Informed Consent and The Legal Framework in India a Critical Study

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Abstract—**Informed consent is one of the central principles of contemporary medical law. It represents the legal and ethical recognition that a patient is not merely the recipient of medical treatment but an autonomous individual entitled to participate in decisions concerning their body, health and medical care. The principle requires healthcare professionals to obtain a patient's valid consent before undertaking medical examination, diagnosis, treatment or surgery, subject to legally recognized exceptions. Informed consent requires more than a signature on a consent form. It involves communication of relevant information, understanding, voluntariness and a genuine opportunity for the patient to accept or refuse the proposed intervention. In India, there is no single comprehensive statute exclusively regulating informed consent in medical treatment. Instead, the legal framework is dispersed among the Constitution of India, judicial precedents, professional regulations, consumer protection law, legislation concerning mental healthcare and persons with disabilities, and principles of medical negligence. Article 21 of the Constitution, particularly through the development of privacy, dignity and personal autonomy jurisprudence, provides an important constitutional foundation. The Supreme Court's decision in Samira Kohli v Dr Prabha Manchanda remains the principal authority on medical consent. The Court held that consent must be real and valid, requiring capacity and competence, voluntariness and adequate information about the proposed treatment. (Samira Kohli v. Dr. Prabha Manchanda, 2008)**

Subsequent jurisprudence, including Common Cause v Union of India, has strengthened the recognition of patient autonomy and the right to refuse medical treatment.(Common Cause v. Union of India, 2018) The Mental Healthcare Act 2017 provides particularly detailed statutory recognition of informed consent in the mental-health context.(Mental Healthcare Act, 2017) The legal position has also acquired new significance with telemedicine, digital health records and the developing framework for protection of personal data. This article examines the meaning and elements of informed consent, its constitutional and statutory foundations, judicial development, professional obligations, special situations involving minors and persons lacking decision-making capacity, emergency treatment, refusal of treatment, research, telemedicine and digital health. It concludes that Indian law has substantially recognized informed consent but remains fragmented, requiring greater legislative clarity and stronger institutional mechanisms for meaningful patient participation.

Index Terms—**Informed consent; patient autonomy; medical law; medical negligence; Article 21; right to privacy; medical ethics; patient rights; Samira Kohli; healthcare law.**

I. INTRODUCTION

Medicine involves an unusual relationship between professional expertise and personal autonomy. A doctor may possess specialized knowledge that a patient does not have, but the possession of medical knowledge does not ordinarily confer an unlimited right to decide what should happen to the patient's body. Modern medical law increasingly treats the patient as a participant in medical decision-making rather than merely an object of treatment. The doctrine of informed consent is a principal legal mechanism through which this transformation has occurred. It requires the patient to be given information sufficiently relevant to the proposed intervention so that a meaningful decision can be made. Consent must also be voluntary and given by a person having the necessary decision-making capacity.

The importance of informed consent becomes particularly evident in invasive procedures. A surgical intervention may be technically successful from a medical perspective, yet still create legal difficulties if it was performed without valid authorization. The distinction is therefore important between medical negligence in the performance of treatment and failure to obtain appropriate consent for treatment.

Indian law has developed the doctrine largely through judicial decisions rather than through one consolidated medical-consent statute. The Supreme Court's judgment in Samira Kohli v Dr Prabha Manchanda provides the leading statement of the law. The Court held that a doctor must obtain real and valid consent before treatment and that consent for one procedure cannot ordinarily be treated as consent for an additional and substantially different procedure. (Samira Kohli v. Dr. Prabha Manchanda, 2008)

The constitutional development of privacy and autonomy has further strengthened this principle. In Justice KS Puttaswamy (Retd) v Union of India, the Supreme Court recognized privacy as a constitutionally protected right and associated it with dignity, autonomy and personal choice.(Justice K. S. Puttaswamy (Retd.) v. Union of India, 2017) These principles are highly relevant to medical decisions because treatment necessarily concerns the individual's body and personal life.

At the same time, informed consent cannot be understood in absolute terms. Emergencies may require immediate treatment. Children may not possess full legal capacity. Patients may temporarily or permanently lack decision-making capacity. Mental healthcare may involve carefully regulated circumstances of supported decision-making. Research participants may require additional safeguards. Telemedicine creates questions concerning electronic consent and communication. The objective of this article is therefore to examine the Indian legal framework comprehensively and to identify the continuing challenges in transforming the principle of informed consent from a formal requirement into a meaningful process of patient participation.

II. CONCEPT AND MEANING OF INFORMED CONSENT

The expression "informed consent" describes a process through which an individual voluntarily authorizes a medical intervention after receiving information necessary for making a meaningful decision. Three ideas are particularly important:

Information – the patient must receive relevant information; Understanding – the information must be communicated in a manner the patient can reasonably understand; and Voluntariness – the decision must be made without coercion or improper influence. Consent therefore has both a legal and an ethical dimension.

The Supreme Court in Samira Kohli observed that consent in the doctor-patient relationship means permission given by a patient for an act to be carried out by a doctor, including diagnostic, surgical or therapeutic procedures. (Samira Kohli v. Dr. Prabha Manchanda, 2008) The Court distinguished between situations where consent may be implied and circumstances requiring express consent. For example, when a patient voluntarily approaches a doctor for ordinary consultation, consent to examination and consultation may ordinarily be implied. However, an invasive procedure ordinarily requires more specific authorization.

The central objective of informed consent is not to transfer medical decision-making from doctors to patients in every clinical matter. Doctors continue to exercise professional judgment regarding diagnosis and treatment. The legal principle instead requires that the patient's choice concerning whether to undergo the proposed intervention be respected after appropriate disclosure. Thus, informed consent can be understood as a shared decision-making process rather than a document.

III. HISTORICAL DEVELOPMENT OF CONSENT IN MEDICAL LAW

Historically, medical practice in many jurisdictions operated on a paternalistic model. The doctor was regarded as the person who knew what was best for the patient. This approach was based partly on the asymmetry of medical knowledge. Modern medical ethics progressively shifted towards autonomy. The patient became recognized as an individual possessing an independent interest in deciding whether to undergo treatment. The development of consent doctrine also reflects broader changes in the law of bodily integrity. A person ordinarily has legal protection against unauthorized physical interference. Medical treatment, even when beneficial, involves an intervention into the body. Consent therefore provides the legal authorizations for that intervention. Indian jurisprudence has gradually incorporated these principles. The Supreme Court's approach in Samira Kohli is particularly significant because it expressly rejected the proposition that a surgeon has unrestricted

authority to undertake additional treatment merely because the surgeon considers it beneficial.

The judgment thus represents a movement from a purely paternalistic model towards one in which patient autonomy is legally significant.

IV. CONSTITUTIONAL BASIS OF INFORMED CONSENT IN INDIA

Article 21 of the Constitution Article 21 provides: "No person shall be deprived of his life or personal liberty except according to procedure established by law." The Supreme Court has interpreted Article 21 expansively. The provision is no longer confined to physical existence but encompasses aspects of dignity, autonomy, privacy and meaningful personal liberty. Medical treatment directly affects bodily integrity and personal choice. Consequently, informed consent can be understood as closely connected with Article 21. The constitutional basis becomes particularly clear in cases involving refusal of treatment and end-of-life decisions.

In Common Cause v Union of India, the Constitution Bench recognized the right to die with dignity as part of the right to life and recognized the legal importance of advance directives. (Common Cause v. Union of India, 2018) The Court's reasoning placed individual autonomy and self-determination at the centre of end-of-life decision-making. The significance of this jurisprudence extends beyond end-of-life treatment. It demonstrates that competent adults have legally protected interests in making important decisions about medical intervention.

Right to Privacy

The Supreme Court's decision in Justice KS Puttaswamy (Retd) v Union of India transformed the constitutional understanding of privacy. The Court recognized privacy as a fundamental right protected by the Constitution and associated privacy with dignity, autonomy and personal choice. (Justice K. S. Puttaswamy (Retd.) v. Union of India, 2017) Medical information is inherently personal. Information regarding disease, diagnosis, reproductive health, mental health and treatment can reveal highly intimate aspects of an individual's life. The principle of informed consent therefore operates alongside medical confidentiality and privacy. A patient should not only have control over whether treatment is undertaken but should also have appropriate protection regarding personal medical information.

Dignity and Bodily Autonomy

The constitutional principle of dignity reinforces the idea that the patient must not be reduced to an object of medical intervention. Respect for bodily autonomy means that the individual has a legitimate interest in determining what medical procedures may be performed on their body. The Supreme Court's reasoning in Samira Kohli reflects this principle by rejecting the idea that a surgeon may undertake a substantially different operation merely because it is considered beneficial.(Samira Kohli v. Dr. Prabha Manchanda, 2008) The constitutional concept of dignity therefore provides a broader foundation within which informed consent operates.

V. ESSENTIAL REQUIREMENTS OF VALID INFORMED CONSENT

The person giving consent must possess the capacity to make the relevant decision. Capacity involves the ability to understand information relevant to the decision, appreciate its consequences and communicate a choice. Capacity is decision-specific. A person may be capable of making some medical decisions while requiring assistance with others. The Mental Healthcare Act 2017 expressly adopts a capacity-based approach in relation to mental healthcare. The Act considers whether the individual can understand the nature and purpose of treatment and its likely effects and consequences. (Mental Healthcare Act, 2017, §§ 4, 86, 89)

A patient should not be compelled through threats, coercion or improper pressure. The fact that a patient signs a form does not automatically establish voluntariness. The Supreme Court in Samira Kohli connected valid consent with freedom of choice. (Samira Kohli v. Dr. Prabha Manchanda, 2008) Voluntariness is particularly important where there is a substantial imbalance of power between the doctor and patient. Patients may naturally feel dependent upon their doctor and may therefore agree to recommendations without understanding their right to ask questions or refuse treatment. The healthcare professional should therefore create an environment in which the patient can make a genuine choice.

Information is the central component distinguishing informed consent from mere consent. The Supreme Court in Samira Kohli stated that information should enable the patient to make a balanced judgment regarding whether to undergo the treatment. (Samira Kohli v. Dr. Prabha Manchanda, 2008) Information ordinarily concerns: the diagnosis or clinical condition; the nature and purpose of the proposed treatment; material risks; expected benefits; significant consequences; reasonable alternatives; consequences of refusing treatment; and the possibility that additional procedures may become necessary. The doctor need not overwhelm the patient with every theoretical or remote possibility. The law requires information that is relevant and sufficiently significant to enable an informed decision.

VI. THE LANDMARK DECISION: SAMIRA KOHLI V DR PRABHA MANCHANDA

The leading Indian authority on informed consent is Samira Kohli v Dr Prabha Manchanda, decided by the Supreme Court in 2008. (Samira Kohli v. Dr. Prabha Manchanda, 2008) Samira Kohli, an adult patient, underwent a medical procedure involving diagnostic laparoscopy. During the procedure, the surgeon performed a more extensive operation involving removal of the uterus and ovaries. The patient subsequently challenged the procedure, arguing that she had not consented to the removal of her reproductive organs. The case therefore required the Supreme Court to examine the legal nature of consent and whether consent for one procedure could authorize a substantially different procedure.

The Supreme Court held that consent for a diagnostic procedure cannot ordinarily be treated as consent for an unrelated or substantially more extensive therapeutic procedure. The Court stated that where a surgeon is consulted and consent is obtained for a particular procedure, that consent does not provide unrestricted authority to perform additional procedures merely because the surgeon believes that they would benefit the patient. (Samira Kohli v. Dr. Prabha Manchanda, 2008)

The Court recognized an exception for genuine emergencies where immediate intervention is necessary to save life or preserve health and it would be unreasonable to delay treatment to obtain consent.

The Court summarized the requirements of valid consent: the doctor must obtain consent before commencing treatment; consent must be real and valid; the patient must possess capacity and competence; consent must be voluntary; consent must be based upon adequate information; the information should enable the patient to make a balanced decision; consent for one procedure does not ordinarily authorize a substantially different procedure; and an emergency may justify necessary additional treatment where delay would endanger life or health.(Samira Kohli v. Dr. Prabha Manchanda, 2008) The judgment remains the central starting point for analyzing informed consent in India.

VII. SPECIFIC CONSENT AND THE LIMITS OF GENERAL CONSENT FORMS

One of the most important lessons from Samira Kohli is that a general consent form cannot automatically authorize every procedure the doctor may subsequently consider desirable. Hospitals commonly use standard forms containing broad language such as consent to "any additional procedure considered necessary". Such clauses may be useful in appropriate circumstances, but they cannot necessarily provide unlimited authority. The more invasive, irreversible or significant the proposed intervention, the stronger the argument for specific consent. For example, consent for: diagnostic laparoscopy, does not automatically amount to consent for: hysterectomy; or consent for: removal of one organ, does not automatically authorize:

removal of another organ. The legal significance of the distinction lies in patient autonomy. The patient may have different personal, reproductive, social or religious reasons for accepting one procedure but refusing another.

VIII. EMERGENCY TREATMENT

Informed consent cannot be applied without regard to emergency medicine.

A patient may arrive unconscious following an accident, with severe bleeding or another immediately life-threatening condition. In such circumstances it may be impossible to obtain conventional consent. Indian law recognizes an emergency exception. In Samira Kohli, the Supreme Court accepted that an

additional procedure may be justified where it is necessary to save the patient's life or preserve health and delaying the procedure until consent is obtained would be unreasonable. (Samira Kohli v. Dr. Prabha Manchanda, 2008) The emergency exception should, however, remain limited to circumstances genuinely requiring immediate intervention. A doctor cannot rely on "emergency" as a general justification for performing an unrelated procedure that could reasonably have awaited consent. The legal principle may therefore be expressed as: Consent is the rule; genuine emergency intervention is the exception.

IX. RIGHT TO REFUSE MEDICAL TREATMENT

The doctrine of autonomy includes the right to refuse medical treatment. A competent patient may decide that the risks, burdens or personal consequences of a particular intervention are unacceptable. The decision may appear medically unwise to the doctor, but personal autonomy means that the patient is not required to justify every medical decision according to the doctor's preferred assessment. This principle received significant constitutional recognition in Common Cause v Union of India. (Common Cause v. Union of India, 2018) The Supreme Court recognized the right of a competent person to refuse medical treatment and considered advance medical directives in the context of end-of-life care. The principle demonstrates that autonomy operates in both directions: the right to accept treatment; and the right to refuse treatment.

X. ADVANCE MEDICAL DIRECTIVES

An advance medical directive allows a person, while competent, to express preferences concerning future medical treatment in circumstances where they may later lose decision-making capacity. In Common Cause, the Supreme Court recognized the constitutional importance of advance directives. (Common Cause v. Union of India, 2018). The decision was significant because it extended autonomy beyond the immediate doctor-patient encounter. An individual's medical preferences can have continuing relevance even when the individual subsequently becomes incapable of communicating. Advance directives are particularly relevant to: terminal illness; prolonged unconsciousness; end-of-life treatment; life-sustaining interventions; and decisions concerning withdrawal or withholding of certain medical interventions.

The Court subsequently modified aspects of the procedural framework governing advance directives, reflecting the continuing development of the law.(Common Cause v. Union of India, 2023)

XI. PROFESSIONAL REGULATION OF CONSENT

India's professional framework for medical practitioners has undergone regulatory transition. The National Medical Commission notified the Registered Medical Practitioner (Professional Conduct) Regulations 2023 in August 2023. However, the NMC subsequently issued an amendment notification placing those regulations in abeyance and expressly adopting the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002 until further notification. (National Medical Commission, 2023a) The NMC's current regulatory materials continue to list the 2023 regulations alongside the notification placing them in abeyance. (National Medical Commission, n.d.) This distinction is important for legal research because the 2023 regulations should not be presented as though they are currently operative professional-conduct rules. The 2002 regulations contain several consent-related provisions.

Regulation 7.16 provides for written consent before an operation and addresses consent by the patient or, in appropriate cases, by a parent or guardian. (Indian Medical Council, 2002, reg. 7.16)

Regulation 7.21 deals with in-vitro fertilization and artificial insemination and requires informed written consent following provision of information regarding the purpose, methods, risks, inconveniences and potential hazards of the procedure. (Indian Medical Council, 2002, reg. 7.21)

The regulations also address research involving patients and volunteers and require compliance with applicable ethical guidelines. (Indian Medical Council, 2002, reg. 7.22)

XII. CONSENT AND MEDICAL NEGLIGENCE

Informed consent must be distinguished from medical negligence. Medical negligence generally concerns

failure to meet the applicable standard of professional care. Informed-consent cases may instead concern whether the patient authorized the intervention in the first place. A doctor may perform a procedure competently but without appropriate consent. Conversely, a patient may provide proper consent but the doctor may nevertheless perform the procedure negligently. The Supreme Court in Jacob Mathew v State of Punjab examined the principles governing medical negligence and the standard applicable to professional medical practice. (Jacob Mathew v. State of Punjab, 2005)

The judgment remains an important authority on the distinction between professional error and actionable negligence. Consent does not provide immunity for negligent treatment. A patient cannot be considered to have consented to negligent performance merely because the patient consented to the procedure.

XIII.CONSUMER PROTECTION AND MEDICAL SERVICES

Medical services have also been examined under consumer protection law. The Supreme Court's earlier decision in Indian Medical Association v VP Shantha established that medical services, subject to the principles stated by the Court, could fall within consumer protection legislation. (Indian Medical Association v. V. P. Shantha, 1995) The Consumer Protection Act 2019 replaced the 1986 legislation and contains the modern consumer dispute framework. The interaction between informed consent and consumer law is significant because a patient may seek compensation where medical services involve deficiency, subject to the statutory framework and judicial interpretation.

The Supreme Court has continued to consider the relationship between medical services and consumer protection under the 2019 Act. (Medicos Legal Action Group v. Union of India, n.d.) Consent-related disputes may therefore arise in consumer proceedings as well as in other forms of civil or professional liability.

XIV. MENTAL HEALTHCARE ACT 2017

The Mental Healthcare Act 2017 represents one of India's most detailed statutory frameworks concerning consent in healthcare. (Mental Healthcare Act, 2017)

The Act expressly recognizes the importance of informed consent and decision-making capacity. Section 86, for example, provides that an independent patient admitted to a mental health establishment shall not be given treatment without informed consent. (Mental Healthcare Act, 2017, § 86) The Act also establishes mechanisms for supported decision-making where a person requires assistance. This represents an important shift away from automatically assuming that a person with mental illness lacks decision-making capacity. The Act adopts a rights-based framework that emphasizes: autonomy; dignity; participation; least restrictive care; informed consent; and supported decision-making.

XV. CONSENT AND PERSONS WITH DISABILITIES

The Rights of Persons with Disabilities Act 2016 provides an important statutory context for autonomy and equality. (Rights of Persons with Disabilities Act, 2016) Disability should not automatically be equated with incapacity. Healthcare professionals must distinguish between: the existence of a disability; and actual inability to make a particular decision. Where assistance is required, appropriate support should be provided to enable participation. This approach is consistent with the broader movement towards supported decision-making and respect for individual autonomy.

XVI. CONSENT OF MINORS

The position concerning minors requires special consideration. Children generally do not possess the same legal capacity as competent adults to make all medical decisions. Consequently, parents or legally authorized guardians may have an important role in consenting to treatment. The NMC's telemedicine guidance provides specific requirements concerning minors, including obtaining consent from a parent, adult sibling or legally appointed guardian in the circumstances addressed by the guidance. (Ministry of Health and Family Welfare, 2020) However, from an ethical and rights-based perspective, the child's views should not automatically be disregarded. The level of participation should take account of: age; maturity; understanding; nature of the treatment; and seriousness of the decision. As the child becomes

capable of understanding the decision, meaningful participation becomes increasingly important.

XVII. CONSENT AND REPRODUCTIVE HEALTHCARE

Reproductive healthcare frequently raises particularly significant questions of autonomy and bodily integrity. The Samira Kohli judgment itself concerned reproductive organs and demonstrated the importance of specific consent for procedures having permanent reproductive consequences. (Samira Kohli v. Dr. Prabha Manchanda, 2008) The older medical ethics regulations also contain specific provisions regarding procedures that may result in sterility and reproductive technologies. (Indian Medical Council, 2002, regs. 7.16, 7.22) Reproductive decisions can involve highly personal interests concerning family, fertility and bodily integrity. Consequently, the requirement of specific and meaningful consent is particularly important.

XVIII. CONSENT IN MEDICAL RESEARCH

Medical research raises a distinctive form of consent. A patient receiving ordinary treatment may expect the intervention to be directed primarily towards their individual medical benefit. A research participant may instead be exposed to an intervention partly or primarily for generating scientific knowledge. This distinction must be communicated clearly. The older professional regulations recognized clinical research involving patients or volunteers and required compliance with applicable ethical standards. (Indian Medical Council, 2002, reg. 7.22) In contemporary India, research involving human participants is also influenced by ethical guidance issued by the Indian Council of Medical Research and applicable regulatory requirements. A proper research-consent process should generally explain: the purpose of the research; procedures involved; foreseeable risks; possible benefits; alternatives, where relevant; confidentiality; compensation and treatment for research-related injury where applicable; voluntary participation; and withdrawal rights. Consent should therefore be understood as an ongoing research relationship rather than a one-time signature.

XIX. TELEMEDICINE AND INFORMED CONSENT

The expansion of telemedicine has created new dimensions of consent. The Telemedicine Practice Guidelines require patient consent for telemedicine consultation and distinguish between implied and explicit consent. (Ministry of Health and Family Welfare, 2020) Where the patient initiates a consultation, consent may ordinarily be implied by the act of seeking the consultation. Where the healthcare professional or another person initiates the consultation, explicit consent is required under the applicable guidance. (Ministry of Health and Family Welfare, 2020) The guidelines also recognize electronic forms of consent. Consent may therefore be communicated through: written documents; electronic records; audio; video; other appropriate digital mechanisms. The underlying legal principle remains unchanged: technological convenience should not eliminate meaningful patient choice.

XX. DIGITAL HEALTH AND DATA PROTECTION

Digital healthcare creates a second dimension of consent: consent to the processing of personal data. The Digital Personal Data Protection Act 2023 establishes a statutory framework for processing digital personal data.(Digital Personal Data Protection Act, 2023) The Act defines consent in terms requiring it to be free, specific, informed, unconditional and unambiguous, with a clear affirmative action for the specified purpose.(Digital Personal Data Protection Act, 2023, § 6)This framework becomes relevant to digital healthcare applications, telemedicine platforms, electronic health records and other systems processing identifiable health information.

The commencement of the DPDP Act is staggered. A November 2025 notification brought specified provisions into force immediately and scheduled other provisions for later commencement. (Ministry of Electronics and Information Technology, 2025) Therefore, legal analysis of healthcare data consent should identify which provisions are operative at the relevant date rather than assuming that every provision of the Act became effective simultaneously. Data consent and medical-treatment consent should also be distinguished. A patient may consent to medical

treatment without necessarily consenting to every possible use of their personal data. Similarly, consent to use data for treatment does not automatically mean consent to: public disclosure; commercial use; unrelated research; or publication identifying the patient. The purposes of each form of consent should therefore be clearly identified.

XXI. CONFIDENTIALITY AND CONSENT

Confidentiality is closely connected with informed consent. Patients disclose sensitive information because they expect healthcare professionals to protect it. The professional ethics framework requires protection of patient confidentiality and privacy.(National Medical Commission, n.d.)

Disclosure of medical information may nevertheless be legally permissible or required in particular circumstances, such as where legislation mandates disclosure or where another recognized legal exception applies. The essential principle is that confidentiality should be the starting point rather than an optional courtesy.

XXII. DOCUMENTATION OF CONSENT

Although informed consent is fundamentally a communication process, documentation has considerable evidentiary significance. A properly maintained medical record should indicate, where relevant: the proposed procedure; information communicated; material risks discussed; alternatives discussed; questions raised by the patient; decision made; refusal, if any; identity of the person providing consent;

date and time; and signatures or other appropriate authentication. A signed form is useful evidence but should not be treated as conclusive proof that informed consent existed. The Supreme Court's approach in Samira Kohli illustrates why courts may examine the substance of the consent rather than merely the existence of a document.(Samira Kohli v. Dr. Prabha Manchanda, 2008)

XXIII. LANGUAGE AND HEALTH LITERACY

India's social and linguistic diversity presents a practical challenge. Medical terminology can be difficult even for educated patients. The problem is greater where a patient has limited health literacy or does not understand the language in which the hospital documents are prepared. The objective of informed consent requires communication at a level the patient can understand. The NMC telemedicine framework expressly requires consent to be obtained in a language that the patient can comprehend with ease.(Ministry of Health and Family Welfare, 2020) Hospitals should therefore consider: regional-language consent forms; interpreters; visual explanations; diagrams; audio-visual materials; plain-language summaries; and opportunities for questions. Such measures can improve both patient autonomy and the quality of medical decision-making.

XXIV. INFORMED CONSENT AND THE DOCTOR-PATIENT RELATIONSHIP

The doctrine of informed consent should not be viewed as an adversarial mechanism directed against doctors. A meaningful consent process can strengthen the doctor-patient relationship. Trust is more likely to develop where patients believe that: information is being provided honestly; risks are not being concealed; alternatives are explained; questions are welcomed; and refusal will be respected.

The NMC's ethical framework emphasizes compassion, respect, communication, transparency, patient rights and autonomy. (National Medical Commission, 2002)

Thus, informed consent can be understood as both a legal obligation and a component of professional good practice.

XXV.CHALLENGES IN THE INDIAN LEGAL FRAMEWORK

The most significant structural issue is fragmentation. Rules relating to consent are distributed across: constitutional law; judicial precedent; professional regulations; consumer law; mental healthcare legislation; disability legislation; research regulations; and data protection law. This can make the law difficult for both patients and healthcare providers to understand. A paternalistic approach may continue to influence medical decision-making. Patients may sometimes be told that the doctor "knows what is best" rather than being given meaningful choices. Such an

approach is difficult to reconcile with the modern principle of autonomy.

Consent forms can become bureaucratic documents rather than instruments of communication. A patient may sign several pages without understanding their contents. The legal objective should therefore be to ensure quality of communication, not merely quantity of paperwork.

Special safeguards are required for: children; persons with disabilities; persons with mental illness; unconscious patients; elderly persons; persons with limited literacy; and persons facing language barriers. The law should promote participation rather than automatically replacing the patient's decision with another person's decision.

Emergency medicine creates a legitimate tension between autonomy and immediate protection of life. The law therefore needs carefully defined exceptions that prevent both: unjustified treatment without consent; and harmful delay in genuinely urgent situations.

Telemedicine and electronic records raise additional concerns concerning: identity verification; electronic consent; data privacy; cybersecurity; communication barriers; remote diagnosis; and documentation. The law must continue to adapt as healthcare becomes increasingly digital.

XXVI. COMPARATIVE PERSPECTIVE

The Indian doctrine can be understood against the development of informed-consent law in other jurisdictions. The English legal system traditionally used the concept of "real consent", whereas American medical law developed a more explicit doctrine of "informed consent".

In Montgomery v Lanarkshire Health Board, the UK Supreme Court adopted a patient-centred approach to disclosure, holding that doctors must take reasonable care to ensure that patients are aware of material risks and reasonable alternatives.(Montgomery v. Lanarkshire Health Board, 2015)

Indian law, however, has its own doctrinal development. In Samira Kohli, the Supreme Court expressly examined comparative principles but formulated the Indian position within the context of Indian medical law.(Samira Kohli v. Dr. Prabha Manchanda, 2008)

The comparison demonstrates a broader international movement towards greater recognition of patient participation, although the precise legal test differs between jurisdictions.

XXVII. CRITICAL ANALYSIS OF THE INDIAN POSITION

Indian law has made substantial progress in recognizing patient autonomy, but important conceptual questions remain. First, the absence of one comprehensive statute makes the framework difficult to navigate. Second, there is a potential distinction between formal informed consent and substantive informed consent. Formal consent asks whether a document was signed. Substantive consent asks whether the patient actually understood the decision. The second approach better reflects the underlying purpose of autonomy. Third, Indian law continues to balance two important interests: Professional medical judgment and patient autonomy. Doctors require professional discretion because patients cannot be expected to make clinical judgments about every technical detail. However, professional expertise cannot become a justification for ignoring patient choice. The appropriate legal balance is therefore not to eliminate medical judgment but to distinguish between: clinical decisions that properly belong to professional expertise; and personal decisions that properly belong to the patient.

Fourth, the regulatory transition concerning the NMC professional-conduct regulations illustrates the need for regulatory certainty. The NMC's 2023 professional-conduct regulations were placed in abeyance, while the 2002 regulations were reinstated. (National Medical Commission, 2023a)

XXVIII. CONCLUSION

Informed consent has become a fundamental component of medical law in India. Although no single comprehensive statute currently governs every aspect of consent in healthcare, the legal framework has developed through constitutional principles, judicial decisions, professional regulations and specialized legislation.

The Supreme Court's decision in Samira Kohli v Dr Prabha Manchanda provides the foundation for the modern Indian doctrine. It establishes that consent

must be real and valid, that the patient must possess capacity and competence, that the decision must be voluntary, and that adequate information must be provided before treatment. (Samira Kohli v. Dr. Prabha Manchanda, 2008)

The constitutional jurisprudence on privacy and dignity has reinforced the importance of personal autonomy. Puttaswamy placed autonomy and privacy within the constitutional protection of Article 21, while Common Cause demonstrated the importance of autonomy in decisions concerning refusal of treatment and end-of-life care. (Justice K. S. Puttaswamy (Retd.) v. Union of India, 2017; Common Cause v. Union of India, 2018)

The Mental Healthcare Act 2017 provides an important statutory example of a rights-based consent framework. It expressly recognises informed consent and decision-making capacity within mental healthcare. (Mental Healthcare Act, 2017, § 86) The professional framework also demonstrates the continuing evolution of medical regulation. The NMC's 2023 professional-conduct regulations were placed in abeyance and the 2002 regulations were adopted in their place, making accurate identification of the operative regulatory framework essential. (National Medical Commission, 2023a) The emergence of telemedicine and digital health has added new dimensions to consent. Consent now concerns not only the physical intervention itself but also, in appropriate circumstances, electronic communication, processing of health information and digital records.

Ultimately, the effectiveness of informed consent depends upon moving beyond the idea of a signed form. Consent should be understood as a continuing process of communication between healthcare professional and patient. A meaningful consent process enables the patient to understand the proposed intervention, appreciate its important consequences and exercise a genuine choice.

The future development of Indian medical law should therefore focus not merely on increasing documentation but on strengthening patient understanding, autonomy, dignity and participation. A legal framework that achieves these objectives can simultaneously protect patients, provide clarity to healthcare professionals and strengthen trust in the healthcare system.

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