patients, surgeons, hospitals, and manufacturers. This may involve the development of guidelines or

regulations that clearly define the respective roles and responsibilities of each party, as well as the establishment of a specialized dispute resolution mechanism to handle cases of medical negligence involving robotic surgical systems.

(d) Addressing ethical and public policy concerns

Policymakers must actively engage with ethical and public policy concerns surrounding robot-assisted surgery, including issues of accessibility, affordability, training, and the impact on traditional surgical practices. This may involve the development of policies and initiatives that promote the equitable distribution of robotic surgical systems, as well as increased investment in training and certification programs for surgeons.