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THE DOCTRINE OF INFORMED CONSENT IN INDIAN HEALTH LAW: FROM PATERNALISM TO AUTONOMY AND THE CHALLENGE OF AI- ASSISTED MEDICAL DECISION-MAKING

AUTHORED BY - JAHNAVI TIWARI,
PRIYAVARDHAN BALOT & YUKTA CHANDA

4th Year B.A.LL.B students

National Law Institute University, Bhopal

Abstract

Informed consent is the legal and ethical hinge on which the modern doctor–patient relationship turns. In India, however, the doctrine has developed unevenly: it is scattered across the criminal law, the law of contract and tort, consumer protection jurisprudence, professional regulations and a growing body of special statutes, without any unifying legislative statement. The Supreme Court's decision in *Samira Kohli v Dr Prabha Manchanda* (2008) gave the doctrine its first authoritative articulation, but deliberately rejected the patient-centred standard of disclosure adopted in the United States and, later, in the United Kingdom in *Montgomery v Lanarkshire Health Board* (2015), preferring a 'real consent' standard anchored in professional practice and Indian social conditions.

This paper argues that the constitutional turn in Indian rights jurisprudence-particularly the recognition of decisional autonomy, bodily integrity and dignity as facets of Article 21 in *Justice KS Puttaswamy v Union of India* (2017) and *Common Cause v Union of India* (2018)-has rendered the *Samira Kohli* standard doctrinally unstable. Tracing the doctrine from its paternalistic origins through its statutory, judicial and constitutional development, and comparing it with the English, American and Australian positions, the paper contends that Indian law should now adopt a materiality-based, patient-centred standard of disclosure. It further examines how the integration of artificial intelligence into clinical diagnosis and treatment tests the doctrine's capacity to protect patient autonomy, and proposes a calibrated duty to disclose material AI involvement. The paper concludes with concrete legislative and regulatory recommendations, including a codified patients' rights framework.

I. Introduction

More than a century ago, Cardozo J declared that every human being of adult years and sound mind has a right to determine what shall be done with his own body.¹ That proposition, now so familiar that it is rarely interrogated, marked the beginning of a long legal journey away from medical paternalism-the belief that the doctor, as the possessor of expert knowledge, is best placed to decide what the patient should know and what should be done to the patient's body. The doctrine of informed consent is the principal legal instrument through which that journey has been made.

Indian law arrived at the doctrine late and by an indirect route. There is no Indian statute that defines informed consent for medical treatment generally, prescribes the content of the disclosure a doctor must make, or states the consequences of failing to make it. Instead, the doctrine must be assembled from fragments: the general exceptions in the criminal law, the law of contract and tort, consumer protection jurisprudence, the codes of medical ethics, and a growing number of special statutes governing mental health, reproduction, organ transplantation and clinical research. The single most important judicial statement of the doctrine remains the Supreme Court's decision in *Samira Kohli v Dr Prabha Manchanda*.² In that case the Court affirmed that consent must be real, voluntary and based on adequate information, but expressly declined to adopt the American 'reasonable patient' standard of disclosure, preferring a standard tied to accepted medical practice and Indian social conditions. The central argument of this paper is that the *Samira Kohli* standard, although a significant advance in its time, is now doctrinally unstable. Three developments compel its reconsideration. The first is comparative: the United Kingdom, whose jurisprudence *Samira Kohli* followed, abandoned the professional standard of disclosure in *Montgomery v Lanarkshire Health Board*.³ The second is constitutional: the nine-judge bench in *Justice KS Puttaswamy (Retd) v Union of India* recognised decisional autonomy and bodily integrity as facets of the right to privacy under Article 21,⁴ and the Constitution Bench in *Common Cause (A Registered Society) v Union of India* held that the right to refuse medical treatment is an incident of the right to live with dignity.⁵ The Court's 2026 decision in *Harish Rana v Union of India*, the first judicial application of the end-of-life framework to an individual patient, has

¹ *Schloendorff v Society of New York Hospital* 211 NY 125, 129 (1914) (Cardozo J).

² *Samira Kohli v Dr Prabha Manchanda* (2008) 2 SCC 1.

³ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [2015] AC 1430.

⁴ *Justice KS Puttaswamy (Retd) v Union of India* (2017) 10 SCC 1.

⁵ *Common Cause (A Registered Society) v Union of India* (2018) 5 SCC 1.

given these principles practical force.⁶ The third development is technological: the use of artificial intelligence (AI) in diagnosis, prognosis and treatment planning raises questions about what a patient must be told that existing doctrine is ill-equipped to answer.⁷ Indian regulators have begun to recognise this, most notably in the Indian Council of Medical Research's 2023 ethical guidelines on AI in healthcare.⁸

The paper proceeds as follows. Part II sets out the conceptual and historical foundations of informed consent. Part III maps the statutory and regulatory architecture of consent in India. Part IV traces the judicial evolution of the doctrine, culminating in *Samira Kohli* and its aftermath. Part V examines how constitutional rights jurisprudence has transformed the normative basis of consent. Part VI compares the Indian position with the English, American, Canadian and Australian approaches. Part VII considers consent in special contexts: mental healthcare, reproductive health, clinical research and the end of life. Part VIII turns to AI-assisted medical decision-making and asks whether, and when, AI involvement must be disclosed. Part IX proposes reforms, and Part X concludes.

The paper's contribution is twofold. Doctrinally, it argues that Indian courts should now adopt a materiality-based, patient-centred standard of disclosure, of the kind articulated in *Montgomery*, and that this shift is required by Article 21 rather than merely permitted by it. Prospectively, it argues that a calibrated duty to disclose material AI involvement follows naturally from that standard, and should be reinforced by regulation.

II. Conceptual and Historical Foundations

A. The elements of informed consent

Informed consent is best understood not as a signature on a form but as a process of shared decision-making. The leading theoretical account, developed by Faden and Beauchamp, identifies the elements of an informed consent as disclosure, understanding, voluntariness, competence and authorisation.⁹ A patient gives informed consent when, having the capacity to decide, she understands the material information disclosed to her and, free from controlling influences, intentionally authorises a professional to carry out a particular intervention. Each element maps onto a distinct legal question: whether the doctor disclosed enough, whether the

⁶ *Harish Rana v Union of India* 2026 SCC OnLine SC 358.

⁷ Eric J Topol, 'High-Performance Medicine: The Convergence of Human and Artificial Intelligence' (2019) 25 *Nature Medicine* 44.

⁸ Indian Council of Medical Research, *Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare* (ICMR 2023).

⁹ Ruth R Faden and Tom L Beauchamp, *A History and Theory of Informed Consent* (OUP 1986).

patient had capacity, whether the consent was voluntary, and whether it covered what was actually done.

The ethical foundation of the doctrine is the principle of respect for autonomy, which Beauchamp and Childress place alongside beneficence, non-maleficence and justice as the four cardinal principles of biomedical ethics.¹⁰ The history of medical law can be read as a contest between beneficence and autonomy. Traditional medical ethics, from the Hippocratic tradition onward, emphasised the physician's duty to benefit the patient, and tolerated, even encouraged, the withholding of distressing information. Katz's influential study described this as a 'silent world' in which patients were neither informed nor consulted.¹¹

B. From Nuremberg to Helsinki

The decisive break came not from clinical medicine but from the horrors of human experimentation. The Nuremberg Code of 1947, formulated in the judgment against Nazi physicians, opened with the declaration that the voluntary consent of the human subject is absolutely essential.¹² The World Medical Association's Declaration of Helsinki, first adopted in 1964 and most recently revised in 2024, built on that foundation and remains the principal international instrument on consent in medical research.¹³

C. The emergence of the legal doctrine

The phrase 'informed consent' first appeared in a judicial opinion in *Salgo v Leland Stanford Jr University Board of Trustees*, where a Californian appellate court held that a physician violates his duty to the patient if he withholds facts necessary to form the basis of an intelligent consent.¹⁴ The doctrine reached maturity in *Canterbury v Spence*, in which the Court of Appeals for the District of Columbia Circuit held that the scope of the duty to disclose is measured by the patient's need for information, not by the practice of the medical profession.¹⁵ *Canterbury* thus established the patient-centred standard that Indian courts would later consider, and reject, in *Samira Kohli*.

¹⁰ Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics* (8th edn, OUP 2019).

¹¹ Jay Katz, *The Silent World of Doctor and Patient* (Free Press 1984).

¹² 'The Nuremberg Code' in *Trials of War Criminals before the Nuernberg Military Tribunals under Control Council Law No 10*, vol 2 (US Government Printing Office 1949) 181, principle 1.

¹³ World Medical Association, 'Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants' (adopted June 1964, most recently amended October 2024).

¹⁴ *Salgo v Leland Stanford Jr University Board of Trustees* 317 P 2d 170, 181 (Cal Ct App 1957).

¹⁵ *Canterbury v Spence* 464 F 2d 772 (DC Cir 1972).

D. Autonomy, trust and the critique of informed consent

The doctrine has not been without critics. O'Neill has argued that an individualistic conception of autonomy fails to capture what matters in the doctor–patient relationship, which depends as much on trust as on information.¹⁶ This critique has particular resonance in India, where decisions about treatment are often made collectively by families, and where wide disparities in literacy and health knowledge affect patients' ability to process complex information. As Part IV shows, the Supreme Court relied on precisely these considerations in *Samira Kohli*. This paper argues, however, that such conditions justify adapting the *manner* of disclosure to the patient, not diluting the *standard* of what must be disclosed.

E. Consent as a human right

Informed consent is now firmly embedded in international human rights law. Article 7 of the International Covenant on Civil and Political Rights, to which India is a party, provides that no one shall be subjected without free consent to medical or scientific experimentation.¹⁷ The UNESCO Universal Declaration on Bioethics and Human Rights requires that any preventive, diagnostic or therapeutic medical intervention be carried out only with the prior, free and informed consent of the person concerned, based on adequate information.¹⁸ The Council of Europe's Oviedo Convention articulates the same general rule.¹⁹ These instruments confirm that consent is not merely a defence to liability; it is an expression of human dignity.

III. The Legal Architecture of Consent in India

Indian law contains no general statute on medical consent. The doctrine instead operates through at least six overlapping sources as discussed below:

A. Contract law

Where treatment is provided under a contract, the Indian Contract Act 1872 requires that the patient's agreement be made with free consent, which is absent where it is caused by coercion, undue influence, fraud, misrepresentation or mistake.²⁰ Contract law thus captures the

¹⁶ Onora O'Neill, *Autonomy and Trust in Bioethics* (CUP 2002).

¹⁷ International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171, art 7.

¹⁸ UNESCO, Universal Declaration on Bioethics and Human Rights (19 October 2005) art 6(1).

¹⁹ Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (adopted 4 April 1997, entered into force 1 December 1999) ETS No 164, art 5.

²⁰ Indian Contract Act 1872, ss 10, 13, 14.

voluntariness and the informational dimensions of consent, but it offers limited guidance on how much a doctor must disclose.

B. Criminal law

The criminal law supplies the oldest statutory recognition of medical consent. The general exceptions in Chapter III of the Bharatiya Nyaya Sanhita 2023 (BNS), which re-enact sections 87 to 92 of the Indian Penal Code 1860, make consent the condition that converts what would otherwise be hurt into lawful treatment.²¹ Section 26 BNS protects acts not intended to cause death done in good faith for a person's benefit with that person's express or implied consent; its illustration is the surgeon who performs a risky operation, with the patient's consent, intending the patient's benefit.²² Section 27 permits consent to be given by a guardian on behalf of a child or a person of unsound mind,²³ and section 28 provides that consent given under fear or misconception is no consent at all. Section 30 creates the emergency exception: an act done in good faith for a person's benefit is protected even without consent where it is impossible for that person to signify consent and there is no guardian from whom consent can be obtained in time.²⁴

Two features of this framework matter. First, section 28 implies that consent procured through a material misconception about the nature of the procedure is legally void, which supplies an informational requirement. Second, the requirement of 'good faith', defined in section 2(11) BNS as action with due care and attention, links criminal immunity to professional standards.

C. Tort and consumer protection

The main forum for consent claims is now civil. In *Indian Medical Association v VP Shantha*, the Supreme Court held that medical services rendered for consideration fall within the definition of 'service' under consumer protection law.²⁵ Treatment without valid consent is therefore actionable both as the tort of battery or negligence and as a deficiency in service before consumer commissions, a position carried forward under the Consumer Protection Act 2019.²⁶

²¹ Bharatiya Nyaya Sanhita 2023, ss 25–28, 30; cf Indian Penal Code 1860, ss 87–90, 92.

²² Bharatiya Nyaya Sanhita 2023, s 26 and illustration.

²³ *ibid* s 27.

²⁴ *ibid* s 30.

²⁵ *Indian Medical Association v VP Shantha* (1995) 6 SCC 651.

²⁶ Consumer Protection Act 2019, s 2(42).

D. Professional regulation

Regulation 7.16 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002 requires a physician, before performing an operation, to obtain written consent from the patient or, as the case may be, the spouse, parent or guardian.²⁷ The provision is notable for what it omits: it says nothing about the content of the information the patient must receive, and its reference to spousal consent sits uneasily with modern conceptions of individual autonomy. The National Medical Commission notified replacement regulations in August 2023 but held them in abeyance within weeks, with the result that the 2002 Regulations continue to apply.²⁸

E. Special statutes

In contrast to general medical law, several special statutes deal with consent explicitly. The Mental Healthcare Act 2017 (MHCA) defines informed consent as consent given for a specific intervention without force, undue influence, fraud, threat, mistake or misrepresentation, after disclosure of adequate information including the risks, benefits and alternatives, in a language and manner the person understands.²⁹ It is the only Indian statute to define the concept in this way, and it offers a ready template for general reform. The Transplantation of Human Organs and Tissues Act 1994 requires authorisation by the donor and regulates living donation closely;³⁰ the Medical Termination of Pregnancy Act 1971 provides that no pregnancy shall be terminated except with the consent of the pregnant woman;³¹ and both the Surrogacy (Regulation) Act 2021 and the Assisted Reproductive Technology (Regulation) Act 2021 require written informed consent from the parties.³²

F. Research and data

Clinical trials are governed by the New Drugs and Clinical Trials Rules 2019, which require written informed consent and, for vulnerable participants in trials of new chemical or molecular entities, an audio-visual recording of the consent process.³³ The ICMR's National Ethical Guidelines for Biomedical and Health Research set out detailed requirements for research

²⁷ Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002, reg 7.16.

²⁸ National Medical Commission Registered Medical Practitioner (Professional Conduct) (Amendment) Regulations 2023 (notified 23 August 2023), holding in abeyance the National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations 2023 (notified 2 August 2023).

²⁹ Mental Healthcare Act 2017, s 2(1)(i).

³⁰ Transplantation of Human Organs and Tissues Act 1994, ss 3, 9.

³¹ Medical Termination of Pregnancy Act 1971, s 3(4)(b).

³² Surrogacy (Regulation) Act 2021, s 6; Assisted Reproductive Technology (Regulation) Act 2021, s 22.

³³ New Drugs and Clinical Trials Rules 2019, GSR 227(E) (19 March 2019), Third Schedule.

consent.³⁴ Finally, the Digital Personal Data Protection Act 2023 requires free, specific, informed, unconditional and unambiguous consent for the processing of personal data, subject to listed 'legitimate uses' that include responding to a medical emergency.³⁵ Its significance for AI-assisted medicine is considered in Part VIII.

The overall picture is one of fragmentation. The National Human Rights Commission's Charter of Patients' Rights lists the right to informed consent among a patient's basic entitlements,³⁶ but it is not binding legislation. Outside special contexts, the content of the duty to disclose has been left almost entirely to the courts.

IV. Judicial Evolution: From Paternalism to 'Real Consent'

A. Early foundations

The Supreme Court's first engagement with medical negligence, *Dr Laxman Balkrishna Joshi v Dr Trimbak Babu Godbole*, established that a doctor owes the patient duties in deciding whether to undertake a case, in deciding what treatment to give, and in administering that treatment.³⁷ The case concerned the standard of care in treatment rather than consent, but its articulation of a duty of care owed directly to the patient provided the foundation on which later consent jurisprudence was built. High Courts addressed unauthorised surgery more directly. In *Ram Bihari Lal v Dr JN Srivastava*, the Madhya Pradesh High Court considered liability for surgery that went beyond what the patient had agreed to, treating the absence of consent as a distinct wrong.³⁸

B. Samira Kohli v Dr Prabha Manchanda (2008)

The defining moment came in *Samira Kohli*.³⁹ The appellant, an unmarried woman of 44, consented to a 'diagnostic and operative laparoscopy'. While she was under general anaesthesia, the surgeon concluded that she had endometriosis and, after obtaining the consent of the appellant's mother who was waiting outside, removed her uterus and ovaries. The National Consumer Disputes Redressal Commission rejected her complaint. The Supreme Court allowed her appeal.

The Court's reasoning yields several principles that remain the bedrock of Indian consent law.

³⁴ Indian Council of Medical Research, *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (ICMR 2017) s 5.

³⁵ Digital Personal Data Protection Act 2023, ss 4, 6, 7(f).

³⁶ National Human Rights Commission, *Charter of Patients' Rights* (NHRC 2018).

³⁷ *Dr Laxman Balkrishna Joshi v Dr Trimbak Babu Godbole* AIR 1969 SC 128.

³⁸ *Ram Bihari Lal v Dr JN Srivastava* AIR 1985 MP 150.

³⁹ *Samira Kohli* (n 2).

A doctor must obtain the patient's consent before commencing any treatment, including surgery, and such consent must be real and valid. Real consent requires that the patient has the capacity and competence to consent, that the consent is voluntary, and that it is based on adequate information about the nature of the procedure, enabling the patient to understand what she is consenting to. Adequate information includes the nature and procedure of the treatment, its purpose, benefits and effect, available alternatives, an outline of the substantial risks, and the adverse consequences of refusing treatment; it need not, however, include remote risks or rare complications. Consent given only for a diagnostic procedure cannot be treated as consent for therapeutic treatment, except where the further procedure is necessary to save life or prevent serious harm. Finally, where the patient is an adult of sound mind, consent cannot be given by a relative on her behalf.

On the facts, the hysterectomy was an unauthorised invasion of the appellant's body amounting to a deficiency in service, even though the surgery itself was not shown to have been negligently performed.

C. The rejection of the 'reasonable patient' standard

The most consequential-and contested-part of *Samira Kohli* concerns the standard by which the adequacy of disclosure is judged. The Court surveyed the English approach in *Sidaway v Board of Governors of the Bethlem Royal Hospital*,⁴⁰ under which the amount of information to be disclosed was a matter of professional judgement, and the American approach in *Canterbury*,⁴¹ under which disclosure is measured by what a reasonable patient would consider material. It chose the former. It reasoned that conditions in India differed from those in the United States: many patients were poor and had limited education, the relationship between doctor and patient rested heavily on trust, and an expansive disclosure duty risked encouraging defensive medicine and frightening patients away from necessary treatment. The adequacy of disclosure was accordingly to be judged by reference to what was considered normal under accepted medical practice-in substance, the *Bolam* test applied to disclosure.⁴²

D. Consent within the negligence framework

Samira Kohli must be read alongside the Supreme Court's general negligence jurisprudence. In *Jacob Mathew v State of Punjab*, the Court adopted *Bolam* as the test for medical negligence

⁴⁰ *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871 (HL).

⁴¹ *Canterbury* (n 15).

⁴² *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 (QB).

in India, and held that criminal liability requires gross negligence or recklessness.⁴³ *Martin F D'Souza v Mohd Ishfaq*⁴⁴ and *Kusum Sharma v Batra Hospital and Medical Research Centre*⁴⁵ reaffirmed that approach and emphasised judicial deference to professional judgement. At the same time, the Court has shown willingness to hold hospitals to account. In *Nizam's Institute of Medical Sciences v Prasanth S Dhananka*, it awarded substantial compensation to a young man rendered paraplegic after a procedure undertaken without adequate investigation.⁴⁶ In *V Kishan Rao v Nikhil Super Speciality Hospital*, it held that consumer fora need not refer every medical negligence complaint to expert evidence.⁴⁷ More recently, in *Arun Kumar Manglik v Chirayu Health and Medicare Pvt Ltd*, the Court cautioned that the *Bolam* standard should not be applied in a manner that allows professional practice to escape scrutiny, drawing on the House of Lords' refinement in *Bolitho v City and Hackney Health Authority* that a professional opinion must be capable of withstanding logical analysis.^{48 49}

E. Assessment

Samira Kohli was an important advance. It established that consent is a distinct legal requirement, independent of the quality of the treatment, and firmly rejected the practice of substituting family consent for that of a competent adult. Its weakness lies in its choice of disclosure standard. By tying the duty of disclosure to medical practice, the Court made the profession the arbiter of what patients are entitled to know, which is difficult to reconcile with the autonomy the doctrine exists to protect.⁵⁰ The empirical premises of the judgment are also open to question: the rejection of patient-centred disclosure on the ground that patients are poor or uneducated risks entrenching the very inequalities that disclosure should help to overcome. As the next Part argues, the constitutional developments of the past decade have made these weaknesses impossible to ignore.

V. Constitutionalising Consent: Article 21, Privacy and Dignity

A. The right to health and its limits

Article 21 of the Constitution has long been read to include a right to health. In *Parmanand*

⁴³ *Jacob Mathew v State of Punjab* (2005) 6 SCC 1.

⁴⁴ *Martin F D'Souza v Mohd Ishfaq* (2009) 3 SCC 1.

⁴⁵ *Kusum Sharma v Batra Hospital and Medical Research Centre* (2010) 3 SCC 480.

⁴⁶ *Nizam's Institute of Medical Sciences v Prasanth S Dhananka* (2009) 6 SCC 1.

⁴⁷ *V Kishan Rao v Nikhil Super Speciality Hospital* (2010) 5 SCC 513.

⁴⁸ *Arun Kumar Manglik v Chirayu Health and Medicare Pvt Ltd* (2019) 7 SCC 401.

⁴⁹ *Bolitho v City and Hackney Health Authority* [1998] AC 232 (HL).

⁵⁰ Omprakash V Nandimath, 'Consent and Medical Treatment: The Legal Paradigm in India' (2009) 25 Indian Journal of Urology 343.

Katara v Union of India, the Supreme Court held that every doctor, whether in government or private practice, is under a professional obligation to extend medical aid to preserve life,⁵¹ and in *Paschim Banga Khet Mazdoor Samity v State of West Bengal* it held that failure by a government hospital to provide timely treatment violated Article 21.⁵² These decisions framed health primarily as a claim *to* treatment. The jurisprudence of the past fifteen years has added a second, equally important dimension: the right to decide *whether* to be treated.

B. Bodily integrity and decisional autonomy

The foundation of this second dimension is the recognition of decisional autonomy as a facet of privacy. In *Puttaswamy*, the plurality opinion of Chandrachud J identified three aspects of privacy-spatial control, informational control and decisional autonomy-and located the right to make intimate personal choices, including choices about one's body, within the protection of Article 21.⁵³ This holding transformed informed consent from a rule of private law into an expression of a fundamental right.

The groundwork had been laid in earlier cases. In *Suchita Srivastava v Chandigarh Administration*, the Court held that a woman's right to make reproductive choices is a dimension of personal liberty, and that the consent of a pregnant woman with an intellectual disability could not be overridden merely because of her condition.⁵⁴ In *Selvi v State of Karnataka*, it held that the involuntary administration of narcoanalysis and similar techniques violated the right to mental privacy and personal liberty.⁵⁵ Both cases treated bodily and mental integrity as constitutionally protected interests that the state may not invade without consent.

C. The right to refuse treatment

The end-of-life cases carried this logic to its conclusion. In *Aruna Ramchandra Shanbaug v Union of India*, a two-judge bench permitted passive euthanasia subject to High Court approval.⁵⁶ In *Common Cause*, a five-judge Constitution Bench went further, holding that the right to live with dignity includes the right to die with dignity, that a competent adult has the right to refuse medical treatment, including life-sustaining treatment, and that this right may be exercised in advance through an advance medical directive.⁵⁷ The procedural safeguards

⁵¹ *Parmanand Katara v Union of India* (1989) 4 SCC 286.

⁵² *Paschim Banga Khet Mazdoor Samity v State of West Bengal* (1996) 4 SCC 37.

⁵³ *Puttaswamy* (n 4) (Chandrachud J).

⁵⁴ *Suchita Srivastava v Chandigarh Administration* (2009) 9 SCC 1.

⁵⁵ *Selvi v State of Karnataka* (2010) 7 SCC 263.

⁵⁶ *Aruna Ramchandra Shanbaug v Union of India* (2011) 4 SCC 454.

⁵⁷ *Common Cause* (n 5).

prescribed in 2018 proved so cumbersome that the Court substantially simplified them in 2023.⁵⁸ In *Harish Rana*, decided in March 2026, the Court for the first time applied this framework to authorise the withdrawal of life-sustaining treatment, including clinically assisted nutrition and hydration, from a patient who had been in a permanent vegetative state for over thirteen years.⁵⁹

D. Reproductive autonomy

In *X v Principal Secretary, Health and Family Welfare Department*, the Court held that the rights of reproductive autonomy, dignity and privacy under Article 21 entitle an unmarried woman to decide whether to bear a child on the same footing as a married woman.⁶⁰ In *Devika Biswas v Union of India*, concerning deaths and injuries in mass sterilisation camps, the Court emphasised that reproductive rights include the right to make an informed and free choice about sterilisation, and that consent obtained through incentives, targets and inadequate information was not genuine.⁶¹

E. Implications for the standard of disclosure

These developments have a direct bearing on the *Samira Kohli* standard. If a competent adult has a constitutional right to refuse even life-saving treatment, it follows that she must have the information needed to exercise that right meaningfully. A right to choose that depends on the chooser being told only what the profession considers appropriate is a hollow right. The constitutional cases do not merely permit a patient-centred standard of disclosure; they presuppose one. Decisional autonomy is exercised by the patient, and the information relevant to it must therefore be measured by what matters to the patient. To the extent that *Samira Kohli* holds otherwise, it rests on a conception of the doctor–patient relationship that the Constitution, as interpreted in *Puttaswamy* and *Common Cause*, no longer supports.

It may be objected that fundamental rights operate primarily against the state, whereas most medical treatment in India is provided privately. The objection carries little weight. The constitutional values articulated in these cases inform the content of private law duties, and the Supreme Court has repeatedly drawn on them in developing the common law of negligence and consumer protection. Moreover, the state is itself the provider of a large share of healthcare,

⁵⁸ *Common Cause (A Registered Society) v Union of India* (2023) 14 SCC 131.

⁵⁹ *Harish Rana* (n 6).

⁶⁰ *X v Principal Secretary, Health and Family Welfare Department, Government of NCT of Delhi* 2022 SCC OnLine SC 1321.

⁶¹ *Devika Biswas v Union of India* (2016) 10 SCC 726.

including through public hospitals and publicly funded insurance schemes.

VI. Comparative Perspectives

A. England: from Bolam to Montgomery

For decades, English law treated disclosure as part of the doctor's general duty of care, measured by the *Bolam* test: a doctor was not negligent if she acted in accordance with a practice accepted as proper by a responsible body of medical opinion.⁶² In *Sidaway*, the House of Lords applied that test to disclosure, although Lord Scarman, dissenting, would have adopted the *Canterbury* approach, and Lord Bridge accepted that some risks might be so obviously necessary to an informed choice that no prudent doctor would fail to disclose them.⁶³ *Bolitho* later qualified *Bolam* by requiring that professional opinion be capable of withstanding logical analysis,⁶⁴ and in *Chester v Afshar* the House of Lords relaxed ordinary causation rules to vindicate the patient's right to make an informed choice.⁶⁵

The decisive shift came in *Montgomery*.⁶⁶ Mrs Montgomery, a diabetic woman of small stature, was not told of the significant risk of shoulder dystocia associated with vaginal delivery of a large baby, nor of the alternative of a caesarean section. Her son suffered serious injury during birth. The Supreme Court, in a joint judgment of Lord Kerr and Lord Reed, held that *Sidaway* should no longer be followed. A doctor is under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative treatments. A risk is material if a reasonable person in the patient's position would be likely to attach significance to it, or if the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it. The Court stressed that the assessment of materiality cannot be reduced to percentages, that the duty requires dialogue rather than the bombardment of the patient with technical information, and that the 'therapeutic exception' is limited and must not be abused.

The Court's justification is instructive for India. It observed that patients are now widely treated as persons holding rights rather than passive recipients of care, and that the law should reflect social and professional change, including professional guidance that already favoured patient-centred disclosure. In *McCulloch v Forth Valley Health Board*, the Supreme Court clarified that the question of which alternative treatments are reasonable remains a matter of professional

⁶² *Bolam* (n 42).

⁶³ *Sidaway* (n 40).

⁶⁴ *Bolitho* (n 49).

⁶⁵ *Chester v Afshar* [2004] UKHL 41, [2005] 1 AC 134.

⁶⁶ *Montgomery* (n 3).

judgement, while the duty to disclose those alternatives and their risks is governed by *Montgomery*.⁶⁷ This refinement answers the concern that a patient-centred standard leaves doctors without guidance.

B. North America

The patient-centred standard originates in *Canterbury*, which held that the duty to disclose is defined by the patient's right of self-decision and not by medical custom.⁶⁸ In Canada, *Reibl v Hughes* adopted a similar standard of disclosure and, on causation, asked whether a reasonable person in the patient's particular circumstances would have declined the treatment if properly informed.⁶⁹

C. Australia

In *Rogers v Whitaker*, the High Court of Australia rejected *Bolam* in the context of disclosure. The patient, almost blind in one eye, underwent surgery on that eye and lost sight in her good eye through a rare complication of which she had not been warned, despite having expressed anxiety about precisely such an outcome. The Court held that a risk is material if a reasonable person in the patient's position would be likely to attach significance to it, or if the doctor knows or should know that the particular patient would do so.⁷⁰ *Montgomery* drew directly on this formulation.

D. Lessons for India

Three lessons emerge. First, the patient-centred standard is now the common law mainstream, and the jurisdiction from which *Samira Kohli* borrowed its standard has itself abandoned it. Second, the experience of these jurisdictions does not support the fear that a patient-centred standard leads to an explosion of litigation or defensive medicine; *Montgomery* largely codified what good professional guidance already required. Third, the 'particular patient' limb of the *Rogers* and *Montgomery* tests directly answers the concerns that animated *Samira Kohli*. A materiality standard is sensitive to the patient's circumstances, including her education and values, because it requires the doctor to engage with the patient in front of her. It is precisely in a society marked by inequality in health knowledge that such engagement matters most.

⁶⁷ *McCulloch v Forth Valley Health Board* [2023] UKSC 26.

⁶⁸ *Canterbury* (n 15).

⁶⁹ *Reibl v Hughes* [1980] 2 SCR 880.

⁷⁰ *Rogers v Whitaker* (1992) 175 CLR 479.

VII. Consent in Special Contexts

The general doctrine is supplemented, and in places displaced, by specific rules in contexts where the patient's vulnerability or the gravity of the intervention calls for added protection. Four contexts are examined here.

A. Mental healthcare

The MHCA represents the most rights-oriented consent regime in Indian law. It presumes that every person, including a person with mental illness, has capacity to make mental healthcare decisions, and it defines capacity functionally, by reference to the person's ability to understand relevant information, appreciate its consequences and communicate a decision.⁷¹ It allows a person to make an advance directive specifying how she wishes, or does not wish, to be treated, and to appoint a nominated representative. Treatment without informed consent is permitted only in narrowly defined circumstances, including emergency treatment for a limited period, and certain procedures-such as electroconvulsive therapy without anaesthesia and muscle relaxants-are prohibited outright. The Act was enacted in part to implement India's obligations under the Convention on the Rights of Persons with Disabilities, which requires states to recognise the legal capacity of persons with disabilities on an equal basis with others and to ensure that healthcare is provided on the basis of free and informed consent.⁷²

The MHCA demonstrates that Indian legislation can adopt a demanding, autonomy-centred conception of consent, including a statutory definition requiring disclosure of risks, benefits and alternatives in a language and manner the person understands. That it does so for patients who are, by definition, among the most vulnerable undercuts the argument that patient-centred disclosure is unsuited to Indian conditions.

B. Minors and persons lacking capacity

Outside the MHCA, Indian law offers little guidance on consent by or for those who lack capacity. Under the Indian Majority Act 1875, a person attains majority at eighteen,⁷³ and the BNS permits guardians to consent on behalf of children and persons of unsound mind, provided the act is done in good faith for their benefit. There is no statutory recognition of the evolving capacity of mature minors, of the kind developed in English law, nor any general framework for supported decision-making for adults with fluctuating capacity outside the mental health

⁷¹ Mental Healthcare Act 2017, ss 4, 5, 14, 94, 95.

⁷² Convention on the Rights of Persons with Disabilities (adopted 13 December 2006, entered into force 3 May 2008) 2515 UNTS 3, arts 12, 25(d).

⁷³ Indian Majority Act 1875, s 3.

context. This gap is especially significant for adolescents seeking sexual and reproductive healthcare.

C. Clinical research

The history of clinical research in India illustrates the cost of weak consent protections. In *Swasthya Adhikar Manch v Union of India*, public interest litigation brought before the Supreme Court exposed serious concerns about trials conducted on poor and illiterate participants without meaningful consent and without compensation for injury or death.⁷⁴ The litigation prompted the requirement of audio-visual recording of consent and the compensation framework now consolidated in the New Drugs and Clinical Trials Rules 2019.⁷⁵ The ICMR's National Ethical Guidelines additionally require that consent documents be in a language the participant understands and that particular care be taken with vulnerable groups.⁷⁶

The research context matters for two reasons. First, it shows that Indian regulators accept that consent must be tailored to literacy and language, rather than diluted because of them. Second, the boundary between research and treatment is increasingly blurred by AI systems that are trained and refined on patient data generated in clinical care, a theme taken up in Part VIII.

D. Reproductive health and the end of life

In reproductive healthcare, the statutory requirement of the woman's consent under the MTP Act, and of written informed consent under the Surrogacy and ART Acts,⁷⁷ now operates against the constitutional backdrop of *X v Principal Secretary* and *Devika Biswas*. At the end of life, *Common Cause* and the 2023 modifications provide a structured process for executing and implementing advance medical directives, including attestation before a notary or gazetted officer and review by primary and secondary medical boards.⁷⁸ The Law Commission of India had earlier recommended legislation on the withdrawal of treatment from terminally ill patients,⁷⁹ and the absence of such legislation means that this area too remains governed by judicial guidelines.

⁷⁴ *Swasthya Adhikar Manch v Union of India* WP (C) No 33 of 2012 (SC).

⁷⁵ New Drugs and Clinical Trials Rules 2019 (n 33) ch VI and Third Schedule.

⁷⁶ ICMR, *National Ethical Guidelines* (n 34).

⁷⁷ See n 32.

⁷⁸ *Common Cause* (2023) (n 58).

⁷⁹ Law Commission of India, *Medical Treatment to Terminally Ill Patients (Protection of Patients and Medical Practitioners)* (Report No 196, 2006); Law Commission of India, *Passive Euthanasia: A Relook* (Report No 241, 2012).

E. Emergencies

In an emergency, consent may be dispensed with where the patient cannot consent and no guardian is available in time, under section 30 BNS. This exception must be read alongside *Parmanand Katara*, which obliges doctors to provide emergency care.⁸⁰ The exception is properly confined to what is immediately necessary; it does not license further non-urgent procedures, as *Samira Kohli* itself makes clear.

VIII. Informed Consent and AI-Assisted Medical Decision-Making

A. The problem

AI systems are increasingly used to read radiological images, screen for diabetic retinopathy and tuberculosis, predict deterioration in hospital patients and recommend treatment plans.⁸¹ India's policy framework has actively encouraged this, with NITI Aayog identifying healthcare as a priority sector for AI deployment and articulating principles for responsible AI.⁸² These tools promise real gains, particularly where specialists are scarce. But they also raise a question that consent doctrine has not yet confronted: must a patient be told that an AI system has shaped the diagnosis or recommendation on which she is asked to act?

Cohen, in the first sustained legal analysis of the question, posed it through the example of a patient advised to undergo surgery on the basis of an AI recommendation of which she is never told.⁸³ His conclusion, under United States law, was that existing doctrine would rarely require disclosure, but that the case for disclosure strengthens where the system is opaque, where it plays an outsized role in the decision, where it is used to reduce costs rather than improve care, or where the patient asks.

B. AI under the current Indian standard

Under *Samira Kohli*, the answer in India is straightforward but unsatisfying. Because disclosure is measured by accepted medical practice, and because there is as yet no settled practice of disclosing AI involvement, a doctor who fails to mention it is unlikely to be in breach of duty. The professional standard thus produces a self-reinforcing silence: no duty arises until the profession adopts a practice of disclosure, and the profession has little incentive

⁸⁰ *Parmanand Katara* (n 51); Bharatiya Nyaya Sanhita 2023, s 30.

⁸¹ Topol (n 7).

⁸² NITI Aayog, *National Strategy for Artificial Intelligence #AIforAll* (Discussion Paper, June 2018); NITI Aayog, *Responsible AI #AIforAll: Approach Document for India, Part 1 – Principles for Responsible AI* (February 2021).

⁸³ I Glenn Cohen, 'Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?' (2020) 108 *Georgetown Law Journal* 1425.

to adopt one while no duty exists. This illustrates the central weakness of the professional standard identified in Part IV.

C. AI under a materiality standard

A *Montgomery*-style standard yields a more principled answer. The question becomes whether a reasonable person in the patient's position would be likely to attach significance to the involvement of AI, or whether the doctor knows or should know that this particular patient would. The mere use of a software tool, any more than the use of a laboratory analyser, will not ordinarily be material. The use of AI is material where the system is opaque and its reasoning cannot be explained to the patient, as the patient cannot evaluate the basis of the recommendation. Materiality also arises where the system plays a decisive role with little independent clinical review, since the recommendation is, in substance, the machine's rather than the doctor's. Similarly, where the system has known performance limits for the patient's particular group, disclosure is material because the training data may under-represent the patient's sex, age, ethnicity or region. Where the doctor departs from the system's recommendation, the use of AI is material because the patient may wish to understand and weigh the disagreement. Finally, where the patient asks about the use of AI or has expressed concern about it, the use of AI is material because the "particular patient" limb is engaged. The third situation deserves emphasis. Obermeyer and colleagues demonstrated that a widely used algorithm in the United States systematically underestimated the health needs of Black patients because it used healthcare costs as a proxy for need.⁸⁴ Systems trained largely on data from other populations may perform differently on Indian patients, and systems trained on urban hospital data may perform poorly in rural settings. Where such limits are known, they are as material as any other risk of a diagnostic test.

The fourth situation reflects the phenomenon of automation bias-the tendency of clinicians to defer to automated recommendations even when they are wrong.⁸⁵ Disclosure, coupled with a genuine dialogue about the recommendation, is itself a safeguard against such over-reliance. Some ethicists have gone further, arguing that patients should have a right to refuse AI-based diagnosis and treatment planning altogether.⁸⁶

⁸⁴ Ziad Obermeyer and others, 'Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations' (2019) 366 *Science* 447.

⁸⁵ Kate Goddard, Abdul Roudsari and Jeremy C Wyatt, 'Automation Bias: A Systematic Review of Frequency, Effect Mediators, and Mitigators' (2012) 19 *Journal of the American Medical Informatics Association* 121.

⁸⁶ Thomas Ploug and Søren Holm, 'The Right to Refuse Diagnostics and Treatment Planning by Artificial Intelligence' (2020) 23 *Medicine, Health Care and Philosophy* 107.

D. Regulatory signals

The ICMR's 2023 guidelines support this analysis. They treat autonomy as a core principle, require that patients be informed about the use of AI in their care, and state that the consent process should give patients the ability to decline AI-based interventions.⁸⁷ The World Health Organization's guidance on AI in health similarly places the protection of human autonomy first among its principles.⁸⁸ Comparatively, the European Union's Artificial Intelligence Act requires deployers of certain high-risk AI systems to inform the persons affected that they are subject to such systems, mandates human oversight, and confers a right to an explanation of the role of the AI system in decisions that significantly affect a person's health, safety or fundamental rights.⁸⁹ Although the scope of these obligations in the clinical setting is still being worked out, and the effectiveness of explanation rights has been questioned in the data protection context,⁹⁰ they signal a clear legislative direction.

E. Consent to data and consent to treatment

AI also introduces a second consent question: the use of patient data to train and improve systems. The Digital Personal Data Protection Act 2023 requires consent that is free, specific, informed, unconditional and unambiguous, preceded by notice of the personal data to be processed and its purpose.⁹¹ Hospitals commonly bundle treatment consent with broad data-use clauses, a practice that sits uneasily with the requirement of specificity. Consent to treatment should never be conditioned on consent to the secondary use of data for model development.

F. Consent and liability

Finally, disclosure interacts with liability. Price, Gerke and Cohen have shown that, under current negligence law, a physician is most exposed when she follows a non-standard AI recommendation that turns out to be wrong.⁹² Clear disclosure and documentation of AI involvement protect both patient and doctor by making the decision a genuinely shared one.

⁸⁷ ICMR, *Ethical Guidelines for Application of Artificial Intelligence* (n 8) s 4.

⁸⁸ World Health Organization, *Ethics and Governance of Artificial Intelligence for Health: WHO Guidance* (WHO 2021).

⁸⁹ Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) [2024] OJ L 2024/1689, arts 14, 26(11), 86.

⁹⁰ Sandra Wachter, Brent Mittelstadt and Luciano Floridi, 'Why a Right to Explanation of Automated Decision-Making Does Not Exist in the General Data Protection Regulation' (2017) 7 *International Data Privacy Law* 76.

⁹¹ Digital Personal Data Protection Act 2023 (n 35) ss 5, 6.

⁹² W Nicholson Price II, Sara Gerke and I Glenn Cohen, 'Potential Liability for Physicians Using Artificial Intelligence' (2019) 322 *JAMA* 1765.

They also support the allocation of responsibility among clinicians, hospitals and developers, particularly as AI-based software increasingly falls to be regulated as a medical device under the Medical Devices Rules 2017.⁹³

The conclusion of this Part is that the AI question is not a separate problem requiring a separate doctrine. It is a test case for the general standard of disclosure. A patient-centred, materiality-based standard handles it coherently; the *Samira Kohli* standard does not.

IX. Recommendations for Reform

The analysis above supports reform at three levels: judicial, legislative and regulatory.

A. Judicial: reconsidering *Samira Kohli*

The Supreme Court should, in an appropriate case before a bench of suitable strength, reconsider the standard of disclosure adopted in *Samira Kohli* and adopt a materiality test along the lines of *Montgomery*.⁹⁴ The reformulated test would require a doctor to take reasonable care to ensure that the patient is aware of the material risks of a proposed intervention and of reasonable alternatives, including the option of no treatment. Materiality would be judged by reference to a reasonable person in the patient's position and to what the doctor knows or should know about the particular patient. Consistently with *McCulloch*, the identification of reasonable alternatives would remain a matter of professional judgement. The reformulation would retain the valuable parts of *Samira Kohli*: the insistence on real consent, the rule that diagnostic consent does not authorise therapeutic procedures, and the rejection of family consent for competent adults.

The Court should also make clear that the therapeutic exception-the doctor's discretion to withhold information that would seriously harm the patient-is narrow, and cannot be invoked merely because the information might lead the patient to refuse treatment the doctor favours.

B. Legislative: a codified framework

Parliament should enact a general statutory framework on consent to medical treatment, whether as a stand-alone Patients' Rights Act or as part of broader health legislation. The framework should define informed consent for all medical treatment, building on the definition in section 2(1)(i) of the MHCA,⁹⁵ to require disclosure of the nature, purpose, material risks,

⁹³ Medical Devices Rules 2017, GSR 78(E) (31 January 2017).

⁹⁴ *Montgomery* (n 3) [87].

⁹⁵ Mental Healthcare Act 2017 (n 29).

benefits and reasonable alternatives of the intervention, in a language and manner the patient understands, recognise the evolving capacity of mature minors, especially for sexual, reproductive and mental healthcare, establish supported decision-making for adults with impaired or fluctuating capacity, consistent with the CRPD, Abolish requirements of spousal consent for treatment of a competent adult, provide a statutory basis for advance directives and end-of-life decision-making, replacing the current reliance on judicial guidelines and give binding force to the core entitlements in the NHRC's Charter of Patients' Rights, including access to medical records and a second opinion.⁹⁶

C. Regulatory: practice standards and AI

The National Medical Commission should replace regulation 7.16 of the 2002 Regulations with a detailed standard on consent that addresses the content of disclosure, documentation, consent in emergencies and the role of interpreters. Consent forms in hospitals should be available in regional languages and supplemented, where appropriate, by visual aids, and a signed form should be treated as evidence of a consent process, not as a substitute for it.

On AI, the following measures are recommended: First, there should be a duty to disclose material AI involvement in the situations identified in Part VIII, accompanied by a right of the patient to ask whether AI was used in her care and to receive a truthful answer. Second, patients should have the right to decline AI-based diagnosis or treatment planning where a reasonable non-AI alternative is available, as already contemplated by the ICMR's 2023 guidelines. Third, consents should be kept separate, such that consent to treatment is never conditioned on consent to the use of data for training or improving AI systems. Fourth, meaningful human oversight should be ensured, including documentation of the clinician's independent assessment of AI outputs, in order to counter automation bias. Finally, developers should be subject to transparency obligations requiring disclosure of the populations on which a system was trained and validated, as well as its known performance limits, so that clinicians can, in turn, adequately inform patients.

These measures would not impose an unreasonable burden on clinicians. They would bring Indian law into line with the direction taken by the ICMR, the WHO and comparable legal systems, and would give practical content to the constitutional promise of decisional autonomy.

⁹⁶ NHRC, *Charter of Patients' Rights* (n 36).

X. Conclusion

The doctrine of informed consent in Indian health law has travelled a considerable distance. From a scattering of criminal law exceptions and professional rules, it has become, through *Samira Kohli*, a recognised legal requirement that is independent of the quality of treatment and that refuses to let relatives speak for competent adults. Through *Puttaswamy*, *Common Cause* and *Harish Rana*, it has acquired a constitutional foundation in the rights to privacy, bodily integrity and dignity.

Yet the doctrine remains incomplete. Its central rule-the standard by which the adequacy of disclosure is judged-still belongs to an earlier era in which the doctor decided what the patient needed to know. That rule is out of step with the constitutional jurisprudence that now underpins consent, with the special statutes that already demand more, and with the common law jurisdictions from which it was borrowed. It is also, as Part VIII demonstrated, unable to answer the most pressing new question facing consent law: whether patients must be told when machines help decide their care.

This paper has argued that the path forward lies in a materiality-based, patient-centred standard of disclosure, adopted by the courts and reinforced by legislation and regulation. Such a standard does not ask doctors to overwhelm patients with information, nor does it ignore the realities of Indian healthcare. It asks doctors to engage with the person in front of them, to tell her what matters to her decision, and to respect the choice she makes. That is what it means to take seriously Cardozo J's proposition that each adult of sound mind has the right to determine what shall be done with her own body. In an age of algorithmic medicine, that right requires, at the least, that she know who-and what-is helping to make the decision.