



Informed Consent In Ai-Assisted Surgery: Rethinking Patient Autonomy And Liability In Robotic Healthcare

Ayesha Majid¹

Research Scholar, Department of Law,
Gurugram University

Submission date 12.04.2026 | Acceptance date: 25.04.2026 | Publication: 29.05.2026

ABSTRACT

The application of artificial intelligence (AI) in surgical practice, especially robotic-assisted surgery, is revolutionizing the field of contemporary healthcare by making it more precise, efficient, and clinically effective. Nonetheless, this technological development poses important legal and ethical issues concerning the doctrine of informed consent and the maintenance of autonomy in patients. Conventional theories of informed consent assume that informed consent is based on the disclosure of material risks, benefits, and options by a human surgeon. In AI-assisted surgery, the decision-making process is being mediated more by complex opaque algorithmic systems, further questioning the sufficiency of the current disclosure standards and put the current legal regime of informed consent to the test.

This paper attempts to examine the question of whether existing legal regulations on informed consent are adequate to consider the specific risks posed by AI-based surgical systems, such as algorithm error, data bias, and system malfunction. It addresses the concern around reasonable patient criterion and questions whether it should be modified to include the disclosures regarding the role, restrictions, and autonomy of AI systems in surgery. Furthermore, the paper examines the allocation of the liability between surgeons, hospitals, and technology developers in situations of negative outcomes, highlighting the dilemma in attributing the fault within a hybrid human-machines decision-making context.

The paper concludes with the recommendation of formation of a new model of consent that focuses on explainability, patient understanding, and responsibility among the institutional stakeholders to ensure that patient autonomy is not compromised in the advancement of technological innovations. This reform is necessary to balance the legal doctrine with the reality of the AI-driven healthcare to ensure trust in the cutting-edge medical technologies.

Keywords: *Informed Consent, AI-Assisted Surgery, Patient Autonomy, Medical Negligence, Robotic Healthcare*

¹ Ayesha Majid, Research Scholar, Department of Law, Gurugram University.



1. INTRODUCTION

With the rapid technological advancement, there has been a significant shift in the domains associated with it as well, particularly in the field of healthcare. Artificial intelligence (AI) has significantly changed the health care sector in the modern world, especially in the field of surgery. Medical procedures that were once carried out manually are gradually being replaced by fully automated systems that are driven by artificial intelligence and robot assisted technologies. This technological change has not only enhanced the efficiency, but has also helped in improving precision and clinical outcomes. Nevertheless, as much as these technological development are an indication of great scientific advancement, there are also some legal and ethical issues which require serious consideration.

Among other things, the recent technological changes has brought about significant transformation in medical decision-making. Conventionally, the relationship between the doctor and the patient was based on human-centric model, wherein the doctor is the one who uses professional judgment and informs the patient of the potential risks. Nevertheless, AI-assisted surgical systems break this paradigm as they bring the element of algorithmic processes to clinical decision-making. Consequently, the process of decision-making turns less human and more hybrid, requiring the human skills to be integrated with the insights produced by the machine. This change poses some critical questions as to how far patients can intelligibly comprehend and agree to the procedures whose internal logic remains potentially incomprehensible even to the medical professionals.

It is worth noting that the adoption of AI in surgical procedures has outpaced the development of corresponding legal and regulatory frameworks in surgery. The current doctrines of informed consent, patient autonomy and medical liability are based on conventional principles which fail to consider the intricacies of AI-based systems sufficiently. Opacity of algorithmic decision-making also makes the issue of disclosure more complicated and makes communication more technical and less accessible to patients.²

Consequently, the outdated regulatory strategies have raised serious concerns about patient autonomy, the validity of informed consent, accountability, risks to privacy and confidentiality and sufficiency of current legal safeguards.³ The regulatory vacuum in healthcare jurisprudence especially regarding the lack of well-defined principles of disclosure and liability in AI assisted procedures, poses a great uncertainty not only to patients but also to the medical practitioners and the developers of the technology.

In this regard, there is a dire need to critically analyse the standards which need to be taken in order to bring fairness in this technological environment, especially by putting in place,

² Carlos Zednik, "Solving the Black Box Problem: A Normative Framework for Explainable Artificial Intelligence" 34(2) *Philosophy & Technology* 265 (2021).

³ Rounak Verma, "Rethinking Medical Ethics and Informed Consent" 7(2) *Global Bioethics Enquiry* 94 (2019) Available at: https://indianmentalhealth.com/pdf/2019/new-issue/9-3-2019/15-Student-Ethical-Viewpoint-Paper_Rethinking-Medical.pdf (last accessed on March 3, 2026).



strong mechanisms of accountability, and providing patients with adequate information about the nature of the procedure, its inherent risks and probable consequences, so that they can make informed decisions, in their best interests. This paper, proposes that the conventional models of informed consent are ineffective in the field of AI-assisted surgery and have to be redefined to include technological transparency, increased disclosure, and collective responsibility. Nevertheless, in order to comprehend the inefficiency of existing models, it is necessary to first consider the doctrinal principles of informed consent.

2. THE DOCTRINE OF INFORMED CONSENT

Ethical and legal practice in the medical field has long been dominated by the doctrine of informed consent. With the increased awareness and rights-based discourse of patients, the duty to educate patients about the nature, risks, and options of medical care has become more fundamental. In its fundamental essence, informed consent reflects the philosophy of people possessing the autonomy to make decisions about their own bodies.

Justice Cardozo famously observed in a case that, “*Every human being of adult years and sound mind has a right to determine what should be done with his body; and a surgeon who performs the operation without his patient's consent, commits an assault for which he is liable in damages*”.⁴

The development of informed consent shows a progressive change towards the medical paternalism to patient-focused care. Traditionally, the Indian Ayurvedic, Siddha and Unani systems of medicine, and practices in Ancient Greece, were governed by a paternalistic paradigm of unilateral decision-making by the physician.⁵ Nevertheless, the horrors of the Second World War resulted in the development of international norms concerning ethics including the Nuremberg Code of 1947⁶ that stated that medical experimentation should be conducted on a voluntary basis. This was also supported by the Belmont Report⁷ and the Declaration of Helsinki⁸ which both emphasized the moral necessity of autonomy, beneficence and justice.

Following this, the Indian Medical Council of Medical research (ICMR) released its first guidelines on ethics in 1980⁹ as, “policy statement on ethical considerations involved in research on human participants.” Under the topic of informed consent it was stated, “*the best way of obtaining informed consent is one that is difficult and one in which the norms and forms*

⁴ *Schoendorff v. Society of New York Hospital*, 211 NY 125 (1914)

⁵ Nandini K. Kumar, “Informed Consent: Past and Present” 4(1) *Perspectives in Clinical Research* 21 (2013), available at: <https://pmc.ncbi.nlm.nih.gov/articles/PMC3601698/> (last accessed on April 3, 2026).

⁶ Nuremberg Military Tribunal, “The Nuremberg Code” 276 *Journal of the American Medical Association* 1691 (1996).

⁷ U.S. Department of Health and Human Services, “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research” (1979), available at: <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/> (last accessed on April 3, 2026).

⁸ World Medical Association, “Declaration of Helsinki” (1964).

⁹ Indian Council of Medical Research, “Policy Statement on Ethical Considerations Involved in Research on Human Subjects” (New Delhi: ICMR, 1980).



used in other countries are really not fully relevant to the conditions prevailing in this country.” However, according to a revised version in 2006, more emphasis was given to the community participation and permission from culturally appropriate authority on account of increasing number of community-based studies in India.¹⁰

In conjunction with these ethical trends, judicial principles also changed to establish the standard of legal disclosure. The case of *Bolam v. Friern Hospital Management Committee*,¹¹ formulated the standard of care through the practices followed by a reasonable group of medical practitioners. This doctor-centered methodology was however contested by the ruling in *Canterbury v. Spence*,¹² which refocused the attention on the reasonable patient standard, which focuses on the obligation of the doctor to disclose material risks through patient-centred deliberation.

The doctrine of informed consent has been identified in the Indian context, as a part of the right to life and personal liberty in Article 21 of the Constitution.¹³ The need to disclose the relevant information to patients to allow them to make informed decisions has been highlighted by judicial pronouncements, notably in the case of *Samira Kohli v. Dr. Prabha Manchanda*.¹⁴

With time, there has been rapid technological change and introduction of very complex medical equipment that has complicated the process of informed consent. The challenge is caused by two main factors, the first one being the complexity of contemporary surgical procedures, and the second one being the difficulty to explain such technical data in a way that is comprehensible, digestible, and significant to patients.¹⁵ It is against this doctrinal backdrop that the advent of AI-assisted surgery systems is essentially challenging the premises of informed consent.

3. AI ASSISTED SURGERIES AND THE TRANSFORMATION OF MEDICAL PRACTICE

The recent innovations in the field of artificial intelligence (AI) have made the implementation of robotic-assisted surgeries (RAS) much faster, which is a radical change in the process of providing healthcare services. Initially designed to help surgeons carry out minimally invasive operations, these systems have since been used to aid more complex surgical operations.¹⁶ The ability to handle large volumes of data, make predictive decisions,

¹⁰ Nandini K. Kumar, “Informed Consent: Past and Present” 4(1) *Perspectives in Clinical Research* 21 (2013) available at: doi:10.4103/2229-3485.106372 (last accessed on March 3, 2026).

¹¹ *Bolam v. Friern Hospital Management Committee*, (1957) 2 All ER 118.

¹² *Canterbury v. Spence*, 464 F.2d 772 (CADC 1972).

¹³ The Constitution of India, 1950, art. 21.

¹⁴ *Samira Kohli v. Dr. Prabha Manchanda*, Appeal (Civil) No. 1949 of 2004, decided on January 16, 2008 (SC).

¹⁵ Alessia Ferrarese et al., “Informed Consent in Robotic Surgery: Quality of Information and Patient Perception” 11(1) *Open Medicine* 279 (2016), available at: <https://pmc.ncbi.nlm.nih.gov/articles/PMC5329841/> (last accessed on April 3, 2026).

¹⁶ Eman Ibrahim Abdalla Osman, Manasik M. ElMurtada Mubarak Ismail, Mohamed Ahmed Hassan Mukhtar, Ahmed Umballi Babiker Ahmed, Nihal Ahmed Abd Elfrag Mohamed and Ali Ahmed Alamin Ibrahim, “Artificial Intelligence and Robotics in Minimally Invasive and Complex Surgical Procedures: A Systematic Review” 17(3)



and even aid in intraoperative decision-making in real-time has changed the boundaries of surgical practice and has moved it towards a more of a hybrid model of decision-making, instead of a completely human-centered model.

The clinical benefits related to the use of AI-assisted surgical systems are emphasized by the available empirical data. These result in decreases in operational time, decreases in the occurrences of intraoperative complications, increased accuracy in the operations like tumour resections, implant placements, and better post-operative recovery.¹⁷ The system enhances accuracy with the aid of advanced power of the robot through highly controlled and precise actions, which offers increased surgical stability and control.¹⁸ Moreover, AI-based systems offer real-time feedback and intraoperative error correction to a minimum, reducing unintentional tissue damage, minimising blood loss and decreasing the rates of surgical site infections.¹⁹ In expert disciplines like orthopaedics and spinal surgery, AI-assisted procedures have shown substantial effects on the accuracy of the procedure, especially when it comes to minimizing errors like in procedures involving screw misplacement.²⁰

However, though the clinical benefits of AI-assisted surgery are extensive yet their successful implementation is dependent upon sufficient institutional readiness and professional competence. Such technologies require systematic training systems, such as simulation-based learning, continuous training and coordination between surgeons, technicians and support staff. Without these mechanisms, both patient safety and clinical efficacy can be compromised by the risks of over-reliance, misuse or misinterpretation of the outputs of the AI.²¹

In addition to its clinical significance, the implementation of AI in surgery is a radical change in the nature of medical decisions as a whole. Historically, the surgeon used to be the main, and in many cases, the only decision-maker, making judgments based on training and experience in a professional manner. Conversely, AI-based systems add one more circle of algorithmic input, which can affect or, in some situations, predetermine clinical decisions. Such redistribution of the decision-making power also introduces a new paradigm where the

Cureus e81339 (2025), available at: <https://pmc.ncbi.nlm.nih.gov/articles/PMC12034508/> (last accessed on April 4, 2026).

¹⁷ Jack Ng Kok Wah, “The Rise of Robotics and AI-Assisted Surgery in Modern Healthcare” 19(1) *Journal of Robotic Surgery* 311 (2025), available at: <https://pmc.ncbi.nlm.nih.gov/articles/PMC12181090/> (last accessed on April 3, 2026)

¹⁸ Muhammad Nadeem et al., “Robot-Assisted Surgery: A Comprehensive Review of Literature, Challenges, Ethical Considerations, and Current Trends” 13 *IEEE Access* 215647 (2025), available at: <https://ieeexplore.ieee.org/document/11308110> (last accessed on April 3, 2026).

¹⁹ H. Liu, Y. Cao, L. Li, Y. Bai and J. Liu, “Effectiveness of Robotic Surgery for Endometrial Cancer: A Systematic Review and Meta-Analysis” 305(4) *Archives of Gynecology and Obstetrics* 837 (2022) DOI: 10.1007/s00404-021-06229-x (last accessed on April 3, 2026).

²⁰ Jack Ng Kok Wah, “The Rise of Robotics and AI-Assisted Surgery in Modern Healthcare” 19(1) *Journal of Robotic Surgery* 311 (2025), available at: <https://pmc.ncbi.nlm.nih.gov/articles/PMC12181090/> (last accessed on April 3, 2026)

²¹ A. Shahi, G. Bajaj, R. Golhar Sathawane, D. Mendhe and A. Dogra, “Integrating Robot-Assisted Surgery and AI for Improved Healthcare Outcomes” *Proceedings of the 9th International Conference on Science, Technology, Engineering and Mathematics (ICONSTEM)* 1 (2024).



responsibility is not solely a human one anymore, which brings some complicated questions about control, accountability, and trust in the clinical context.

Another issue is that many AI systems are opaque in nature, which complicates them. In contrast to traditional medical tools, whose operation is relatively easy to comprehend and explain, AI-powered technologies operate as black boxes which generate results without any clear and understandable rationale.²² This inability to explain has serious ramifications both to the practitioners and patients. In the case of medical workers, it limits their authority to critically or independently check the recommendations provided by algorithms. In the case of patients, it builds significant obstacles to knowledge of the nature, risks, and implications of the procedures that they have been requested to consent to.²³

These trends have significant legal implications. The growing use of AI in decision-making undermines the very premises of the current doctrines of informed consent, which assume that the physician possesses the required knowledge and the ability to disclose all the material facts about a suggested intervention. With AI-assisted surgery, this assumption is no longer possible in its traditional version. Resultantly, although AI technologies clearly improve clinical capacities, they at the same time counter the traditional legal and ethical paradigms, thus suggesting a reconsideration of the standards of consent and accountability systems in modern clinical practice. Thus, these developments pose a direct challenge to the basic premise of informed consent leading to a number of doctrinal and practical challenges.

4. CHALLENGES TO INFORMED CONSENT IN AI ASSISTED SURGERY

The integration of AI into surgery practice essentially disputes the doctrine of informed consent by bringing intricacies that the current legal frameworks are poorly prepared to tackle. The AI system introduces degrees of transparency and explainability that vary based on the form of Machine Learning (ML). The lack of explainability of AI systems is one of the most serious challenges. Explainability of AI system, can be explained as the ability of the AI technology to provide intelligible information of how a conclusion has been reached- be it a prediction, recommendation or decision.²⁴

Informed consent is predicated on the assumption that the physician is capable of understanding and communicating all material aspects of a procedure to the patient. However, when decisions are influenced by algorithmic processes that lack transparency, this assumption is undermined. The opacity of AI systems raises critical questions regarding the extent to which information about algorithmic decision-making can be meaningfully disclosed to patients.²⁵

²² European Commission, *Ethics Guidelines for Trustworthy Artificial Intelligence* (2019), available at: <https://op.europa.eu/en/publication-detail/-/publication/958117aa-0c91-11ed-b11c-01aa75ed71a1/language-en> (last accessed on April 4, 2026)

²³ European Commission, *Ethics Guidelines for Trustworthy AI* (2019)

²⁴ Live Sunniva Hjort, "Informed Consent to AI-Based Decisions in Healthcare: Must Patients Understand the AI's Output?" 11(1) *Oslo Law Review* 1 (2025), available at: <https://doi.org/10.18261/olr.11.1.7> (last accessed on April 3, 2026).

²⁵ Ivan Glenn Cohen and Andrew Slottje, "Artificial Intelligence and the Law of Informed Consent" in Barry Solaiman and I. Glenn Cohen (eds), *Research Handbook on Health, AI and the Law* 168 (Edward Elgar Publishing, 2024), available at: <https://doi.org/10.4337/9781802205657.ch10> (last accessed on April 3, 2026).



Moreover, physicians themselves may lack a complete understanding of how an AI system arrives at a particular recommendation, thereby limiting their ability to provide effective explanations. Consequently, “black box” models—whose internal decision-making processes remain opaque even to physicians—pose a significant challenge to the validity of informed consent.²⁶

Besides transparency concerns, AI-assisted surgery presents an additional and broadened risk environment. Traditional informed consent centers on the revelation of risks that are familiar, foreseeable, and that are linked directly to the procedure. On the contrary, AI systems pose risks, which are probabilistic, dynamic, and usually hard to foresee. These are algorithmic errors due to erroneous training data, biases in datasets and system failures that can be experienced during the operation of the system. It is a difficult task not only to identify these risks but also to present them in a way that patients can understand. Such risks are probabilistic in nature, which complicates the disclosure process because it becomes hard to measure and describe the probability of negative occurrences. However, even in such a case, the healthcare providers must disclose the foreseeable risk of the treatment, which involves communicating of the fundamental facts about the AI model that they are based on, but not the technical explanations.²⁷

The move towards hybrid decision-making makes the concept of consent even more challenging. In conventional medicine, patients submit to the opinion and the experience of a human physician. But, when it comes to AI-assisted surgery, the choice is made by both human and machine factors, which introduces the uncertainty of the object of consent. The question arises on whether patients are giving consent to the proficiency of the surgeon, the suggestions of the AI system or both. The risk of this ambiguity is that it could create the illusion of informed consent, in which patients formally consent to a procedure without necessarily knowing how much technology affects the decision-making process.

These issues are especially acute in the Indian context where there are already barriers to effective communication that compromise the process of informed consent. Introduction of AI systems with its inbuilt complexity can worsen these barriers, which will further reduce the quality of patient understanding. Thus, the classical model of informed consent, based on effective communication and understanding, seems to be more and more insufficient in the context of AI-based healthcare.

5. LIABILITY IN AI-ASSISTED SURGERY: THE EMERGING LEGAL DILEMMA

The introduction of AI into surgery not only makes the process of informed consent more complicated but also poses deep questions about the distribution of legal liability.

²⁶ *Ibid.*

²⁷ Katharina Ó Cathaoir, “Digital Healthcare Technologies and Human Rights” in Birgit Toebe and others (eds), *Health and Human Rights: Global and European Perspectives* (2nd edn, Intersentia 2022) 349.



Conventional doctrines of medical negligence rely on the assumption that a human agent makes judgments and can be held liable in cases where the standard of care is not met.

In AI-assisted practices, however, there is a sharing of responsibility between various players, such as the surgeon, the hospital, and the creators of the AI technology. Such decentralization of responsibility leads to what has been termed as a liability gap, whereby it is hard to pin down blame on any one party. For instance if in a robotic surgery, the AI system autonomously modifies a surgical technique during the procedure, resulting into unforeseen complications, then the delineation of liability becomes blurred.²⁸

With respect to medical practitioners, the use of AI-generated recommendations casts doubt on the quality of care. Although it is anticipated that surgeons should apply independent judgment, the growing complexity of AI systems potentially promotes the use of algorithmic results. In situations where an adverse outcome results from an AI-generated recommendation, it becomes unclear whether the surgeon can be held liable for following a system that is widely accepted within the medical community. On the other hand, a liability on surgeons who failed to follow AI advice can be a source of perverse incentive and hinder the role of professional judgment.

The possible liability of AI developers is also a rather complicated issue. In conventional systems of product liability, manufacturers can be held responsible for defects in their products. Nevertheless, AI systems, especially those that are grounded in machine learning, progress with time and can deliver results that were not deliberately designed by their creators. This brings to mind foreseeability and control, which are the key to determining liability. The dynamism of AI systems makes it more challenging to apply the existing legal doctrines hence the need to establish new methods of addressing liability.

Hospitals as an organization that adopts and implements AI technologies are also highly significant in this framework. They are also responsible to provide adequate training, supervision and maintenance of these systems.²⁹ A breach of these commitments can result in liability to institutions especially where lack of proper training or supervision is a cause of negative consequences. The moral crumple zone concept also emphasises the propensity to shift the blame onto the human operators, despite the fact that the root of failure is in the technological system. This brings up the issue of fairness and the sufficiency of current legal regulations to handle the reality of AI-assisted healthcare.

²⁸ Arian Arjomandi Rad, Robert Vardanyan, Thanos Athanasiou, Jos Maessen and Peyman Sardari Nia, “The Ethical Considerations of Integrating Artificial Intelligence into Surgery: A Review” 40(3) *Interdisciplinary CardioVascular and Thoracic Surgery* ivae192 (2025), available at: <https://academic.oup.com/icvts/article/40/3/ivae192/8042349> (last accessed on April 3, 2026).

²⁹Victor Derek and Michael Watson, “Artificial Intelligence and Informed Consent: Reimagining Patient Education and Ethical Disclosure in AI-Supported Healthcare Decisions” (2025), available at: <https://www.authorea.com/doi/full/10.22541/au.174845022.24373824> (last accessed on April 3, 2026).



6. RECONCEPTUALIZING INFORMED CONSENT IN THE AGE OF AI

Considering the issues presented by AI-assisted surgery, it is crucial to redefine the doctrine of informed consent to respond to the realities of modern practice. This necessitates a radical re-evaluation of the old models of disclosure to a more sophisticated system that incorporates the interactions of algorithmic decision-making. The foundational principle of this reconceptualization is the necessity to increase the amount of information that is given to patients. Besides the usual risks and benefits, patients should be educated in relation to the purpose of AI systems in the decision-making process, the level of autonomy applied by these systems, and the constraints of their operation.³⁰

The introduction of explainability as a legal standard is a very important move in this direction. Although it might not be possible to completely explain the inner mechanics of complicated algorithms, attempts should be undertaken to present simplified and understandable explanations that will allow patients to learn about what AI involvement entails. This can include visual aids, analogies and interactive tools that are aimed at helping to bridge the gap in the understanding of technical complexity and the patient comprehension. Also, the informed consent process should be considered an ongoing and dynamic process, as opposed to a singular process. Constant dialogue between the healthcare provider and the patient is vital in order to make sure that informed consent is maintained throughout the treatment process.

The necessity of the standardized consent frameworks in AI-assisted procedures should also be the subject of policy reforms. These frameworks ought to require that AI engagement be disclosed, that there be principles of communication of algorithmic risks, and that there be certainty on how responsibility is distributed across various stakeholders. Medical professional training programs must concentrate on the ethical and legal aspects of AI use and provide medical professionals with the necessary skills to convey complex information to patients. On a structural level, healthcare providers should establish effective supervision systems to protect patient rights and accountability.

7. CONCLUSION

The informed consent doctrine has been a significant pillar of medical law, as it is based on the basic ideas of autonomy, dignity, and self-determination. The introduction of artificial intelligence in the practice of surgery has however unveiled a lot of constraints on the traditional framework of consent and liability. The fact that human-centric decision-making systems are being replaced by hybrid systems complicates the task of disclosure, comprehension, and accountability, which in turn is a challenge to the sufficiency of the law that already exists.

Although AI has significant potential to improve clinical outcomes and advance medical science, it also poses a certain regulatory gap, which needs to be filled by developing extensive legal and policy changes. In the absence of such intervention, the doctrine of

³⁰ *Supra* note 25.



informed consent becomes a sham exercise in formalities that does not achieve its desired goal of empowering patients. The issue of AI-assisted surgery highlights the necessity to redefine the framework and integrate technological transparency, collective responsibility, and patient-centred communication.

Conclusively, the challenge facing the legal and medical fraternity is to balance the need to embrace innovation and the need to protect fundamental rights. The informed consent as it develops in the era of AI should not just adapt to the newly introduced technological progress but also support the importance of patient autonomy as its core value. Such a balanced approach is the only way the law can be made flexible to the dynamics of the contemporary healthcare and retain the fundamental ethical commitments. Unchecked, the increasing use of algorithmic decision-making would undermine informed consent to a mere formality instead of a right granted to patients.