INDIAN JOURNAL OF LEGAL AFFAIRS AND RESEARCH

Peer-reviewed, open-access, refereed journal

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Introduction

Welcome to the Indian Journal of Legal Affairs and Research (IJLAR), a distinguished platform dedicated to the dissemination of comprehensive legal scholarship and academic research. Our mission is to foster an environment where legal professionals, academics, and students can collaborate and contribute to the evolving discourse in the field of law. We strive to publish high-quality, peer-reviewed articles that provide insightful analysis, innovative perspectives, and practical solutions to contemporary legal challenges. The IJLAR is committed to advancing legal knowledge and practice by bridging the gap between theory and practice.

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Preface

The Indian Journal of Legal Affairs and Research is a testament to our unwavering commitment to excellence in legal scholarship. This volume presents a curated selection of articles that reflect the diverse and dynamic nature of legal studies today. Our contributors, ranging from esteemed legal scholars to emerging academics, bring forward a rich tapestry of insights that address critical legal issues and offer novel contributions to the field. We are grateful to our editorial board, reviewers, and authors for their dedication and hard work, which have made this publication possible. It is our hope that this journal will serve as a valuable resource for researchers, practitioners, and policymakers, and will inspire further inquiry and debate within the legal community.

Description

The Indian Journal of Legal Affairs and Research is an academic journal that publishes peer-reviewed articles on a wide range of legal topics. Each issue is designed to provide a platform for legal scholars, practitioners, and students to share their research findings, theoretical explorations, and practical insights. Our journal covers various branches of law, including but not limited to constitutional law, international law, criminal law, commercial law, human rights, and environmental law. We are dedicated to ensuring that the articles published in our journal adhere to the highest standards of academic rigor and contribute meaningfully to the understanding and development of legal theories and practices.

BEYOND THE SURGEON: LEGAL ACCOUNTABILITY FOR ROBOTIC MEDICAL FAILURES IN INDIA

A Critical Study of Medical Negligence, Institutional Responsibility, Product Liability and Emerging Technological Challenges

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ABSTRACT:

The increasing use of robotic systems in healthcare has altered the relationship between medical professionals, patients and the technologies used in diagnosis and treatment. Robotic-assisted surgery may improve visualisation, dexterity and the performance of certain complex procedures, but it also introduces risks associated with mechanical components, software, training, maintenance, system design and human-machine interaction. When a patient suffers injury during a robotic procedure, the legal inquiry may extend beyond the conduct of the operating surgeon to the responsibilities of the hospital, manufacturer, importer, service provider and, in some cases, software developer.

This paper examines whether the existing Indian legal framework is capable of allocating responsibility for robotic medical failures in a fair and effective manner. It analyses the law of medical negligence, consumer protection, product liability, medical-device regulation, professional ethics, informed consent and criminal negligence. Particular attention is given to the Consumer Protection Act, 2019, including its product-liability provisions, and to the Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2017. The paper also considers the relevance of the Bharatiya Nyaya Sanhita, 2023, and the regulatory treatment of medical-device software.

The central argument is that liability should not automatically be imposed on the surgeon merely because the surgeon was present during the procedure, nor should the use of a robot operate as a defence to professional negligence. Responsibility should instead be allocated by examining each participant's duty, control, knowledge, capacity to prevent the risk and causal contribution to the injury. A surgeon may be liable for negligent selection, operation or supervision; a hospital may be liable for deficient credentialing, maintenance or governance;

and a manufacturer or service provider may be liable where a defect, inadequate warning or deficient service caused harm. The paper argues for a structured, evidence-sensitive approach supported by device traceability, incident reporting, preservation of system logs, informed consent, competency standards and accessible patient remedies.

Using doctrinal and comparative legal research, the paper draws on Indian judicial decisions and selected developments in the United Kingdom, United States and European Union. It concludes that India does not necessarily require an entirely separate tort system for robotic healthcare, but it does require clearer regulatory duties and practical procedures for investigating technologically complex adverse events. The proposed framework seeks to protect patients while avoiding strict or automatic liability for every unsuccessful medical outcome.

Keywords: Robotic surgery; medical negligence; product liability; hospital liability; medical devices; artificial intelligence; informed consent; patient safety; India.

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LIST OF ABBREVIATIONS:

AI – Artificial Intelligence

BNS – Bharatiya Nyaya Sanhita, 2023

CDSCO – Central Drugs Standard Control Organisation

CPA – Consumer Protection Act, 2019 **DPDP –** Digital Personal Data Protection **EU –** European Union

IT Act – Information Technology Act, 2000 **MDR –** Medical Devices Rules, 2017 **MDSW –** Medical Device Software

MHRA – Medicines and Healthcare products Regulatory Agency

RAS – Robotic-Assisted Surgery

SCC – Supreme Court Cases

INTRODUCTION

1.1 Background of the Study

Medical practice has never been wholly separate from technology. From diagnostic imaging and anaesthesia equipment to minimally invasive instruments and intensive-care monitoring, technological tools have long shaped the manner in which treatment is delivered. The recent development of robotic-assisted systems, however, raises a distinct set of questions because the technology may directly influence the movement of instruments, the visual information available to the surgeon and the execution of a procedure.

Robotic-assisted surgery is commonly described as surgery performed by a human surgeon using a computer-controlled platform that translates the surgeon's hand movements into movements of specialised instruments. In many widely deployed systems, the robot does not independently decide what operation should be performed. The surgeon remains the principal clinical decision-maker and controls the instruments through a console. This is important: the term "robotic surgery" should not be used as though every such system were an autonomous surgeon. The degree of autonomy differs between systems and applications.

The legal significance of this distinction is considerable. A complication may arise from the surgeon's decision, the manner in which the system was operated, an equipment defect, an installation or maintenance failure, a software issue, a communication breakdown within the surgical team or a combination of these factors. The patient experiences one injury, but the causal chain may involve several actors who owe different duties.

1.2 Statement of the Problem

Indian medical-negligence law has developed around the professional duty of doctors and the obligations of hospitals. Product-liability law separately addresses harm caused by defective products, while medical-device regulation establishes requirements for the safety, quality and performance of regulated devices. These bodies of law may all be relevant to a robotic medical failure, but they were not drafted as a single, integrated scheme for allocating responsibility among a surgeon, hospital, manufacturer and software provider.

The practical difficulty is evidentiary as well as doctrinal. A patient may not have access to the robotic system's event logs, software version history, maintenance records, training records or technical investigation. The hospital and manufacturer may possess most of the relevant information. A claimant may therefore face difficulty identifying whether the failure resulted from negligent operation, a product defect, inadequate maintenance or a software problem. The problem addressed by this paper is whether existing legal rules, when applied together, provide a sufficiently clear and accessible route to establish responsibility and obtain compensation.

1.3 Research Questions

The research is guided by the following questions: (a) What legal principles govern medical negligence involving robotic healthcare in India? (b) In what circumstances may a surgeon be liable for injury involving a robotic system? (c) What duties may arise for hospitals in relation to procurement, credentialing, maintenance, staffing and incident response? (d) To what extent can the product-liability provisions of the Consumer Protection Act, 2019 apply to defective robotic equipment and associated services? (e) How should software-related failures and difficult questions of causation be addressed? (f) What disclosures are necessary for valid patient consent? (g) What regulatory and procedural reforms could improve accountability without treating every adverse outcome as negligence?

1.4 Hypothesis

The working hypothesis is that Indian law contains several routes through which responsibility for robotic medical harm may be established, but the absence of a clearly articulated, coordinated accountability framework may make investigation and proof difficult. A fair model should allocate liability according to each actor's duty, control, knowledge and causal contribution, supported by mandatory preservation of relevant technical records and effective

patient access to those records through appropriate legal processes.

1.5 Objectives

The objectives are to explain the legal and technological features of robotic healthcare; examine the Indian law of medical negligence and product liability; analyse the duties of surgeons, hospitals and manufacturers; consider software-related issues and evidentiary barriers; assess consent and patient rights; compare selected international approaches; and recommend a practical accountability framework for India.

1.6 Research Methodology

This is a doctrinal legal study supported by comparative analysis. Primary materials include statutes, rules, judicial decisions and regulatory publications. Secondary materials include peer-reviewed medical and legal scholarship, professional guidance and institutional reports. The paper does not claim to be an empirical study of the incidence of robotic surgical injuries in India. Where foreign adverse-event data or litigation statistics are mentioned in the literature, they are treated as jurisdiction-specific and not assumed to represent Indian experience. The comparative discussion is selective and is used to identify principles that may inform Indian reform, not to suggest that foreign law applies directly in India.

1.7 Scope and Limitations

The study concentrates on robotic-assisted surgery and related medical-device software where technology materially participates in treatment. It does not assess the clinical superiority of a particular robotic platform. Nor does it assume that every system incorporates machine learning or autonomous decision-making. The paper distinguishes conventional surgeon-controlled systems from systems with more autonomous functions. A further limitation is the limited publicly accessible Indian case law specifically concerning injury caused by robotic surgery. Accordingly, general medical-negligence and product-liability precedents are analysed by analogy, and no claim is made that those cases themselves concerned robotic systems.

1.8 Significance

The subject matters because the patient should not lose effective legal protection merely because treatment is technologically complex. At the same time, innovation should not be

chilled by imposing liability simply because a complication occurred. A carefully reasoned allocation of duties can protect patients, encourage safer institutional practices and provide manufacturers with clear expectations regarding design, warnings, updates and post-market monitoring.

REVIEW OF LITERATURE AND RESEARCH GAP

2.1 Literature on Robotic Surgery and Medicolegal Risk

The literature on robotic-assisted surgery commonly identifies three recurring legal concerns: training and credentialing, informed consent, and the allocation of liability among multiple participants. Pai and co-authors, in their 2023 review, discuss the medicolegal implications of robotic surgery and emphasise the need for structured training, adequate consent and clearer responsibility among stakeholders. Their work is useful because it treats robotic surgery as a team-based clinical activity rather than a simple substitution of a machine for a surgeon.

Earlier scholarship on robotic surgery and malpractice also notes that traditional elements of negligence remain relevant: duty, breach, injury and causation. The presence of a robotic system does not remove the need to examine the surgeon's conduct. However, it may expand the evidence required to determine whether the standard of care was met. Relevant questions may include the surgeon's experience with the platform, the suitability of the patient, the availability of a trained bedside assistant, the system's warnings and the decision to convert to conventional surgery when necessary.

Research on artificial intelligence and autonomous robotic surgery goes further by distinguishing accountability, liability and culpability. This distinction is valuable. Accountability concerns the obligation to explain and answer for decisions; liability concerns legal responsibility and remedies; culpability concerns blameworthiness. A machine may be involved in an event, but it is not thereby a legal person capable of bearing criminal blame in the ordinary sense. Legal responsibility must be traced to natural or legal persons who designed, supplied, selected, deployed, controlled or supervised the system.

2.2 Product Liability Literature

Product-liability scholarship provides a second foundation. The Consumer Protection Act, 2019 expressly recognises product-liability actions against manufacturers, product service providers and product sellers. Sections 82 and 83 establish the scope and availability of such

actions; sections 84 to 86 address the liability of manufacturers, service providers and sellers; and section 87 provides exceptions. These provisions are particularly relevant where harm is alleged to have resulted from a manufacturing defect, defective design, departure from specifications, inadequate instructions or warnings, or deficient product-related services.

A robotic platform is not merely a single metal instrument. It may consist of hardware, software, consumables, accessories, remote support, updates and maintenance services. The legal classification of each component and the relationship between the manufacturer, importer, distributor and service provider may therefore matter. The literature also cautions against assuming that every software error automatically proves a product defect. A claimant must connect the alleged defect or deficient service to legally recognised harm and satisfy the applicable statutory requirements.

2.3 Medical Negligence and Patient Rights Literature

Indian medical-negligence scholarship is shaped by decisions such as Indian Medical Association v V.P. Shantha, Jacob Mathew v State of Punjab, Samira Kohli v Dr Prabha Manchanda, Kusum Sharma v Batra Hospital and Spring Meadows Hospital v Harjol Ahluwalia. These authorities address the scope of consumer protection, the standard for professional negligence, informed consent, and the responsibilities of medical institutions. They do not concern robotic surgery as such, but they provide the doctrinal foundation against which robotic failures can be assessed.

The literature on informed consent is especially relevant because robotic procedures may involve additional material information: the role of the system, the surgeon's experience, the possibility of conversion to conventional surgery, device-specific risks and the availability of reasonable alternatives. Consent should not be reduced to a generic form stating that "advanced technology" may be used. The information must be meaningful to the patient and adapted to the clinical circumstances.

2.4 Regulatory Literature

The Medical Devices Rules, 2017 establish a risk-based regulatory framework for medical devices in India. The CDSCO explains that the regulatory definition includes instruments, apparatus, appliances, implants, materials and certain software intended for specified medical purposes. The Rules classify devices into Classes A, B, C and D according to risk parameters. The 2026 CDSCO Guidance Document on Medical Device Software provides further

regulatory guidance on software intended for medical purposes under the Rules. These materials show that software is not necessarily outside medical-device regulation merely because it is intangible.

However, regulatory approval and civil liability answer different questions. Regulatory compliance may be relevant evidence of due care, but it does not necessarily prove that a device was non-defective in every respect or that a hospital used it appropriately. Conversely, a regulatory breach may be relevant to a negligence or product-liability claim, but the claimant must still establish the applicable legal elements and causal connection.

2.5 Research Gap

The existing literature identifies the broad challenges of robotic surgery, but a focused Indian legal analysis must bring together four strands that are often treated separately: professional negligence, institutional governance, product liability and medical-device software regulation. The distinctive contribution of this paper is to examine how those strands interact in a single adverse event. It proposes a responsibility-mapping approach that asks who had the relevant duty, who controlled the risk, who possessed the information, who could reasonably have prevented the harm and how each contribution should be proved.

The paper also identifies an evidentiary gap. A patient may know that a robotic system was used but may not know which software version was installed, whether the system recorded an alert, whether a service bulletin had been issued or whether the surgeon had completed platform-specific training. A coherent accountability framework must therefore address not only substantive liability but also record preservation, disclosure, technical investigation and access to expert evidence.

CONCEPTUAL AND TECHNOLOGICAL FRAMEWORK

3.1 Meaning of Robotic-Assisted Surgery

Robotic-assisted surgery generally involves a surgeon controlling instruments through a computer interface. The system may provide magnified three-dimensional visualisation, tremor filtration, articulated instruments and motion scaling. The robot's role is to translate and support the surgeon's movements; it does not necessarily select the operation or independently decide the clinical objective. The legal analysis must therefore begin by identifying the actual technical architecture and degree of autonomy of the system involved.

The term "robotic medical failure" is used in this paper as an analytical expression, not as a statutory category. It refers to an adverse event in which the design, manufacture, software, operation, maintenance, supervision or integration of a robotic healthcare system materially contributes to patient injury. A complication that occurs despite reasonable care and without a defect is not automatically a legally actionable failure.

3.2 Human-Machine Interaction

Robotic surgery changes the distribution of tasks within the operating theatre. The primary surgeon may sit at a console, while bedside personnel manage instruments, patient positioning, emergency access and other tasks. Communication, situational awareness and the ability to respond to system alerts become important. A loss of haptic feedback, restricted field of view, equipment collision, delayed response or confusion over control may create risks that differ from conventional surgery.

These human factors do not automatically establish negligence. They may, however, inform the standard of reasonable care, the content of training and the hospital's obligation to organise a safe team. A surgeon who is unfamiliar with a system may require additional supervision. A hospital that introduces a new platform without adequate team preparation may create an institutional risk.

3.3 Categories of Failure

Mechanical failure may include breakage, unintended movement or loss of function. Software failure may include incorrect processing, system crashes, inaccurate display or faulty communication between components. Human-operation failure may include improper instrument selection, failure to respond to an alarm or use beyond the operator's competence. Institutional failure may involve inadequate maintenance, unsuitable procurement, lack of trained support or failure to establish emergency conversion protocols. Product failure may involve design, manufacturing, warning or instruction defects.

These categories can overlap. A device may issue an alarm, but a poorly trained team may not understand it. A software update may address a known risk, but a hospital may fail to install it. A manufacturer may provide adequate instructions, but the hospital may fail to train staff. Liability must be assessed from the facts rather than assigned by category alone.

3.4 Distinguishing Complication from Negligence

The law must preserve the distinction between an adverse outcome and negligence. Surgery is inherently risky. A recognised complication may occur even when the surgeon exercises reasonable care. The fact that a robot was used, or that the patient suffered injury, cannot by itself establish breach. A claimant must ordinarily show a duty, a departure from the applicable standard of care, causation and damage. Product-liability claims have their own statutory requirements and should not be collapsed into the negligence test.

This distinction protects both patients and responsible medical professionals. It prevents the law from treating medicine as a guarantee of success while ensuring that technological complexity does not become an excuse for avoidable harm.

INDIAN LEGAL FRAMEWORK

4.1 Law of Torts and Medical Negligence

The law of torts provides the general framework for civil claims based on negligence. A claimant ordinarily needs to establish that the defendant owed a duty of care, breached that duty, and caused legally recognised damage. In medical cases, the standard is assessed with reference to the reasonable skill and care expected of a professional in the relevant circumstances. The court does not simply substitute its own view for a responsible professional judgment merely because another approach might also have been possible.

In Jacob Mathew v State of Punjab, the Supreme Court discussed the standard of negligence applicable to medical professionals and distinguished civil negligence from the higher threshold relevant to criminal prosecution. The decision is important because it cautions against treating an unsuccessful treatment as proof of criminal negligence. In robotic surgery, this principle means that a complication or equipment event must be investigated carefully before blame is attributed.

4.2 Consumer Protection Act, 2019

The Consumer Protection Act, 2019 is central to the analysis. In Indian Medical Association v V.P. Shantha, the Supreme Court held that medical services rendered for consideration generally fall within consumer-protection law, subject to the principles and exclusions explained in that decision. The 2019 Act now contains a separate product-liability chapter.

Section 82 applies the chapter to claims for compensation for harm caused by a defective

product manufactured, serviced or sold by the relevant person. Section 83 permits a product-liability action against a product manufacturer, product service provider or product seller. Section 84 identifies circumstances in which a manufacturer may be liable, including manufacturing defect, defective design, deviation from specifications, failure to conform to express warranty and inadequate instructions or warnings. Section 85 addresses product service providers, while section 86 addresses product sellers. Section 87 sets out exceptions.

The statutory definition of harm includes personal injury, illness or death and certain associated losses. This is relevant to a patient injured by a defective robotic instrument or device. However, the Act does not make every manufacturer liable whenever a product is involved in an adverse outcome. The claimant must establish the statutory basis for liability and the connection between the defect or service deficiency and the harm. The statutory exceptions and the facts of use must also be considered.

4.3 Medical Devices Rules, 2017

Medical devices in India are regulated under the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017. The Rules use a risk-based classification system, including Classes A, B, C and D. The classification depends on the intended use and applicable risk parameters. The regulatory framework addresses matters such as licensing, manufacture, import, quality management, conformity assessment and post-market obligations.

The CDSCO's published material confirms that the regulatory definition of medical device includes certain software intended for medical purposes. In July 2026, CDSCO issued a Guidance Document on Medical Device Software under the MDR-2017. The guidance clarifies regulatory expectations relating to classification, documentation, safety and performance, quality-management considerations and post-market obligations. It is guidance under the existing regulatory framework, not a substitute for the Act and Rules.

For robotic healthcare, this framework matters because a system may contain hardware and software that together perform or support a medical function. The precise regulatory treatment depends on intended purpose and product configuration. Regulatory compliance is important evidence, but it should not be confused with a complete answer to civil liability. A device may be licensed yet still be used negligently; a hospital may breach a duty even where the device itself is not defective.

4.4 Bharatiya Nyaya Sanhita, 2023

Criminal liability may arise in a sufficiently serious case where the statutory elements of an offence are established. Section 106(1) of the Bharatiya Nyaya Sanhita, 2023 addresses causing death by negligence and includes a specific provision concerning a registered medical practitioner performing a medical procedure. The provision must be read with its text, definitions and applicable procedural law.

It should not be treated as creating automatic criminal liability whenever a patient dies during robotic surgery.

The principles in Jacob Mathew remain relevant to the caution required before prosecuting medical professionals for negligence, subject to the current statutory framework. Criminal responsibility is personal and depends on proof of the required degree of negligence and other legal elements. A product defect or institutional failure may raise separate questions about the conduct and liability of other actors.

4.5 Contract, Consumer Service and Hospital Responsibility

The relationship between a patient and a hospital may involve contractual obligations, consumer-service obligations and duties arising in tort. A hospital may be responsible for its own acts and omissions, including the provision of deficient facilities, failure to maintain equipment, inadequate staffing or failure to select appropriately trained personnel. Depending on the facts, principles of vicarious liability may also make an institution answerable for the acts of employees acting in the course of their employment.

The precise basis of liability depends on the nature of the relationship and the conduct complained of. A hospital cannot avoid all responsibility by describing the surgeon as an independent professional if the claim concerns the hospital's own systems, facilities or employees. Equally, a hospital is not automatically liable for every independent act of every doctor who uses its premises. The factual and legal relationship must be examined.

4.6 Data Protection and Cybersecurity

Robotic systems may generate sensitive patient information, including video, imaging, instrument telemetry, procedure logs and clinical records. The Digital Personal Data Protection Act, 2023 is relevant to digital personal data processed in India, subject to its scope, commencement and applicable rules. Healthcare institutions and technology providers should

assess their respective roles, lawful processing grounds, security safeguards, retention practices and response obligations under the law in force at the relevant time.

Cybersecurity is also a patient-safety issue. Unauthorised access, disruption or manipulation of a connected medical system could potentially affect treatment. This paper does not assume that every robotic system is remotely operated or internet-connected. The risk depends on system design and deployment. Hospitals should nevertheless assess connectivity, access controls, software updates, incident response and vendor access as part of clinical governance.

LIABILITY OF SURGEONS AND HEALTHCARE PROFESSIONALS

5.1 Professional Duty of Care

The surgeon remains responsible for exercising reasonable professional judgment before, during and after a robotic procedure. The use of advanced equipment does not transfer the surgeon's professional duty to the machine. The surgeon must determine whether the procedure is clinically appropriate, whether the patient is suitable, whether the surgeon has the necessary competence and whether the available team and equipment are adequate.

The duty is not a guarantee of success. A surgeon is not negligent merely because a known complication occurs. The relevant question is whether the surgeon acted with the care and skill reasonably expected in the circumstances, taking account of the particular procedure, available technology, professional standards and information reasonably available at the time.

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5.2 Training and Competence

Robotic systems may require platform-specific training and a learning curve. A surgeon's general surgical qualification does not necessarily establish competence to operate every robotic platform. Competence may depend on formal instruction, simulation, supervised cases, familiarity with emergency procedures and continuing education. Hospitals should have transparent credentialing criteria and periodically review performance.

A surgeon who undertakes a procedure without adequate training may breach the duty of care if the lack of competence contributes to injury. Conversely, where the surgeon has completed appropriate training and follows reasonable protocols, an unforeseen system malfunction may not establish negligence. The inquiry should focus on the actual level of competence required and the evidence of training available.

5.3 Intraoperative Monitoring and Conversion

Robotic assistance does not eliminate the surgeon's obligation to monitor the patient and the procedure. The surgeon must respond appropriately to warnings, loss of visualisation, abnormal instrument behaviour and other signs of danger. Depending on the procedure, a safe plan may require the ability to pause, undock, convert to laparoscopic or open surgery, or otherwise manage the complication.

A failure to convert is not automatically negligent. The question is whether conversion was clinically indicated and whether a reasonable surgeon in the same circumstances would have taken that step. The decision must be evaluated with reference to the information available at the time, not solely by hindsight.

5.4 Reliance on the Robotic System

A surgeon may reasonably rely on equipment that has been properly approved, maintained and used according to its instructions. But reliance cannot be absolute. Professional responsibility includes understanding the system's known limitations, recognising warning signs and exercising independent clinical judgment. A surgeon cannot defend an obviously unsafe decision merely by stating that the machine produced an output.

The opposite position is equally important. A surgeon should not be held automatically responsible for an obscure internal defect that could not reasonably have been identified through ordinary professional checks. Where the defect lies within the manufacturer's control and the surgeon followed the prescribed protocol, product liability may be more appropriate than a finding of professional negligence.

5.5 Civil and Criminal Liability

Civil liability may arise where the elements of negligence are established. Criminal liability requires satisfaction of the relevant offence and a higher level of culpability where the law so requires. The distinction protects medical practice from being judged solely by outcomes. In a robotic procedure, the presence of technical complexity should neither lower the standard of care nor create an assumption of criminal fault. Expert evidence may be required to explain the system's operation, the clinical standard and the causal sequence.

5.6 Practical Illustration

Assume a surgeon is operating a robotic platform and receives a clear warning that an instrument is malfunctioning. The surgeon ignores the warning and continues, causing injury. If the warning was understandable, the risk was foreseeable and a reasonable response could have prevented the harm, the surgeon may face a negligence claim. Now assume the system gives no warning because of a latent software defect that was not reasonably discoverable by the surgeon. The liability analysis may shift toward the manufacturer or service provider, depending on the defect, control and evidence. These examples show why liability must be fact-specific.

INSTITUTIONAL LIABILITY OF HOSPITALS

6.1 Hospital as a Healthcare Institution

Robotic surgery is not delivered by the surgeon alone. The hospital selects or leases the system, provides the operating theatre, employs or contracts technical staff, arranges sterilisation and maintenance, establishes emergency procedures and determines who may use the platform. These functions create independent institutional responsibilities.

A hospital may be liable for its own negligence where it fails to provide a reasonably safe system of care. It may also be vicariously liable for negligent acts of employees acting within the scope of employment, depending on the legal relationship. The analysis should distinguish direct institutional negligence from vicarious liability for another person's conduct.

6.2 Procurement and Due Diligence

Before acquiring a robotic platform, a hospital should consider the intended clinical use, regulatory status, compatibility with existing facilities, service arrangements, consumables, training requirements and total lifecycle costs. Procurement should not be driven solely by commercial prestige or marketing claims. The hospital should assess whether the platform is suitable for the procedures it intends to perform and whether sufficient clinical volume and expertise exist to use it safely.

Failure to conduct reasonable due diligence may contribute to institutional negligence if an avoidable risk materialises. The hospital's obligations may also be shaped by applicable regulatory requirements, contractual warranties and professional standards.

6.3 Credentialing and Privileging

Hospitals should establish criteria for granting robotic-surgery privileges. These may include recognised qualifications, platform-specific training, supervised experience, simulation assessments, procedure-specific competence and periodic review. Credentialing should not be a purely administrative exercise. It should be linked to patient safety and the actual complexity of the procedures undertaken.

A hospital that allows a surgeon to use a robotic platform without checking competence may face liability if the lack of credentialing contributes to harm. A manufacturer's training certificate may be relevant but should not necessarily be treated as a complete substitute for independent institutional assessment.

6.4 Maintenance, Servicing and Updates

Hospitals should maintain records of inspections, repairs, calibration, sterilisation, software versions, service bulletins and updates. A device may become unsafe if maintenance is delayed or if a known safety notice is ignored. At the same time, software updates should be managed carefully because an update may affect compatibility, workflow or device performance. Hospitals should have documented procedures for testing and approving updates before clinical deployment.

Where the hospital controls maintenance or engages a service provider, a failure to perform the agreed or reasonably required service may support a claim based on negligence, contract or product-service liability, depending on the facts.

6.5 Emergency Preparedness and Team Training

A robotic operating theatre requires coordinated work among the primary surgeon, bedside assistant, anaesthesia team, nursing staff and technical personnel. The hospital should establish procedures for system failure, emergency undocking, conversion to conventional surgery, power interruption and other foreseeable contingencies. Training should involve the team rather than only the console surgeon.

The hospital's responsibility is not to eliminate all risk. It is to take reasonable steps to anticipate and manage foreseeable risks associated with the technology it chooses to deploy.

6.6 Vicarious Liability and Direct Liability

A hospital may be directly liable for deficient systems, facilities or supervision. It may also be

vicariously liable for an employee's negligence in appropriate circumstances. The Supreme Court's medical-negligence jurisprudence recognises that hospitals can be responsible for the acts of staff and for institutional failures. Spring Meadows Hospital v Harjol Ahluwalia and Savita Garg v Director, National Heart Institute are relevant to understanding institutional accountability, although neither should be described as a robotic-surgery decision.

The distinction matters because a hospital cannot avoid a claim concerning its own maintenance or credentialing failures by pointing to the surgeon. Equally, the fact that a procedure occurred in a hospital does not establish institutional negligence without proof of a relevant duty and breach.

PRODUCT LIABILITY AND RESPONSIBILITY OF MANUFACTURERS

7.1 Product Liability under the Consumer Protection Act, 2019

The product-liability chapter of the Consumer Protection Act, 2019 offers a statutory route where harm is caused by a defective product. Section 84 identifies grounds for manufacturer liability, including manufacturing defect, design defect, deviation from specifications, failure to conform to express warranty and inadequate instructions or warnings. Section 85 deals with product service providers, including deficient services and omissions or negligence that cause harm. Section 86 sets out circumstances in which a product seller may be liable. Section 87 contains exceptions, including certain cases of misuse, alteration or modification.

These provisions may be relevant to robotic surgical systems, instruments, accessories and qualifying software. A patient would still need to identify the relevant defendant and establish the statutory elements. The Act should not be interpreted as making the manufacturer an insurer against every complication or every unsuccessful procedure.

7.2 Manufacturing Defect and Design Defect

A manufacturing defect concerns a product that departs from its intended specifications or design. A design defect concerns the safety of the design itself. In a robotic system, a manufacturing defect might involve a component that fails to meet specifications. A design defect might involve a foreseeable risk created by the architecture of the instrument or a control interface that fails to provide adequate safeguards.

The assessment of defectiveness may require technical expert evidence, comparison with

specifications, risk analysis, testing records and the manufacturer's design documentation. A court should distinguish a defect from an inherent risk that was adequately disclosed and reasonably controlled. The existence of a known risk does not necessarily prove that the product was defective, but a failure to design against an unreasonable and foreseeable risk may be relevant.

7.3 Warnings and Instructions

Robotic systems are complex products that may be intended for use only by trained professionals. Instructions should explain appropriate use, contraindications, limitations, maintenance, emergency procedures and known risks. Warnings must be sufficiently clear to support safe use by the intended professional user. The manufacturer's obligation may extend to communicating important safety updates and product recalls where required by law and the circumstances.

A manufacturer may argue that the device was used contrary to instructions or that the relevant danger was obvious to a trained professional. Section 87 contains statutory exceptions that must be considered. The facts of the case, the adequacy of the warning and the professional context will be important.

7.4 Product Service Providers and Sellers

Robotic systems often depend on installation, maintenance, calibration, technical support and software services. A service provider may be liable under section 85 where the service is deficient or where an omission, negligence or failure to warn causes harm. A seller may be liable under section 86 in specified circumstances, including substantial control over design or testing, modification, independent warranty, inability to identify or proceed against the manufacturer in the statutory circumstances, or failure to exercise reasonable care in inspection or maintenance.

The distribution chain should therefore be examined rather than assuming that the original manufacturer is the only possible defendant. Importers, distributors, service providers and hospitals may have different roles and legal exposures.

7.5 Causation and Defences

A product-liability claim must establish a causal relationship between the defect or statutory

ground and the harm. The fact that a robotic system was used during surgery is not enough. The claimant may need to show that the defect caused or materially contributed to the injury. Defences may include misuse, unauthorised modification, failure to follow instructions or other statutory exceptions, depending on the claim and evidence.

Causation can be difficult where multiple factors operate together. A device may be defective, but the surgeon's conduct may also contribute. The law should permit the evidence to be assessed as a whole and should avoid forcing a patient to choose one defendant prematurely where the relevant facts are controlled by several participants.

7.6 Manufacturer's Post-Market Duties

A manufacturer's responsibilities do not necessarily end when a device is placed on the market. Applicable medical-device regulation may require quality systems, complaint handling, vigilance, corrective action and post-market monitoring. A manufacturer may also have obligations concerning software updates and safety communications. The precise duties depend on the device classification, regulatory permissions and applicable rules.

The 2026 CDSCO guidance on medical-device software is relevant to the regulatory treatment of software intended for medical purposes. It should be read with the Medical Devices Rules and the underlying statute. It does not itself create a general civil-liability code for AI or robotic surgery.

SOFTWARE, ARTIFICIAL INTELLIGENCE AND CAUSATION

8.1 Software as Part of the Medical Device

Modern medical devices may rely on embedded software, standalone medical-device software or software that controls or influences the functioning of hardware. The CDSCO framework recognises that software intended for medical purposes can fall within the medical-device definition. The regulatory question depends on the intended purpose and the product's characteristics, not simply whether the software is installed on a computer, mobile device or cloud platform.

For robotic systems, software may control movement, display images, process signals, monitor system status or provide decision-support information. A software failure may therefore have clinical consequences even where the mechanical components are functioning normally.

8.2 Distinguishing Automation from Autonomy

Automation performs a defined task according to programmed rules or instructions. Autonomy implies a greater capacity to select or execute actions without continuous human direction. Many robotic surgical systems are surgeon-controlled and should not be inaccurately described as autonomous. However, as systems incorporate more advanced decision-support and adaptive functions, the degree of human control may become more difficult to describe.

The legal allocation of responsibility should correspond to the actual system. Where the surgeon directly controls instrument movement, professional duties remain central. Where software independently recommends or performs a clinically significant action, the responsibilities of the manufacturer, deploying institution and supervising professional may require closer examination.

8.3 The Causation Problem

A patient may be able to prove that an injury occurred during a robotic procedure but may not know whether the cause was a mechanical fault, software error, user input, maintenance failure or a combination. Causation becomes especially difficult when the system is technically complex and the relevant information is held by the manufacturer or hospital.

Courts may need expert evidence from surgeons, biomedical engineers, software specialists and device-safety professionals. The evidence should be directed to specific questions: what happened, what the system recorded, what the operator saw, what warnings were available, what maintenance had been performed and whether the alleged defect or omission caused the injury. Expert evidence should explain technical matters without replacing the court's role in determining legal responsibility.

8.4 Evidence Preservation and Access

A robotic procedure may generate event logs, instrument telemetry, video recordings, system alerts, software version data, maintenance records and service communications. Such records may be crucial to reconstructing an incident. Hospitals and manufacturers should have clear procedures for preserving relevant data once an adverse event is reported or litigation is reasonably anticipated.

A patient should have a practical route to seek relevant records, subject to lawful protections for confidential information, cybersecurity and third-party data. The fact that a record is

technically complex should not make it inaccessible. Courts may use confidentiality protections, expert inspection and controlled disclosure to balance the interests involved.

8.5 Cybersecurity and Remote Access

Where a robotic system is network-connected or permits remote service access, cybersecurity risks may affect patient safety. Unauthorised access, malicious interference, compromised updates or system downtime may disrupt treatment. These risks should be assessed according to the actual system architecture; they should not be assumed for every device.

Hospitals and manufacturers should define responsibility for access control, vulnerability reporting, secure updates, audit logs and incident response. A cyber incident that causes injury may raise questions of negligence, product defect, regulatory compliance and data protection. The legal analysis must identify which party controlled the relevant security measure and whether the risk was reasonably foreseeable.

8.6 Algorithmic Opacity

Some AI systems produce outputs that are difficult for users to interpret. This is often described as the "black box" problem. In a medical context, opacity may make it difficult for clinicians to understand why a system generated a particular recommendation. It may also complicate a patient's ability to challenge the decision after harm occurs.

The response should not be to assume that every AI output is inexplicable. Many systems can provide documentation, performance information, version histories and explanations appropriate to their design. Regulatory and contractual requirements should encourage traceability, validation and meaningful information for clinicians. Where a manufacturer claims that a system is too complex to explain, that claim should not automatically defeat a patient's claim. Disclosure and expert procedures may help test the evidence.

INFORMED CONSENT, PRIVACY AND PATIENT RIGHTS

9.1 Informed Consent in Robotic Procedures

Consent is a process of communication, not merely the signing of a form. In Samira Kohli v Dr Prabha Manchanda, the Supreme Court explained important principles of valid consent, including the need for consent to the nature and purpose of treatment and the procedure proposed, subject to recognised exceptions. These principles are relevant where robotic

technology forms a material part of the proposed procedure.

A patient should receive information that is material to the decision, including the fact that robotic assistance will be used, the role of the surgeon, significant device-related risks, reasonable alternatives and the possibility that the procedure may need to be converted to a conventional approach. The level of detail will depend on the procedure, the patient's circumstances and professional standards. Consent should not be overloaded with technical detail that a patient cannot reasonably understand, but it must not conceal material information.

9.2 Does Robotic Use Require Separate Consent?

There may not be a universal legal rule requiring a separate form for every use of robotic assistance. The more appropriate question is whether the use of the technology is material to the patient's decision and whether the patient has been adequately informed. If robotic assistance changes the nature of the procedure, introduces material risks, affects available alternatives or is a significant feature of the treatment plan, disclosure is likely to be important. Hospitals should develop clear consent protocols that identify the system, explain the surgeon's role and disclose material risks in accessible language. The consent process should also allow the patient to ask questions and should be documented in the medical record.

9.3 Patient Autonomy and Human Oversight

The use of robotics should not diminish the patient's right to participate in treatment decisions. A patient may reasonably wish to know whether the surgeon will directly control the instruments, whether software will provide recommendations and whether any part of the procedure is performed with limited human intervention. The answer should be accurate and should not exaggerate the system's autonomy.

The principle of human oversight is especially important where AI-enabled systems influence diagnosis or treatment. A clinician should understand the intended use and limitations of the system sufficiently to interpret its output. The patient should not be led to believe that technology guarantees a better outcome.

9.4 Privacy and Confidentiality

Robotic procedures may produce sensitive recordings and technical data. Hospitals must ensure that such information is collected, used, stored and disclosed for lawful purposes and with

appropriate safeguards. Patient video, imaging and telemetry should not be used for product development, research or commercial purposes without a lawful basis and any required consent or ethics approval.

The DPDP Act, 2023 and applicable rules should be considered according to their commencement and the processing activity in question. Medical confidentiality and professional obligations continue to matter. A patient's right to access relevant records must be balanced with lawful protections, but confidentiality should not be used as a blanket reason to withhold information needed to investigate an alleged injury.

9.5 Right to Explanation and Records

A patient harmed during a robotic procedure should receive a meaningful explanation of the event, the immediate clinical response and the steps taken to investigate it. This does not mean that the hospital must speculate before facts are known. It means that communication should be timely, truthful and respectful. The patient should be informed of available records and the procedure for requesting them.

A transparent incident-response process can improve trust and may help resolve disputes. Concealment, alteration or unexplained loss of records may seriously undermine the credibility of the institution and obstruct access to justice.

COMPARATIVE LEGAL PERSPECTIVES

10.1 United Kingdom

The United Kingdom provides useful comparative material through its general law of negligence, product-liability legislation and medical-device regulation. The Consumer Protection Act 1987 establishes a statutory regime for damage caused by defective products. The Medicines and Healthcare products Regulatory Agency oversees the regulation of medical devices, including relevant post-market safety processes. The professional standards of the General Medical Council also inform the duties of doctors.

The UK Supreme Court's decision in Montgomery v Lanarkshire Health Board is important for informed consent. It emphasises the patient-centred duty to take reasonable care to ensure that a patient is aware of material risks and reasonable alternatives. The decision is not a robotic-surgery case, but its approach is relevant when considering disclosure of material risks associated with robotic assistance.

The UK framework illustrates the value of combining general negligence principles with product regulation and patient-centred consent. It does not, however, provide a complete answer to every question raised by software-driven or increasingly autonomous medical systems.

10.2 United States

The United States has developed substantial litigation and regulatory experience involving medical devices and robotic-assisted surgery. Product-liability claims may be brought under state law, while the Food and Drug Administration regulates medical devices and receives adverse-event reports. The FDA's MAUDE database is a source of reported device-related adverse events, but reports are not necessarily proof that a device caused the event and may be incomplete or subject to reporting limitations.

US scholarship identifies training, informed consent, device malfunction and allocation of responsibility as recurring medicolegal issues in robotic surgery. The US experience is useful for understanding the kinds of evidence that may arise in litigation, but its legal rules should not be transplanted directly into India. The federal structure, tort law and regulatory pathways differ.

10.3 European Union

The European Union's Medical Device Regulation (EU) 2017/745 establishes a detailed regulatory framework for medical devices, including requirements concerning conformity assessment, clinical evaluation, vigilance and post-market surveillance. The EU Artificial Intelligence Act, Regulation (EU) 2024/1689, introduces a risk-based framework for AI systems, with high-risk requirements applying to relevant categories and subject to the Regulation's scope and transitional timetable.

The revised Product Liability Directive (EU) 2024/2853 is particularly relevant to digital products and complex technology. It expressly addresses difficulties that claimants may face in proving defectiveness and causation in technically or scientifically complex cases. It also recognises software and certain related services within the modern product-liability framework. Member States must transpose the Directive according to its implementation timetable; it should not be treated as already identical law in every Member State.

The EU approach demonstrates the importance of aligning product regulation, AI governance

and civil liability. For India, the lesson is not to copy the EU regime wholesale, but to consider clearer rules for software updates, technical evidence, post-market monitoring and access to information.

10.4 Lessons for India

The comparative material suggests four practical lessons. First, medical-device regulation and civil liability should be coordinated but not confused. Second, consent should be based on material risks and patient understanding. Third, manufacturers and institutions should preserve information needed to investigate adverse events. Fourth, the law should address the evidentiary imbalance that arises when technical information is controlled by a manufacturer or hospital.

India should adapt these principles to its own statutory structure, healthcare system and institutional capacity. A reform model should be proportionate, enforceable and sensitive to the difference between surgeon-controlled robotics and more autonomous AI-enabled systems.

FINDINGS AND CRITICAL ANALYSIS

11.1 Existing Law Provides Multiple Routes, but They Are Fragmented

The first finding is that Indian law is not entirely silent on robotic medical failures. Tort principles may address professional and institutional negligence; consumer law may address deficiency in medical services and product liability; medical-device regulation governs the safety and performance of regulated devices; contract law may apply to relevant service arrangements; and criminal law may apply in exceptional cases where the statutory elements are established. The challenge is that these routes are not presented to patients as one coherent process for investigating a complex robotic incident.

The existence of several causes of action can be beneficial because different defendants may be responsible for different failures. Yet fragmentation may increase cost and complexity. A patient may have to identify the correct defendant, obtain expert evidence and distinguish a device defect from professional negligence before the relevant information is accessible.

11.2 The Surgeon-Centred Model Is Incomplete

The surgeon remains central to patient care, but the surgeon is not the only actor who controls risk. The hospital controls procurement, credentialing and maintenance; the manufacturer

controls design and much of the technical documentation; and service providers may control installation and repair. A legal analysis that begins and ends with the surgeon risks overlooking these independent duties.

At the same time, distributed responsibility must not become diluted responsibility. The surgeon's duty of professional care remains real. The hospital's duty to provide safe systems remains real. The manufacturer's product obligations remain real. The purpose of a distributed model is to identify the correct duty-bearer, not to make responsibility disappear among multiple actors.

11.3 The Evidentiary Imbalance Is a Central Problem

Technical evidence is often held by parties other than the patient. This includes device logs, software updates, maintenance records, incident reports and internal safety communications. Without preservation and disclosure, the patient may be unable to determine what happened. Courts can address this through discovery, expert inspection and appropriate evidentiary orders, but a clearer incident-preservation protocol would reduce avoidable disputes.

The problem is especially acute where a system is updated after an event or where data retention is limited. A hospital should preserve the relevant version and records once an incident is identified. Manufacturers should cooperate with lawful investigations and preserve technical evidence within their control.

11.4 Regulatory Compliance Is Not the Same as No Liability

Regulatory approval or compliance is important, but it is not a universal defence to negligence or product liability. Approval indicates that the device has passed the applicable regulatory pathway for its intended use; it does not prove that every use was appropriate, that every maintenance task was completed or that no defect could exist. Similarly, a device's regulatory status should not be treated as irrelevant. It may inform the standard of care and the assessment of product safety.

Courts should therefore consider regulatory evidence alongside clinical records, technical logs, expert opinions and the conduct of each defendant.

11.5 Avoiding Automatic Liability

A patient-centred system must also avoid imposing liability merely because a robotic procedure

failed. Medical treatment involves uncertainty, and an adverse outcome may occur despite reasonable care. Strict liability should arise only where a statute or recognised doctrine provides for it. Product-liability provisions must be applied according to their terms. Negligence claims must establish breach and causation. This balance is necessary to protect patients without treating healthcare providers as guarantors of success.

11.6 Need for a Structured Allocation Test

A useful analytical test should ask: (1) what specific risk materialised; (2) which actor owed a duty relevant to that risk; (3) who had control over the relevant decision, component or process; (4) what information was reasonably available to that actor; (5) what reasonable preventive step could have been taken; (6) whether the omission or defect caused or contributed to the injury; and (7) whether another actor's conduct also contributed. This test does not replace statutory elements. It is a practical framework for organising evidence and applying existing law.

RECOMMENDATIONS AND PROPOSED ACCOUNTABILITY FRAMEWORK

12.1 Adopt a Responsibility-Mapping Approach

Hospitals and regulators should use a responsibility map for robotic procedures. The map should identify the surgeon, bedside team, hospital department, biomedical engineering unit, manufacturer, importer and service provider. It should record who is responsible for clinical decisions, device operation, maintenance, updates, training, incident reporting and data preservation. This would not predetermine legal liability, but it would make duties clearer before an incident occurs.

12.2 Minimum Credentialing and Competency Standards

Hospitals should establish written criteria for robotic-surgery privileges. These should include platform-specific training, supervised practice, simulation where appropriate, emergency-conversion competence and periodic review. Credentialing should be procedure-specific where the risks and skills differ. National professional bodies and regulators may consider developing model standards in consultation with surgeons, hospitals, engineers and patient representatives. The objective should be competence, not a rigid numerical threshold divorced from clinical context. Case volume may be relevant, but it should be considered with observed skill,

outcomes, supervision and the complexity of the procedure.

12.3 Mandatory Incident Reporting and Investigation

A proportionate reporting system should capture serious adverse events and significant device malfunctions involving robotic systems. Reports should distinguish between suspected device malfunction, user error, maintenance failure, cybersecurity incident and unexplained event. Reporting should support learning and regulatory vigilance rather than automatically imply fault. Confidentiality and protection against misuse of reporting data should be considered, while preserving accountability for serious negligence or concealment.

12.4 Preserve Logs and Technical Records

Hospitals should preserve system logs, video where lawfully collected, device identifiers, software versions, maintenance history, training records, service communications and relevant clinical records after a serious incident. Manufacturers and service providers should preserve technical records within their control. A common protocol should define retention periods, access, integrity checks and disclosure procedures. Any protocol must comply with privacy and data-protection requirements.

12.5 Strengthen Product and Software Transparency

Manufacturers should provide clear instructions, warnings, maintenance requirements, known limitations and update information to professional users. Where software materially affects device performance, documentation should identify version history, relevant safety changes and known failure modes. Regulators should encourage traceability and post-market monitoring. The CDSCO's 2026 medical-device software guidance provides a regulatory foundation for software-related compliance, but further sector-specific operational guidance may be useful for complex robotic systems.

12.6 Improve Patient Consent

Hospitals should use consent materials that explain the role of robotic assistance in plain language. The patient should be informed of material risks, the surgeon's role, relevant alternatives and the possibility of conversion to conventional surgery. The process should not promise superior outcomes or describe a surgeon-controlled system as autonomous. Where a

system has a meaningful autonomous function, that function should be explained with particular care.

12.7 Create a Technical Expert Panel or Roster

Courts and consumer commissions may face difficulty evaluating evidence involving robotics, software and biomedical engineering. A roster of independent experts with relevant technical and clinical expertise could assist in appropriate cases. Experts should disclose conflicts of interest, explain limitations and avoid deciding the ultimate legal question. A structured expert process may reduce delay and improve the quality of adjudication.

12.8 Clarify Allocation Where Multiple Actors Contribute

Where more than one defendant's conduct contributes to the same injury, courts should apply existing principles governing causation, contribution and joint liability according to the facts and applicable law. The law should avoid both extremes: imposing the entire burden on the surgeon without examining a proven product defect, or allowing each participant to blame another until the patient is left without an effective remedy. A clear statutory or regulatory explanation of record access and cooperation could assist this process.

12.9 Consider a National Guidance Framework

India should consider a national guidance framework for robotic healthcare accountability developed by the Ministry of Health and Family Welfare, CDSCO, professional medical bodies and relevant technical experts. The framework could address credentialing, consent, maintenance, cybersecurity, incident reporting, data preservation and post-market communication. It should be periodically reviewed as technology develops and should distinguish between different levels of autonomy and clinical risk.

12.10 Proposed Accountability Matrix

The following matrix is a practical guide, not a rule of automatic liability:

Surgeon: clinical indication, patient selection, professional competence, operation, monitoring and response to warnings.

Hospital: procurement, credentialing, staffing, maintenance oversight, operating protocols, emergency preparedness and record preservation.

Manufacturer: design, manufacture, testing, instructions, warnings, regulatory compliance, safety updates and post-market action.

Importer or seller: obligations applicable to the distribution chain, product information, warranty and statutory seller liability.

Service provider: installation, calibration, repair, maintenance and service-related warnings.

Software provider: duties arising from the product's role, contract, applicable medical-device regulation, defect or negligent service, and control over updates.

The matrix should be applied with attention to actual control and causation. It is not a claim that every category of actor is liable in every case.

12.11 Protect Innovation While Prioritising Patients

Regulation should be sufficiently clear to encourage responsible innovation. Excessively broad or automatic liability may discourage hospitals from adopting useful technology and may make manufacturers reluctant to introduce improvements. Conversely, weak accountability can undermine patient trust and permit preventable risks to persist. A balanced framework should encourage reporting, learning and correction while preserving compensation and legal remedies where the elements of liability are established.

CONCLUSION

13.1 Conclusion

Robotic technology has created important possibilities for modern healthcare, but it has also complicated the legal relationship between patients, medical professionals, hospitals and manufacturers. A robotic procedure is not simply a conventional operation performed with a more advanced instrument. It is a coordinated process involving clinical judgment, specialised equipment, software, technical support and institutional governance. When harm occurs, the legal inquiry must reflect that reality.

The central conclusion of this research is that the surgeon should not automatically be treated as the sole person responsible for every robotic medical failure. The surgeon remains under a professional duty to act with reasonable care, understand the system's limitations, operate within the limits of competence and respond appropriately to foreseeable risks. But hospitals also control important aspects of safety, including procurement, credentialing, maintenance, staffing and emergency arrangements. Manufacturers and service providers may be responsible

where defective design, manufacturing, inadequate warnings or deficient services cause harm. Software providers may also be relevant where their product or service falls within the applicable legal framework and contributes to the injury.

Indian law already contains several legal mechanisms that may apply. The law of torts and medical negligence can address professional and institutional failures. The Consumer Protection Act, 2019 provides routes for deficiency in services and product-liability claims. The Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2017 regulate medical devices, including qualifying software. Criminal law may apply in exceptional cases where its specific requirements are met. The existence of these mechanisms is important, but their application to complex robotic incidents can be difficult because the evidence is distributed among several actors and the technical chain of causation may not be apparent to the patient.

The paper therefore supports a responsibility-mapping approach. Liability should be assessed by identifying the risk that materialised, the duty owed by each actor, the actor's control and knowledge, the reasonable steps available to prevent the harm and the causal contribution of the alleged breach or defect. This approach avoids the unfairness of placing the entire burden on a surgeon where the decisive failure was outside the surgeon's reasonable control. It also prevents the use of technology as a shield where a surgeon or hospital failed to meet ordinary professional or institutional obligations.

The research further concludes that procedural reform is as important as substantive law reform. Patients need access to meaningful explanations and relevant records. Hospitals and manufacturers should preserve event logs, software versions, maintenance records and incident communications. Training and credentialing should be structured. Consent should explain the material role of robotic assistance without exaggerating its capabilities. Regulators should encourage traceability, post-market monitoring and transparent safety communication. Courts and consumer commissions should have access to independent technical expertise where necessary.

India may not need to create a wholly separate legal personality or an entirely new tort system for robotic devices. The more immediate need is to clarify how existing duties apply when technology participates in medical care and to improve the mechanisms through which evidence is preserved, disclosed and evaluated. A machine cannot simply become the final destination for legal blame. Responsibility must remain traceable to the people and institutions that design, supply, select, operate, maintain and supervise it.

Ultimately, technological advancement in healthcare must be measured not only by precision or efficiency, but also by the strength of the protections available to patients when something goes wrong.

The law must move beyond the assumption that every medical failure is a failure of the surgeon, while ensuring that the presence of a robot never becomes an excuse for the absence of accountability.

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