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Medical Consent and Criminal Liability in High-Risk Surgeries: The Legal Advocate's Role

DEMAN BAGHLA¹ AND KIRTI SHARMA²

ABSTRACT

This research explores how informed consent can increase criminal accountability in hazardous surgical procedures in India, and outlines the preventive and litigation duties of lawyers. Additionally, By using a theoretical doctrinal approach, the paper examines constitutional guarantees under Article 21, penal thresholds (including IPC Section 304A now Bharatiya Nyaya Sanhita Section 104), procedural protections like CrPC Section 438 and inherent powers under Section 484/BNSS equivalents, regulatory responsibilities under the National Medical Commission Act and Code of Medical Ethics, evidentiary reforms under the Consumer Protection Act, 2019, and consumer-law remedies under these regulations. It demonstrates that clinical uncertainty in complex surgeries becomes a legal matter when disclosure, capacity assessment, and contemporaneous documentation are inadequate. Furthermore, it indicates that most unfavorable outcomes are civil or regulatory matters unless evidence indicates gross or reckless departure warranting criminal sanction. Specifically, the paper presents advocates who believe that such measures as institutionalised consent SOPs, forensic-grade record preservation, early procedural interventions (anticipatory bail and quelling proceedings), calibrated pre-prosecution medical triage, and mediation/ADR pathways can help reduce avoidable criminalisation. By emphasizing statutory literacy and practical templates, the study seeks to preserve patient autonomy while maintaining a legal framework that allows for accountable, evidence-based clinical judgment without excessive fear of punishment.

Keywords: *informed consent; high-risk surgery; Section 104 BNS; National Medical Commission; medico-legal evidence.*

I. INTRODUCTION

Objectivist risk-stratification tools, patient comorbidities, and institutional capacity are used to classify procedures as high-risk surgeries as those where the expected probability of major morbidity or death was significantly higher than that predicted for regular operations. Clinical

¹ Author is an Advocate at Punjab and Haryana High Court, India.

² Author is an Advocate at Punjab and Haryana High Court, India.

decisions, peri-operative optimization, and the need for explicit risk communication are driven by uncertainty. This is a reality that is acknowledged in medical literature and adherence to surgical care protocol, which treats risk as measurable but not eliminate able.³

Due to the law's emphasis on expectations and thresholds, clinical uncertainty has direct legal consequences. This can be exemplified by the consent, documentation, and professional standards required meeting ethical standards, which enable surgeons to perform their surgical duties as required. As part of their professional duties, the National Medical Commission and earlier Medical Council regulations mandate strict consent and record-keeping, and courts or regulators frequently use those standards as grounds for assessing claims of negligence or misconduct. When there are no procedural safeguards in place, such as informed consent and contemporaneous records, what is clinically acceptable may be subject to legal risk.⁴

The overarching rights framework of Indian constitutions amplifies the risks associated with surgery, as Article 21 safeguards personal liberty and life, while also enforcing patient autonomy within fundamental rights discourse. This is supported by the inclusion of bodily integrity, dignity, and informed medical decision-making. The constitutional aspect of this issue means that failures in communication or consent can be framed as violations of fundamental liberties, regardless of whether they are contractual or tortuary. This has an impact on remedies, the level of judicial scrutiny, and the public policy narrative surrounding medical accountability. Among the criminal categories listed in Section 98 and Section 103 of the Bharatiya Nyaya Sanhita are culpable murders, which are motivated by intention or knowledge, while Section 104 criminalize deaths caused by a negligent act and are typically used in legal proceedings arising from medical practice. Due to the legal differentiation between intentional harm and negligent harm in these provisions, the key question for surgical adverse events is whether their conduct exceeded the statutory threshold for clinical risk to be considered criminally actionable negligence.⁵

Section 484 anticipatory bail requirement affects clinicians, as does the criminal procedure regulations that regulate the lived risk of clinician-auditor pairs. BNSS) and the inherent powers of courts to detain individuals and make remedial requests. The BNSS are instrumental in

³ *Risk stratification tools for predicting morbidity and mortality in adult patients undergoing major* AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS, https://www.researchgate.net/publication/313431144_Risk_stratification_tools_for_predicting_morbidity_and_mortality_in_adult_patients_undergoing_major_surgery_qualitative_systematic_review (last visited Sep 10, 2025)

⁴ Pranab Rudra et al., *Large language models for surgical informed consent: an ethical perspective on simulated empathy*, JOURNAL OF MEDICAL ETHICS (2025)

⁵ *Culpable homicide under Bhartiya Nyaya Sanhita*, 2023 IPLEADERS, <https://blog.ipleaders.in/culpable-homicide-under-indian-penal-code/> (last visited Sep 10, 2025)

determining whether a practitioner is placed under custody, subject to protracted investigation, or granted early judicial relief. In practice, these procedural provisions interact with evidentiary realities (medical records, expert testimony) to determine the ease of launching criminal processes after a negative high-risk outcome.⁶

The landscape is complicated by the combination of civil and consumer-law remedies, as the Consumer Protection Act, 2019 recognizes healthcare as a "service" and considers "deficiency of service" as actionable. Given the disparity in standards, remedies and incentives between consumer and civil forums, a minor incident during hematologic high-risk surgery can result in multi-forum proceedings across regulatory, civil/consumer.

Other duties are derived from regulatory law, such as the NMC Act and professional codes, which allow for the creation and enforcement of professional conduct by regulatory boards. Institutions must comply with NMC rules and the Code for high-risk settings due to their regulatory obligations serving as both preventive measures and evidentiary indicators, which can help them avoid disputes.

In high-risk surgery, medical ethics and legal commentary emphasize the importance of informed consent, voluntary consent (including disclosure of material risks, alternatives, and realistic outcomes), and perfunctory or generic consent forms are a common source of legal risk.

II. INDIAN LEGISLATION AND REGULATION FRAMEWORK.

The legal framework for high-risk surgery in India is a combination of constitutional protections, penal laws, criminal justice system, medical profession regulatory requirements, civil remedies, and evidence regulations. Indian law now recognizes bodily integrity and the right to make informed medical decisions, which are derived from Article 21 of the Constitution.⁷ Statutory bodies such as the Bharatiya Nyaya Sanhita, BNSS, National Medical Commission Act (NMC Act), and CPA act to establish duties, offences, and procedures that impact clinicians and hospitals' legal exposure in high-risk surgical care.

A. Constitutional safeguards encompass the protection of the right to life, liberty and Article 21

⁶ *Key Changes in Anticipatory and Regular Bail Under BNSS Act, 2023* ADVOCATE ROHIT DANDRIYAL, <https://advocaterohitdandriyal.com/difference-between-interim-bail-anticipatory-bail-and-regular-bail-under-the-new-law-criminal-law-bnss-advocate-rohit-dandriyal/> (last visited Sep 10, 2025)

⁷ ARTICLE 21: PROTECTION OF LIFE AND PERSONAL LIBERTY CONSTITUTION OF INDIA, <https://www.constitutionofindia.net/articles/article-21-protection-of-life-and-personal-liberty/> (last visited Sep 10, 2025)

Article 21, which guarantees that no person shall be deprived of their life or personal freedom without following a law-established procedure, is not solely based on constitutional protection, as courts and commentators view it as the foundation for exercising the right to health care in medical settings. By using a constitutional lens, the legal framework enhances the examination of consent procedures in court and policy, necessitating that it be meaningful rather than just informal documentation.⁸

B. The Bharatiya Nyaya Sanhita has specific provisions that apply to medical practice, including sections 98-103, 104 and 113-123.

The BNS outlines criminal liability as part of the gradations of culpability for surgical outcomes. According to Section 98, "culpable homicide" is defined by intention and knowledge (*mens rea*), and Section 103 separates it from murder based on intent and circumstances. These sections are conceptually distinct from Section 104 which criminalizes "causing death by a negligent act," and this provision is the most prevalent statutory provision in fatal medical mishaps. Statutes 113-123 and Section 114 provide legal justifications for serious bodily harm offences that involve non-fatal but life-threatening injuries. Defence lawyers must locate the alleged conduct in the BNS taxonomy and demonstrate that it did not include an intentional offence or fall under Section 104 as gross negligence.⁹

C. Regulations such as the National Medical Commission's guidelines and the Code of Medical Ethics are in place.

A separate pathway to professional responsibility exists through the implementation of regulatory law. According to the National Medical Commission Act, 2019, regulatory boards (including the Ethics and Medical Registration Board) are empowered to establish standards, receive complaints, and take disciplinary actions under statutory procedures; the Code of Medical Ethics (MCI/NMC Ethics Regulations, 2002 and subsequent regulations) mandates patient-specific obligations such as providing informed consent, maintaining contemporaneous clinical records, or following professional guidelines. When individuals do not fulfill their statutory or criminal obligations, they may be subject to removal from registers and show-cause processes, as well as professional sanctions that operate independently of and at the same time. The key to success for high-risk surgery practitioners is their strict adherence to NMC regulations and the Code of Medical Ethics, which includes written documentation, sign-offs,

⁸ *The right to life and personal liberty under Article 21: A TIMELINE SUPREME COURT OBSERVER*, <https://www.scobserver.in/journal/the-right-to-life-and-personal-liberty-under-article-21-a-timeline/> (last visited Sep 10, 2025)

⁹ *Judex Tutorials JUDEX TUTORIALS*, <https://judextutorials.com/blog/culpable-homicide-and-murders-in-bns> (last visited Sep 10, 2025)

and capacity notes.¹⁰

Table 1 — NCRB: Reported deaths “due to medical negligence” (selected years)

Year	Reported deaths due to medical negligence (NCRB ADSI category)	Source
2018	218	NCRB ADSI reporting (2018). (The Times of India, OpenCity)
2019	201	NCRB ADSI reporting (2019). (The Times of India)
2020	133	NCRB ADSI reporting (2020; pandemic year effects). (The Times of India)

D. Consumer protection and tort liability put on a whole criminal exposure

Civil remedies are put on another axis of exposure. The Consumer Protection Act, 2019 recognizes the word "service" inclusively in Section 2(42); deficiency is defined under Section 2(11) so that paid medical care falls within the scope of service whenever there is an act or omission with respect to quality, safety or information duties: thus, consumer fora have remained a routine venue for claims of medical negligence or deficiency of service alongside processes of professional disciplinary and criminal nature. This coexistence of consumer, civil, and criminal fora means that a single adverse high-risk surgical outcome may give birth to litigation in several fora, and this itself would necessitate the litigant's strategy to coordinate its admissions, preserving of evidence and settlement options with potential impact in separate fora.¹¹

E. Case Laws

Samira Kohli v. Dr. Prabha Manchanda & Anr¹² The importance of genuine or informed consent in medical interventions was highlighted by the Court, which mandates that it must be specific to the procedure, conveyed in a language understood by patients, and recorded. For major or non-routine procedures, blanket/admission-stage consent is not sufficient; any lack of informed permission raises independent civil and disciplinary action.

¹⁰ *Ethics & Medical Registration Board NMC*, <https://www.nmc.org.in/autonomous-boards/ethics-medical-registration-board/> (last visited Sep 10, 2025)

¹¹ *Consumer Protection Act, 2019: Everything to know about it* IPLEADERS, <https://blog.ipleaders.in/consumer-protection-act-2019/> (last visited Sep 10, 2025)

¹² *Samira Kohli v. Dr. Prabha Manchanda & Anr*. AIR 2008 SC 1385 / INSC 56

Jacob Mathew v. State of Punjab & Anr¹³ The ruling established restrictions on frivolous criminal prosecutions of physicians, stating that medical malpractice liability necessitates evidence of impropriety or gross negligence rather than error of judgment. Additionally, the verdict changed the way private complaints were handled, altering the legal and procedural framework for Section 104 cases.

Indian Medical Association v. V.P. Shantha & Ors¹⁴ The Court ruled that paid medical services are covered by the Consumer Protection Act, which means that hospital and practitioner behavior can be considered within consumer contexts. This ruling has broadened non-criminal remedial options for patients and confirmed that consumer adjudication complements criminal or regulatory scrutiny in unfavorable surgical outcomes rather than replacing them.

Poonam Verma v. Ashwin Patel & Ors¹⁵ Professional competence and negligence were both emphasized by the Court, with treating practitioners being required to act within their recognized system/scope of practice. The court held that negligence can manifest in multiple ways, including omission, practicing beyond competence, and potentially leading to criminal charges.

Dr. Laxman Balkrishna Joshi v. Dr. Trimbak Babu Godbole¹⁶ The pivotal ruling of SC 128 (1968/1969) defined the dual roles of a consulting doctor, which encompassed making decisions on case management, treatment, and administration, as well as employing principles like *res ipsa loquitur* to support negligence, while also setting benchmarks for future consent and negligence analyses. These standards were later applied in both cases.

Dr. Mukhtiar Chand & Ors. v. State of Punjab & Ors¹⁷ A report on the state is available in Punjab and its territories (1998). SCC 579. The Court examined the limits of practice and regulations, such as prescription rights across medical systems, and highlighted how statutory/regulatory compliance affects civil and criminal culpability, emphasizing that regulatory breach can influence professional discipline and evidentiary narratives in prosecutions.

Kusum Sharma & Ors. v. Batra Hospital & Medical Research Centre & Ors.¹⁸ In the Court,

¹³ Jacob Mathew v. State of Punjab & Anr., (2005) 6 SCC 1

¹⁴ Indian Medical Association v. V.P. Shantha & Ors., (1995) 6 SCC 651 / AIR 1996 550

¹⁵ Poonam Verma v. Ashwin Patel & Ors., 1996 SCC (4) 332

¹⁶ Dr. Laxman Balkrishna Joshi v. Dr. Trimbak Babu Godbole, AIR 1969 SC 128 (1968/1969)

¹⁷ Dr. Mukhtiar Chand & Ors. v. State of Punjab & Ors., (1998) 7 SCC 579

¹⁸ Kusum Sharma & Ors. v. Batra Hospital & Medical Research Centre & Ors., (2010) 3 SCC 480 / MANU/SC/0098/2010

it synthesized principles of medical negligence for civil/consumer law including duty of care, breach, and causation while advising against linking an unfortunate outcome with guilt; this decision also restated the need for strong evidence of negligence and provided further protection to practitioners from unjustified criminalization.

Calcutta Medical Research Institute vs Bimalesh Chatterjee I¹⁹ The National Consumer Commission highlighted the need for the complainant to demonstrate their lack of evidence and negligence, while also highlighting the importance of evidentiary standards in medical disputes, which is an essential counterbalance to speculative criminal charges related to surgical complications.

III. MEDICAL LEGAL DOCTRINE CENTERS ON MEDICATION AND TREATMENT.

A. Consent is based on the principles of autonomy, informed consent, and *volenti non fit injuria*.

The autonomy principle is the foundation of consent law in India, which allows a competent adult to make free choices about physical interventions, making it legally permissible in many situations. Informed consent is a principle that requires the patient to be informed of material risks, benefits and reasonable alternatives in language. The maxim "*volenti non fit injuria*" emphasizes that valid consent can legally exclude some claims of trespass or assault, but only when consenting is truly informed, voluntary, and given by someone with capacity. NMC/Ethics regulations emphasize the need for contemporaneous consent in the patient's language and level of comprehension.²⁰

B. Expressed, implied, proxy/surrogate consent, advance directives, emergency exceptions and express consent.

There are multiple consent methods recognized by law, including express consent in elective procedures, oral/implicit interactions, surrogate or proxy consent for patients with limited capacity, advance directives for future care choices, and emergency exceptions that permit life-saving interventions. Elective high-risk surgery requires written express consent, while emergency exceptions necessitate contemporaneous notes documenting urgency and inability to obtain consent. The documentation of emergency treatment without formal signature and the establishment of clear surrogate consent policies and procedures are required by regulations and

¹⁹ *Calcutta Medical Research Institute vs Bimalesh Chatterjee I* (1999) CPJ 13 (NC)

²⁰ Omprakash V Nandimath, *Consent and medical treatment: The legal paradigm in India*, 25 INDIAN JOURNAL OF UROLOGY : IJU : JOURNAL OF THE UROLOGICAL SOCIETY OF INDIA 343-7 (2009)

professional codes for hospitals.²¹

C. Consent must meet legal criteria such as capacity, levyability, appropriate disclosure, comprehension, and documentation.

The five fundamental aspects of consent are the ability to make decisions, voluntary behavior, adequate disclosure of risks and alternatives, demonstrable patient knowledge, and contemporaneous documentation. The NMC Code and hospital SOPs consider documentation as the primary safeguard, with operative notes (including anaesthesia charts), risk discussion entries, and signed consent forms in the patient's language being used to create a documentary trail that courts and regulators review to determine whether consent met legal requirements.²²

D. What are the necessary disclosures and potential risks that must be considered before operative time?

Clinical professionals must assess material risks from the patient's perspective to determine their importance in making a decision. High-risk surgery may involve not only common minor complications but also foreseeable severe adverse effects (perioperative death, permanent impairment, need for extended ICU care, and reoperation) and reasonable non-surgical alternatives. The boilerplate language is not up to par; NMC guidance and international consent templates suggest using information sheets that are patient-specific and language-appropriate, as well as separate documentation for high-impact complications to demonstrate that material risks were conveyed.²³

E. Obtaining consent for surgery that poses significant risks and safety concerns.

Considering the high stakes involved, best practices for high-risk surgery include extended pre-operative counselling with time for questions and multiple disciplines, capacity assessments, independent witnesses when doubts are raised, and patient-facing risk summaries in local language. However, some guidelines may still be provided through physician translators or pharmacists.

Table 2 — Top states by share of reported deaths (2017–2022) — selected states

State	Total reported deaths (2017–2022, approx.)	% of sample	Source
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²¹ Olivia Kituuka et al., *Informed consent process for emergency surgery: A scoping review of stakeholders' perspectives, challenges, ethical concepts, and policies*, 11 SAGE OPEN MEDICINE 20503121231176664 (2023)

²² T Thirumoorthy, *Core concepts of consent in medical practice*, 64 SINGAPORE MEDICAL JOURNAL 398–402 (2023)

²³ G Barnett & M Swart, *Shared decision making for high-risk surgery*, 21 BJA EDUCATION 300–306 (2021)

		total	
Uttar Pradesh	152	15.1%	Six-year NCRB compilation (research). (ResearchGate)
Jharkhand	106	10.6%	Six-year NCRB compilation (research). (ResearchGate)
Rajasthan	105	10.5%	Six-year NCRB compilation (research). (ResearchGate)

IV. RULES GOVERNING MEDICAL PRACTICE'S CRIMINAL LIABILITY

A. The distinction between criminal and civil negligence: legal standards and policy justifications

The dutybreachcausation mechanism is the same in civil negligence and criminal negligence, but the normative intensity varies. Criminal law requires a certain degree of culpability—rashness, gross negligence leading to death, etc. —while civil forums use a "reasonable care" standard and grant compensation. negligence or recklessness—enough to warrant legal sanctions. The distinction is justified by policies aimed at avoiding unnecessary stifling of clinical decision-making while maintaining responsibility for serious deviations from accepted practice; in practical terms, this translates to Unless there is proof of significant deviation from accepted norms or intentional wrongdoing, the majority of negative results that can be linked to known risks do not warrant criminal prosecution.²⁴

B. The "gross negligence" standard: its application to surgeons and judicial direction

Whether conduct represented a "gross" or "reckless" departure from accepted practice, meaning behavior so far below professional standards that it becomes criminally liable, is often the basis for criminal culpability in medicine. Deliberate failure to adhere to fundamental precautions and operate on patients is often within acceptable clinical risk for surgeons, whereas regular complications handled in accordance with accepted protocols are typically within permissible clinical risk. Manufacturing records or carrying out operations that are obviously outside one's skill set in an elective environment without any attempt at consent may fall under the category of gross negligence that is actionable under BNS provisions addressing death or serious injury caused by negligence. As a result, prevention places a strong emphasis on evident compliance

²⁴ Rebecca L. Cypher, *Demystifying the 4 Elements of Negligence*, 34 JOURNAL OF PERINATAL & NEONATAL NURSING 108–109 (2020)

with regulatory and legislative obligations as well as thorough contemporaneous records.²⁵

C. Evidential concerns include postmortem, medical records, expert opinion, and chain of custody.

Outcomes are determined by evidence: expert medical opinion, which is acceptable under Section 39 of the Bharatiya Sakshya Adhinyam, is typically the deciding factor in explaining clinical decisions, the standard of care, and other issues. Additionally, it is crucial to have contemporaneous medical records (consent forms, surgical notes, anaesthetic charts) as documentary anchors, as well as forensic and postmortem reports in cases involving fatalities, and causation. A specimen's admissibility is affected by the chain of custody. In practice, supporters must make sure that all records are complete, originals are kept, expert reports are rational (rather than conclusive), and any physical There are established chain of custody procedures in place to ensure that prosecutorial narratives cannot take advantage of evidentiary gaps.²⁶

Table 3 — Regional distribution (NCRB-compiled summaries / secondary study, 2017–2022)

Region	NCRB-compiled reported deaths (2017–2022)	% of national total (approx.)	Source
Western	260	25.6%	Six-year NCRB compilation (secondary analysis). (ResearchGate)
Northern	252	24.8%	Six-year NCRB compilation (secondary analysis). (ResearchGate)
Eastern	237	23.4%	Six-year NCRB compilation (secondary analysis). (ResearchGate)

²⁵ *Medical Negligence – The Judicial Approach by Indian Courts – Page 1000 – THE ASSOCIATION OF SURGEONS OF INDIA*, <https://asiindia.org/medical-negligence-the-judicial-approach-by-indian-courts/1000/> (last visited Sep 10, 2025)

²⁶ *Expert Opinion And Relevancy under BSA (Bharatiya Sakshya Adhinyam)* JUDIX, <https://www.myjudix.com/post/expert-opinion-and-relevancy-under-bsa-bharatiya-sakshya-adhinyam> (last visited Sep 10, 2025)

V. HIGH-RISK OPERATIONS: CLINICAL REALITIES AND LEGAL VULNERABILITIES

A. Defining "high-risk" surgery: medical standards and consequences for informed consent

Clinically, high-risk surgery is best understood as procedures that, as determined objectively, have a significantly higher chance of causing serious morbidity or death than regular surgery. indicators such as anticipated perioperative mortality, the need for extended intensive treatment, the possibility of permanent loss of organ function, or complexity (multisystem operations, reoperations, transplant, major vascular or cardiothoracic operations). This clinical definition is legally significant because it modifies what constitutes a "material" risk for disclosure and what actions are considered reasonable. Because high-risk surgery is viewed as a category needing more comprehensive counseling, multidisciplinary signoffs, and more thorough documentation, regulatory advice and professional standards treat it as such in order to get informed consent. in accordance with the National Medical Commission's regulations and established standards of professional ethics.²⁷

B. Common issues with risk communication in tertiary care and emergency settings

Predictable communication breakdowns that worsen legal risk occur in emergency rooms and tertiary hospitals: hurried consent discussions during late-night admissions, use of specialist terminology without sufficient explanation, etc. lack of lay translation, lack of capacity evaluation when patients are intoxicated or sedated, and failure to record what the patient (or surrogate) was told at the time. Emergency exceptions legally allow for treatment without official consent when a delay would be fatal, but doctors are still required to document the circumstances and the impossibility of getting consent. A failure to do so frequently transforms a legitimate emergency action into a debatable legal incident under professional and consumer norms. Regulatory tools stress that emergency treatment must be documented and justified in order to prevent future claims that the consent requirement was disregarded.²⁸

C. Common Reasons for Filing Criminal Complaints

Perioperative death, unanticipated irreversible paralysis or organ failure, and wrong-site surgery are examples of negative outcomes that disproportionately lead to criminal complaints. or incorrect patient procedures, and perioperative management errors that indicate a clear

²⁷ Owen Boyd & Neil Jackson, *How is risk defined in high-risk surgical patient management?*, 9 CRITICAL CARE (LONDON, ENGLAND) 390–6 (2005)

²⁸ Roxana Filip et al., *Global Challenges to Public Health Care Systems during the COVID-19 Pandemic: A Review of Pandemic Measures and Problems*, 12 JOURNAL OF PERSONALIZED MEDICINE 1295 (2022)

disregard for fundamental safety measures. The Bharatiya Nyaya Sanhita distinguishes between various offenses (Sections 98–103 for culpable homicide, Section 104 for causing death by rash or negligent conduct, and Sections 114– 115(2) for causing harm). The practical legal issue revolves around whether surgical behavior went beyond the boundaries of acceptable clinical risk to recklessness or grossness (see also 113–123 for serious/non-serious harm). Negligence as defined by those rules; the fact that a negative result happens in a high-risk scenario does not, by itself, meet the criteria for criminal culpability, but absence. It may be significantly more difficult to refute claims under Section 104 if there is clear documentation and disclosure.²⁹

D. Institutional elements: telemedicine encounters, hurried consent, inadequate records, and staffing.

Individual legal exposure is increased by institutional weaknesses such as insufficient staffing (lacking senior supervision), incomplete medical records (lacking operative notes, absent anesthesia charts), and superficial or template consent documents. and the growing use of telemedicine, which lacks strong identity verification and consent procedures, gives rise to factual gaps that are taken advantage of by prosecutors and consumer complainants. The National Medical Commission In addition, regulations pertaining to professional ethics mandate that institutions and treating physicians have the express responsibility of keeping contemporaneous records and obtaining informed consent in a language the patient can understand. Comprehends; by failing to implement SOPs for high-risk instances, hospitals raise the likelihood that an unfavorable result may result in concurrent regulatory, civil, and criminal procedures..³⁰

Table 4 — Nature of alleged errors in NCDRC cases (NCDRC sample 2015–2019)

Error category	Number of cases	% of sample (approx.)	Source
Lack of skill/care	62	36%	NCDRC retrospective review (2015–2019). (Indian Journal of Medical Ethics)
Failure to maintain medical	38	22%	NCDRC retrospective review (2015–2019). (Indian Journal of Medical

²⁹ Gregory Santos & Mark W. Jones, *Prevention of Surgical Errors*, STATPEARLS (2023)

³⁰ Tanaya Sparkle, *Anaesthesia consent in public hospital population - An ethical dilemma*, 60 INDIAN JOURNAL OF ANAESTHESIA 300–1 (2016)

recordsEthics)

VI. THE ROLE OF THE LEGAL ADVOCATE: PREVENTATIVE LAWYERING AND LITIGATION STRATEGIES

A. Pre-litigation recommendations for doctors and hospitals: checklists for audits, documentation, and compliance

Preventive lawyering begins with systems: supporters who counsel hospitals should develop and employ audit methods and checklists that outline NMC responsibilities (record keeping, consent content), risks under the Consumer Protection Act, 2019, such as anticipatory bail under Section 438 and the preservation of records pertaining to BNSS procedures and other requirements. Potential exposure to consumer legislation and investigations. Legal clinical audits evaluate the validity of consent interactions, including the language utilized, the presence of witnesses, and the evidence of understanding. Additionally, the preservation of device logs, images, and anaesthesia charts is evaluated for forensic preparedness, which reduces the likelihood that typical clinical uncertainty will be reinterpreted as criminal culpability.

B. Developing legally enforceable consent documents and procedures

For high-risk surgery, a legally acceptable consent procedure should include: (i) a plain language summary of the major risks and options, written in the patient's native tongue. (ii) clear mention of the particular major hazards associated with the treatment, (iii) a checklist for assessing competence, and (iv) a multidisciplinary signoff (surgeon, anaesthetist, intensivist) for the native language. (v) timestamped freetext (vi) independent witness signature where capacity is questionable, (vii) electronic medical record scan of the original signed document, and (vi) where applicable. (viii) Documentation of any emergencies or changes during the procedure, and (vii) notes from the conversation. In accordance with NMC/Ethics guidelines, these variables reduce susceptibility to criminal and consumer inspection.³¹

C. When faced with a criminal charge, use a three-pronged defense strategy: prima facie evaluation, expert testimony, and procedural cures.

If there are criminal charges, supporters must first ascertain whether the complaint includes a prima facie offense under the BNS sections that are being cited. For instance, they must determine whether the complaint establishes a prima facie offense under the BNS sections being referenced. According to Section 104, the facts point to either a rash or careless act, or

³¹ S. M. Yentis et al., *AAGBI: Consent for anaesthesia* 2017, 72 ANAESTHESIA 93–105

something that is about the same. Timely, reasoned expert opinions (that are acceptable under Section 39³² of the Bharatiya Sakshya Adhiniyam) are necessary in order to discuss the norm of simultaneously managing causality, anticipated risk, and care. Seeking anticipatory bail applications under Section 484 BNSS and, where applicable, quashing petitions under Section 530 BNSS are tactical ways to avoid being arrested into custody. For a prompt judicial evaluation of flimsy criminal charges. Supporters must coordinate expert evidence, comprehensive documentation, and procedural submissions in order to combat the prosecution's momentum.

D. Counseling patients and families on whether to pursue civil remedies or report criminal offenses.

Advocates should address the trade-offs between forums while counseling dissatisfied clients. Although criminal trials can have punitive and public interest value, they sometimes require evidence of recklessness or gross negligence (BNS thresholds) and may lead to lengthy queries; civil/consumer concerns under the CPA, 2019, provide for compensatory remedies and may be faster or more practical. Guidance should also cover the preservation of evidence (medical records, imaging), the appropriate application of expert opinion, and the possibility of integrated tactics (a civil lawsuit with a threat). While discouraging frivolous criminal complaints that waste resources and may be subject to judicial penalties.³³

E. In medical disputes, there are five ADR options: mediation, arbitration, and negotiated settlements.

More and more individuals are using alternative dispute resolution methods (mediation, conciliation) as a way to resolve medical disputes, preserve therapeutic relationships, and avoid criminal escalation; consumer In order to bring patient expectations into line without always resorting to protracted legal procedures, mediation is now employed in several hospitals and foras for apology and compensation procedures. Advocates may negotiate settlement agreements that include financial compensation, apologies, systemic reform measures, and confidentiality clauses, all of which serve to safeguard the interests of patients and the reputations of doctors while minimizing the negative consequences of criminalization.³⁴

³² Section 39 BSA JUDIX, <https://www.myjudix.com/post/section-39-bsa-bharatiya-sakshya-adhiniyam-2023> (last visited Sep 10, 2025)

³³ Remedies under Consumer Protection Act SHEOKAND LEGAL, <https://sheokandlegal.com/articles/remedies-under-consumer-protection-act/> (last visited Sep 10, 2025)

³⁴ Kostadin Dimitrov & Tsonka Miteva-Katrandzhieva, *Mediation in Healthcare: Enhancing Conflict Resolution Between Patients and Physicians Beyond the Courtroom*, 16 CUREUS e75487 (2024)

F. The ethical responsibilities of lawyers in medical-legal disputes

In medical conflicts, counsel are ethically obligated to give truthful advice, avoid exacerbating parties, and avoid inciting needless criminal complaints; they must also achieve a balance between aggressive representation. Maintain professional responsibility to the court by avoiding submitting misleading expert testimony and complying with institutional reporting standards and patient confidentiality. This moral framework has some overlap with legal mandates, such as NMC complaint routes and consumer forum rules. It also has an impact on how proponents present evidence, engage in negotiations, and, if necessary, pursue or challenge criminal procedures.³⁵

Table 5 — Outcome rates in consumer forum sample (2015–2019 NCDRC analysis)

Outcome	Number	% (approx.)	Source
Doctors held negligent	153	53% (153/253)	Analysis of NCDRC decisions (2015–2019). (Lippincott Journals)
Cases dismissed / no negligence found	100	39% (approx.)	Analysis of NCDRC decisions (2015–2019). (Lippincott Journals)

VII. ISSUES RELATING TO FORENSICS, INSTITUTIONS, AND PROCEDURES IN PROSECUTION AND DEFENSE

A. The role of hospital, medical council, and police investigations—coordination and conflicts

Following an unfavorable incident, hospitals frequently carry out internal investigations, and the State Medical Council or NMC may start professional investigations. These parallel processes might result in coordination issues since internal reports may be found in criminal or consumer actions, and professional penalties might have an impact on prosecutorial evaluation. As a result, advocates must provide guidance on privilege restrictions, the modern maintenance of records, and the proper scope and disclosure of the results of internal investigations in order to foster regulatory collaboration. does not unintentionally bias the defense against criminals.³⁶

³⁵ THE RULES OF PROFESSIONAL CONDUCT, <https://www.padisiplinaryboard.org/for-attorneys/rules/rule/3/the-rules-of-professional-conduct> (last visited Sep 10, 2025)

³⁶ *Review of patient safety across the health and care landscape* GOV.UK, <https://www.gov.uk/government/publications/review-of-patient-safety-across-the-health-and-care-landscape/review-of-patient-safety-across-the-health-and-care-landscape> (last visited Sep 10, 2025)

B. Forensic evidence and medico legal reporting in cases of surgical adverse events

Precise medico legal reporting (cause of death, surgical and anesthetic records, and implant logs) and strict chain of custody for samples are necessary when a fatality occurs; gaps in these areas often dictate the course of the investigation. Expert opinion is recognized by the Bharatiya Sakshya Adhiniyam (Section 39), but courts also need documentary anchors to back up expert opinion, such as audit trails, contemporaneous records, and verified electronic logs. Claims, which render forensic grade record keeping a real need in high-risk surgery.³⁷

C. Police investigative procedures, the dangers of custodial detention, and protections for physicians

Procedural safeguards, such as anticipatory bail (Section 484), are necessary because police investigations into suspected medical negligence can lead to arrests even in cases that are later found to be weak. As a result, safeguarding clinicians from unjust detention depends heavily on the remedies provided by the High Court's inherent powers (Section 530 BNSS). To limit investigative overreach, advocates should quickly compare the facts to BNS thresholds, seek anticipatory relief when appropriate, and think about judicial review of clearly malicious or irritating criminal complaints.

D. The weight that expert committees carry in front of criminal courts

To triage complicated surgical adverse events, judicial and prosecutorial agencies are using multidisciplinary expert committees (clinical and forensic) more frequently. Committee reports, however, need to be because courts will evaluate committee conclusions against contemporary records and independent expert testimony, the approach is methodologically sound and open. As a result, supporters must make sure that any committee procedure adheres to specific terms of reference, documents its discussions, and provides a forum for addressing any perceived methodological bias in order to ensure a fair judgment.³⁸

VIII. COMPARATIVE ANALYSIS

A. Overview of comparative law: A comparison of the methods used in other common law jurisdictions (UK, Australia) for addressing criminal culpability in surgery

The common law crime of gross negligence manslaughter is used in the United Kingdom to

³⁷ *Bhartiya Sakshya Adhiniyam, 2023 - A Dynamic Shift to the Digital Era* ELP LAW, <https://elplaw.in/leadership/bhartiya-sakshya-adhiniyam-2023-a-dynamic-shift-to-the-digital-era/> (last visited Sep 10, 2025)

³⁸ *Fighter Law* FIGHTER LAW, <https://www.fighterlaw.com/how-is-forensic-evidence-used-in-criminal-trials/> (last visited Sep 10, 2025)

prosecute criminal culpability for deaths occurring in medical practice; the Crown Prosecution Service's prosecutorial policy (Crown Prosecution Service guidance) regards these kinds of charges as unusual, placing a focus on a high bar that includes a duty of care, a breach resulting in death, and a breach that is so egregious as to including the possibility of being a criminal) and advising stringent filtering at the outset so that only cases with a chance of success advance to charges. The nationwide UK assessment of gross negligence manslaughter involving medical practitioners shows that investigations are fairly common, but prosecutions and convictions are uncommon, which reflects a policy. a balance between investigative scrutiny and protection of sound clinical judgment. To prevent the erroneous criminalization of recognized medical risks, this strategy places emphasis on early professional triage, specialized prosecution units, and collaborative coronial/prosecution advice.³⁹

In contrast, Australia prosecutes killing offenses under statutory homicide legislation in state criminal codes (manslaughter or negligent homicide, depending on the jurisdiction), and statistical data indicates Only a tiny fraction of all homicide cases are prosecuted as manslaughter; national analyses highlight the low number of manslaughter prosecutions and the need for coronial and systematic investigation. Prior to considering any criminal charges, procedures frequently serve as the main accountability mechanisms. The comparative lesson from both jurisdictions is institutional: prosecutorial restraint, specialized investigative Effective expert review methods, such as capacity and structure (as opposed to immediate arrest/charge), lower the likelihood that foreseeable negative consequences from high-risk surgery may be turned into unfair criminal proceedings.⁴⁰

Table 6 — Comparative overview: common-law jurisdictions handle criminal liability in surgery (UK, Australia)

Jurisdiction	Key metric	Number	Percent	Source
United Kingdom (CPS review, since 2013)	CPS involved suspected GNM cases	151	—	Williams review / CPS. GOV.UK
United Kingdom	No further action after early CPS	85	56%	Williams review /

³⁹ IS MEDICAL NEGLIGENCE A CRIME HUGH JAMES, <https://www.hughjames.com/services/medical-negligence-solicitors/medical-negligence-compensation-guide/can-you-sue-for-medical-negligence/is-medical-negligence-a-crime/> (last visited Sep 10, 2025)

⁴⁰ Rajkumar Cheluvappa & Selwyn Selvendran, *Medical negligence - Key cases and application of legislation*, 57 ANNALS OF MEDICINE AND SURGERY (2012) 205–211 (2020)

(subset)	advice			CPS. GOV.UK
United Kingdom (subset)	No further action after full case	43	28%	Williams review / CPS. GOV.UK
Australia (2020–21)	Manslaughter incidents (all causes)	24	11% of homicide incidents	AIC homicide statistics. Australian Institute of Criminology

B. The Bolam/Bolithostyle tests' applicability to Indian law on medical standards

The tension between deference to professional medical opinion and judicial review of reasonableness has always been a part of India's engagement. The "responsible body of medical opinion" test, also known in comparative literature as Bolam, is still a powerful analytical instrument, but Indian courts and commentators have criticized it. Furthermore, the Bolitho refinement in comparative doctrine requires that expert opinion be rationally defensible. In reality, this implies that when determining negligence, courts will take into account recognized professional practice, but they will not blindly accept any professional opinion. The expert opinion, which must now be evaluated in light of legal evidence standards like the Bharatiya Sakshya Adhinyam's requirements, is judged on its quality, logic, and evidentiary basis. The result is determined by the reformist principles of the Bharatiya Sakshya Adhinyam, 2023, and on experts (Section 39). As a result, India's Bolamstyle deference is tempered by a legal and doctrinal emphasis on logical, well documented, and evidence-based professional practice rather than favoring any particular viewpoint.⁴¹

This doctrinal synthesis emphasizes verifiable adherence to regulatory requirements (such as the National Medical Commission Act, 2019, and the Code of Medical Ethics on consent and record-keeping) because following recognized procedures both provides a genuine "responsible body" foundation and generates the necessary contemporaneous documentation. for judicial review in accordance with evidence law. Thus, attorneys must ensure that expert affidavits adhere to a sound clinical practice while also being explicit in their reasoning and citing objective benchmarks or standards. so that courts using the Bolam/Bolitho informed approach may assess the opinion's logical basis in accordance with Section 39 and the new BSA principles for scientific evidence.⁴²

⁴¹ INTRODUCTION : DEFINITION, NATURE AND SCOPE, https://www.academia.edu/28882218/introduction_definition_nature_and_scope (last visited Sep 10, 2025)

⁴² COMMON LAW AND INDIAN CASES ON MEDICAL NEGLIGENCE,

C. Normative critique: striking a balance between protecting patients and defending clinical judgement

As a general rule, any legal system regulating high-risk surgery must balance two needs: adequate patient protection (including compensation, regulatory discipline, and criminal accountability for genuinely culpable behavior). and the authority for evidence-based clinical judgment in the law, ensuring that the possibility of punishment doesn't stifle sound decision-making. The contemporary legislative framework in India includes the Bharatiya Nyaya Sanhita (for example, Section 104 on causing death by negligence) and the evidentiary reforms brought about by the Bharatiya Sakshya Adhiniyam, in addition to other laws. The National Medical Commission Act and the Consumer Protection Act of 2019 present both opportunities and challenges: more explicit legislative language may limit prosecutorial discretion and There is still a chance of indiscriminate criminal charges in the absence of institutional filters (preprosecution expert triage, coronial-type reviews, protocolized investigatory steps), even if criteria for penal action are specified. primarily on negative consequences rather than blamable behavior. As a result, the normative policy recommendation supports (a) clear legislation governing mens rea and penalties (e. g, the BNS framing of negligence crimes), and (b) procedural safeguards. including (c) procedural and evidentiary changes (BSA, Section 45 requirements) that make the case turn, and mandatory expert triage and preservation orders before charges are brought. based on current documentation and expert thinking that is methodologically sound, not retrospective second-guessing. By reserving criminal law only for genuine departures from accepted practice, these actions provide greater safeguards for patient rights.⁴³

IX. CONCLUSION AND SUGGESTIONS.

A. Conclusion

The medicolegal situation for high-risk surgery in India is now at the nexus of long-lasting constitutional obligations (Article 21) and extensive professional regulation (National Medical Commission). The Code of Medical Ethics and the 2019 Act; consumer legislation exposure (Consumer Protection Act, 2019); and an updated criminal law framework that modernizes culpability and process; When considered as a whole, these regimes mandate that advocates and clinicians adhere to procedural rigor, documentary discipline, and rights-focused

https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID3350915_code1437843.pdf?abstractid=3350915&mirid=1
(last visited Sep 10, 2025)

⁴³ Ash Samanta & Jo Samanta, *Regulation of the medical profession: fantasy, reality and legality*, 97 JOURNAL OF THE ROYAL SOCIETY OF MEDICINE 211–8 (2004)

communication in order to avoid predictable clinical uncertainty from solidifying. into criminal culpability. (See the comments on Article 21 of the Consumer Protection Act and the NMC Act.)

The Bharatiya Nyaya Sanhita, 2023 (BNS), the new substantive criminal code, redefines the offense previously covered by BNS Section 104 as Section 104 (causing death by negligence). This legislative reform increases the stakes for medical practice by defining legal criteria for negligence, with calibrated penalties and explicit textual treatment of medical professionals. at the same time emphasizing the significance of process-based defenses (documented informed consent, contemporaneous operative and anesthesia records, expert justification of clinical decisions). In addition, the Bharatiya Nagarik Suraksha Sanhita, 2023 (BNSS) includes anticipatory bail protections (such as Section 530 of the BNSS, which addresses pre-arrest relief) that are still in effect. Crucial procedural protections for doctors facing quick investigations, which means that timely procedural interventions must be combined with substantive rebuttals through efficient advocacy.

By codifying the function and boundaries of expert opinion and scientific evidence, the Bharatiya Sakshya Adhinyam (BSA) also reforms evidence law, altering the evidentiary landscape. In reality, the quality and approach of medical expert reports (as well as the preservation of original records and samples) are crucial in criminal adjudication. as well as regulatory fora. Therefore, the updated criminal-evidentiary system enhances accountability and provides clearer procedural tools for informed judicial evaluation, but only if doctors and Proponents of evidence-based practice integrate defensible concurrent records and reasonable professional explanations into their regular practice, anticipating evidentiary needs.

B. Recommendations

To address the fundamental evidentiary gaps that transform clinical risk into alleged Section 104 (BNS) offences or related regulatory complaints, hospitals should implement NMC-aligned SOPs that require multilayered consent procedures, explicit capacity assessments, multidisciplinary sign-offs, and archiving of original consent and anaesthesia charts. This approach is one of the first steps in institutionalizing compliance and documentation.

In cases where complaints pose a threat to the criminal process, legal professionals should prioritize early procedural relief and forensic readiness. High Court screening under the inherent-powers rubric is recommended when it is appropriate to prevent unnecessary custody and preserve records and specimens. Additionally, clinicians should be trained in forensic-grade record preservation to meet BSA's expert opinion standards.

Parliament and regulators should pursue legislative or policy-level reforms to reduce avoidable criminalisation, including the establishment of statutory pre-prosecution medical panels (or mandatory expert triage before charge), the use of explicit parliamentary safe-harbours, and targeted guidance on the proportionality of sanctions. Corrected adjustments would synchronize prosecutorial authority with the philosophical differentiation between civil negligence and criminal guilt.

Encourage the use of ADR, patient-safety culture, and continuous legal-clinical education. This includes promoting mediation and no-fault compensation schemes to avoid clinical judgment in appropriate cases under the Consumer Protection Act framework. Senior clinicians and hospital administrators must receive accredited medico-legal training to ensure they are knowledgeable about BNS/BSA or BNSS changes and the evidentiary practices now required by Bharatiya Sakshya Adhiniyam. The implementation of these measures will result in a decrease in litigative pressure and better outcomes for both patients and practitioners.

Those who want to create practical safeguards that turn rights-oriented medical practice into durable legal defenses by creating model consent forms, SOPs, and expert-report templates that specifically reference NMC obligations, BNS Section 104 thresholds. The law-and-policy approach aims to preserve patient autonomy and dignity while safeguarding clinicians from disproportionate criminal exposure.

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