Indian Journal of Forensic and Community Medicine 2024;11(4):159–172

Content available at: https://www.ipinnovative.com/open-access-journals

Indian Journal of Forensic and Community Medicine

Journal homepage: https://www.ijfcm.org/

Review Article

# The role of consent in Indian judiciary: Implications for cancer treatment practices

**Anmol Mahani**[1]*, **Rudranath Zadu**[2]

[1]*Dept. of Radiation Oncology, Himalayan Institute of Medical Sciences, Dehradun, Uttarakhand, India*
[2]*Corporate Consultants, Pune, Maharashtra, India*

ARTICLE INFO

*Article history:*
Received 03-10-2024
Accepted 12-11-2024
Available online 26-11-2024

*Keywords:*
Informed consent
Cancer treatment
Indian judiciary
Medical ethics
Patient autonomy
Healthcare law

ABSTRACT

**Background:** Informed consent is a fundamental ethical and legal requirement in medical practice, especially critical in high-risk treatments such as cancer care. The evolution of consent laws in India reflects the judiciary's commitment to safeguarding patient autonomy and ensuring informed decision-making. Article 21 of the Indian Constitution underpins the right to life, which courts have interpreted to include the right to informed consent in medical treatments. This is particularly relevant in oncology, where treatment choices involve complex and often life-threatening procedures.

**Aims and Objectives**: This manuscript aims to examine the role of informed consent in cancer treatment practices within the Indian judiciary framework. It seeks to explore the ethical implications, legal standards, and challenges in obtaining valid consent, particularly in Oncological procedures. Additionally, the manuscript aims to analyse key legal cases and their impact on shaping medical practices in cancer care across India.

**Material and Methods**: The manuscript is based on a comprehensive review of legal statutes, including the Indian Constitution, the Indian Penal Code, and the Indian Contract Act, alongside Medical Council of India (MCI) guidelines. Judicial rulings and case laws related to informed consent in cancer treatment were analysed. The legal and ethical frameworks surrounding patient autonomy and healthcare practitioner responsibility are examined through case studies and statutory interpretation.

**Conclusion:** The Indian judiciary has advanced the principles of informed consent, particularly in cancer care, ensuring that patients are fully informed about their treatment choices. However, challenges persist in ensuring that consent is not only informed but also voluntary and comprehensible. The judiciary's rulings have created a robust legal framework for consent in cancer treatment, yet further clarity and practical guidelines are required to address the complexities of modern medical practice.

This is an Open Access (OA) journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: reprint@ipinnovative.com

## 1. Introduction

Informed consent is a cornerstone of modern medical ethics and legal practice, empowering patients to make autonomous decisions about their treatment.[1] The concept, rooted in the Nuremberg Code of 1947 and reinforced by the Declaration of Helsinki in 1964, establishes that no medical procedure should be performed without the patient's voluntary agreement.[2] Informed consent is especially significant in oncology, where treatment choices often involve high-risk, invasive, and life-altering procedures such as surgery, chemotherapy, or radiation therapy.[3] For patients undergoing cancer treatment, the ability to make informed decisions is essential, as these treatments carry significant potential risks and long-term consequences.

The Indian legal system has gradually developed a robust framework surrounding informed consent, especially in

* *Corresponding author*.
*E-mail address*: dranmolmahani@gmail.com (A. Mahani).

https://doi.org/10.18231/j.ijfcm.2024.034
2394-6768/© 2024 Author(s), Published by Innovative Publication.

medical treatment.[4] Article 21 of the Indian Constitution, which guarantees the right to life and personal liberty, has been interpreted by the courts to include the right to informed consent.[5] Indian judiciary has played a crucial role in shaping the contours of consent in medical practice, defining the principles that govern doctor-patient relationships, particularly the patient's right to bodily autonomy.

Historically, Indian courts have faced numerous cases involving medical negligence where the issue of consent was central. These rulings have not only emphasised the importance of informed consent but have also clarified what constitutes valid consent. For example, the courts have ruled that consent must be "prior informed consent," meaning that the patient must be informed of all risks, benefits, and alternatives before any medical procedure, except in emergencies.[6]

In cancer treatment, where procedures are often complex and fraught with uncertainty, informed consent ensures that patients are aware of their treatment options, including possible side effects, success rates, and other critical information.[7] Moreover, cancer treatments frequently involve a continuum of care, including diagnostic tests, therapeutic interventions, and post-treatment follow-ups. Each stage requires separate, detailed consent from the patient, as outlined by Indian judicial rulings.[8] This legal requirement not only protects patient autonomy but also shields medical practitioners from legal liabilities associated with medical malpractice.[9–11]

Thus, the evolution of the legal doctrine of informed consent in India has significant implications for cancer care practices. This paper seeks to explore the current state of informed consent within the Indian judiciary, focusing on its application in cancer treatment, and discussing the legal, ethical, and practical dimensions that impact both patients and healthcare providers.

## 2. Aims and Objectives

The primary aim of this manuscript is to explore and analyse the legal and ethical dimensions of informed consent within the framework of cancer treatment practices in India. With the evolving complexity of oncology care, the issue of patient autonomy, particularly in relation to informed consent, has taken center stage. The manuscript seeks to provide an in-depth understanding of how the Indian judiciary has shaped and enforced the standards of informed consent in medical practice, with a particular focus on cancer care.

1. **Examine the role of informed consent in cancer treatment**: To highlight the importance of informed consent in oncology, ensuring patients fully understand their treatment options, risks, and outcomes.
2. **Analyse legal precedents on informed consent**: To review key Indian legal rulings that shape consent standards in cancer care and their implications for medical professionals.
3. **Investigate ethical implications of consent in oncology**: To explore ethical challenges in balancing patient autonomy with medical decision-making in cancer treatment.
4. **Assess practical challenges of obtaining consent in Indian medical practice**: To evaluate barriers such as literacy, language, and emotional states that affect valid consent in cancer care.
5. **Explore the impact of Indian law on consent procedures in oncology**: To assess how Indian legal frameworks standardise consent procedures and protect patient rights in cancer treatment.
6. **Identify areas for future legal and medical reforms**: To propose reforms in consent practices and legal frameworks to enhance patient autonomy and improve cancer care.

## 3. Methodology

The Material and Methods section of this manuscript is structured around a comprehensive review of legal cases, judicial rulings, statutes, and medical guidelines that define and shape the principles of informed consent in cancer treatment within India. This section outlines the methodologies employed to gather and analyse legal, ethical, and medical data concerning consent practices in oncology, specifically focusing on Indian law and judicial interpretations. Below are the key elements of the research framework and methodology:

### *3.1. Legal and judicial analysis*

This manuscript is based on a thorough analysis of the Indian legal system, particularly the judicial rulings and laws governing informed consent in medical practice. Key sources include:

1. **Indian constitution**: The primary legal framework used is Article 21, which guarantees the right to life and personal liberty. The courts have interpreted this article to include the right to bodily autonomy and, by extension, the right to informed consent.
2. **Indian penal code (IPC)**: The IPC provides legal guidelines for dealing with offences related to medical negligence and lack of informed consent, particularly Sections 87 to 91, which outline the limitations of consent in medical procedures.
3. **Indian contract act**: This law is critical in understanding the contractual relationship between a doctor and a patient, highlighting the conditions under which consent is deemed valid or invalid.

4. **Landmark case laws:** The analysis focuses on key judgments from the Supreme Court of India and various High Courts. These cases provide essential precedents that have shaped the legal discourse on informed consent in medical procedures, particularly cancer treatments. Key cases include Samera Kohli v. Dr. Prabha Manchanda and Another, which clarifies the requirement of prior informed consent in surgical procedures.[12]

### *3.2. Medical guidelines and ethical frameworks*

The research also delves into the guidelines provided by medical regulatory bodies and ethical frameworks that govern the practice of informed consent in India. Major sources include:

1. **Medical Council of India (MCI) regulations**: The MCI provides clear guidelines on obtaining consent, especially before conducting surgeries or any invasive medical procedures. These guidelines form the benchmark for ethical medical practice in India, ensuring that healthcare providers follow a standard protocol when obtaining informed consent from patients, particularly in complex fields such as oncology.
2. **International ethical codes:** Ethical principles derived from international frameworks like the Nuremberg Code (1947) and the Declaration of Helsinki (1964) are examined to show how these global standards have influenced Indian consent practices. These codes emphasise patient autonomy and informed consent as central to ethical medical practices worldwide.
3. **Informed consent models**: The manuscript reviews various models of informed consent (professional model, reasonable patient model, and subjective model) that guide the practice of securing consent. These models are evaluated within the Indian context to understand which practices are prevalent and how they align with the ethical principle of patient autonomy.

### *3.3. Judicial case study methodology*

To explore the judicial perspectives on informed consent, the manuscript employs a case-study methodology that examines notable rulings related to informed consent in cancer treatment. The case studies are selected based on their significance in shaping the legal landscape of medical consent in India. Each case is analysed to understand the court's reasoning, the legal principles established, and their implications for both medical practitioners and patients. The focus is on:

1. **Cases of medical negligence**: These cases are critical to understanding how courts adjudicate situations where informed consent was not adequately obtained. Examples include cases where the distinction between consent for diagnostic versus therapeutic procedures has been contested.
2. **Cases on patient autonomy**: Key rulings that reinforce the patient's right to make informed decisions about their treatment, particularly in high-risk cancer therapies.
3. **Cases involving emergency situations**: Special focus is given to cases where consent was not required due to life-threatening circumstances and the subsequent legal protections afforded to healthcare providers in such situations.

### *3.4. Statutory and legislative review*

A review of Indian statutes and amendments that govern medical practices and patient rights is conducted. Specific attention is paid to the following legal instruments:

1. **The Consumer Protection Act (COPRA)**: COPRA's role in addressing medical negligence and the breach of informed consent is explored. It allows patients to seek legal redress under the framework of consumer rights, adding an additional layer of accountability to healthcare practices.
2. **The transplantation of human organs act (1994, amended in 2011)**: This legislation is critical in cases involving organ transplants for cancer patients, where informed consent is required not only from the patient but also from family members in certain situations. The act also covers consent related to cadaveric organ donation.
3. **The mental health act, 1987**: This law is reviewed to understand how consent is obtained in cases involving patients with mental health challenges, ensuring they receive appropriate cancer treatment without violating their rights.

### *3.5. Ethical review and best practices*

The manuscript incorporates a critical review of ethical considerations surrounding the consent process in oncology, focusing on:

1. **Autonomy and beneficence:** Balancing patient autonomy with the doctor's ethical responsibility to provide the best possible care, even when patients refuse certain treatments. The manuscript explores situations where doctors might struggle between respecting patient decisions and acting in the patient's best interest (beneficence).
2. **Cultural and societal influences**: Consideration of the cultural, social, and linguistic challenges that may affect the quality and validity of informed consent in India, especially when dealing with a

diverse population with varying levels of literacy and healthcare knowledge.

### 3.6. Data sources and collection

The data used in this manuscript are derived from:

1. **Court records**: Legal databases and records of Indian Supreme Court and High Court rulings on medical consent issues are reviewed to gather relevant case laws.
2. **Medical journals**: Academic papers and medical journal articles related to oncology, medical ethics, and informed consent are analysed to provide insights into the medical community's practices and challenges in securing valid consent.
3. **Statutory and regulatory documentation**: Official documentation, such as the Indian Penal Code (IPC), Medical Council of India (MCI) regulations, and various health laws, is used to contextualise the legal obligations of healthcare providers in India.

### 3.7. Analysis and interpretation

The manuscript systematically analyses the material collected, with a focus on interpreting how the legal precedents and ethical guidelines are applied in the practical context of oncology. Special attention is given to how these rulings and guidelines protect patient rights while balancing the responsibilities of healthcare providers.

By utilising a combination of legal, ethical, and medical analyses, this manuscript aims to provide a comprehensive understanding of the principles and practices of informed consent in cancer care in India, offering insights into its challenges, judicial interpretations, and areas for future reform.

## 4. Role of Consent in Indian Judiciary for Cancer Practices

In the field of cancer treatment, the role of consent within the Indian judiciary is of paramount importance. Given the invasive and high-risk nature of oncology treatments, ensuring that patients are fully informed and consent voluntarily to their procedures is a critical legal and ethical obligation.[13] The judiciary in India has made significant contributions to developing the standards and requirements for informed consent, particularly in complex medical fields like oncology, where the consequences of treatment decisions can be life-altering.[14] This section explores the judicial interpretation, regulatory guidelines, and practical challenges surrounding consent in cancer care practices in India.

### 4.1. Judicial foundation of consent in cancer treatment

In India, the foundation of consent in medical treatment is derived from Article 21 of the Constitution, which guarantees the right to life and personal liberty.[15] The judiciary has interpreted this article to include the right to make decisions about one's own body, emphasising that no medical procedure can be performed without the patient's informed consent. In the context of cancer care, where treatment options like surgery, chemotherapy, and radiation therapy involve significant risks, the right to informed consent takes on heightened importance.

The Indian courts have consistently upheld that consent must be obtained prior to any medical intervention, barring emergency situations. This judicial stance was reinforced in cases like Samira Kohli v. Dr. Prabha Manchanda & Another (2008), where the Supreme Court clarified the distinction between diagnostic and therapeutic consent.[16] The court ruled that broad consent for diagnostic procedures does not automatically extend to therapeutic treatments unless explicitly mentioned. This ruling is particularly relevant in oncology, where diagnostic procedures like biopsies or exploratory surgeries are often followed by more invasive treatments, such as the removal of tumours or organs. The judiciary has made it clear that each stage of cancer treatment requires separate and explicit informed consent, reinforcing the patient's autonomy at every step.[17]

### 4.2. Legal requirements for informed consent in cancer care

The Indian judiciary has played a pivotal role in defining the legal requirements for informed consent in cancer treatment. The courts have laid down that consent must meet the following conditions to be legally valid:

1. Prior and informed: Consent must be obtained before any treatment begins and must be fully informed.[18] Patients must be made aware of all aspects of their treatment, including potential risks, benefits, alternatives, and consequences of not undergoing treatment. This is particularly important in cancer care, where patients may face significant risks, and the outcomes of treatment are uncertain.
2. Voluntary: Consent must be given voluntarily, without any coercion or undue influence.[19] In cancer treatment, where patients may feel vulnerable due to the life-threatening nature of their diagnosis, the judiciary has emphasised the importance of ensuring that consent is truly voluntary.[20]
3. Specific and detailed: Consent must be specific to the procedure being performed. As per the Indian judiciary, blanket consent or broad consent for one type of procedure cannot be extended to another, more invasive intervention without specific patient approval. For example, if a patient consents to a diagnostic

biopsy, the surgeon cannot proceed with tumour removal without obtaining additional consent.[21]

### 4.3. Consent for high-risk procedures in oncology

Cancer treatments often involve high-risk procedures, such as the removal of tumours, organ transplants, and radiation therapy, all of which carry the possibility of severe side effects or long-term complications. The judiciary has underscored the necessity for heightened scrutiny in securing consent for these procedures, given the potential risks involved.

In high-risk cancer treatments, written consent is usually mandatory. Although oral consent may be sufficient for minor or routine treatments, written consent is required for complex procedures like surgeries or chemotherapy.[22] The Medical Council of India (MCI) has issued guidelines mandating written consent for any surgical procedure, particularly those involving anaesthesia or significant pain. In oncology, where surgeries may involve the removal of vital organs or tissues, the judiciary has reinforced that written consent provides a higher standard of protection for both patients and healthcare providers. Written consent serves as a legal document that can be referenced in cases of medical disputes or malpractice claims.

### 4.4. Proxy consent and the role of family members in cancer treatment

In cases where cancer patients are incapacitated or unable to give consent themselves, the courts have addressed the issue of proxy consent.[23] Indian law allows for a legally authorised representative, such as a family member or guardian, to give consent on behalf of the patient. This is especially relevant in cancer care, where patients may be rendered unconscious or mentally incapacitated due to the severity of their illness or treatment.

However, the judiciary has been cautious in limiting the scope of proxy consent. The courts have ruled that proxy consent should only be used when absolutely necessary, and the decision must be made in the best interests of the patient. For instance, in the case of an incapacitated cancer patient who requires an urgent operation, the courts allow family members to provide consent, provided that the attending doctor fully informs the family about the risks, benefits, and potential outcomes of the procedure.

Notably, the courts have restricted the use of proxy consent for procedures that are not lifesaving. For example, in the case of Samira Kohli v. Dr. Prabha Manchanda, the court ruled that proxy risk, was invalid. The court emphasised that even though the procedure may have been medically beneficial, it did not constitute an emergency. Therefore, the consent provided by the patient's mother was not sufficient to justify the removal of the patient's reproductive organs. This ruling highlights the judiciary's firm stance on protecting patient autonomy, even when family members or guardians are involved in decision-making.

### 4.5. Emergency situations and consent in cancer treatment

One of the most complex issues surrounding informed consent in cancer care is the management of emergency situations. The Indian judiciary recognises that there are instances where obtaining consent is not feasible, such as when a patient's life is at immediate risk. In such cases, medical practitioners are allowed to perform life-saving procedures without obtaining prior consent. However, the courts have stipulated that this exception should be narrowly applied to ensure that it is not used to bypass the need for informed consent in non-emergency situations.

The courts have ruled that in cases of cancer, where the patient is unconscious or incapacitated and the delay in treatment could result in death or serious harm, doctors have a duty to act in the best interest of the patient. The Supreme Court of India in several rulings has emphasised that in such emergencies, doctors should proceed with necessary medical interventions without waiting for formal consent, as preserving life is paramount. However, the judiciary has also made it clear that such actions must be taken with the sole aim of saving the patient's life, and the scope of the intervention should be limited to addressing the immediate life-threatening condition.

## 5. Impact of judicial rulings on cancer treatment practices

The rulings of the Indian judiciary on informed consent have had a profound impact on cancer treatment practices. These judicial guidelines have not only reinforced the necessity of respecting patient autonomy but have also placed a significant legal and ethical burden on healthcare providers to ensure that they obtain valid and informed consent at every stage of the treatment process.

For oncologists, these rulings translate into a heightened responsibility to communicate clearly and transparently with patients, explaining the risks and benefits of each treatment option in detail. They must ensure that patients or their legal representatives fully understand the implications of their choices. This legal obligation goes beyond merely obtaining a signature on a consent form; it requires doctors to engage in meaningful discussions with patients, answering their questions and addressing any concerns they may have about the proposed treatment.

Furthermore, these judicial rulings have contributed to the development of standardised practices in hospitals and medical institutions across India. Medical facilities, especially those offering cancer care, are now more likely to have formalised consent procedures in place. This includes

providing patients with written consent forms that outline the specific details of the treatment, as well as ensuring that the process of obtaining consent is well-documented to protect both patients and healthcare providers in the event of legal disputes.

### *5.1. Challenges in implementing judicial standards*

Despite the clarity provided by judicial rulings, there are still practical challenges in implementing the standards of informed consent in cancer treatment across India. One of the major challenges is the varying levels of health literacy among patients. Cancer is a complex disease, and the treatments involved are often difficult for patients to understand, especially when medical terminology is used. Informed consent, therefore, becomes a challenge in situations where patients may not fully comprehend the risks, benefits, or alternatives due to limited education or language barriers.

Additionally, the emotional and psychological state of cancer patients, who may be grappling with the severity of their diagnosis, can affect their ability to make fully informed decisions. In such cases, doctors must take extra care to ensure that patients are not making decisions based on fear or misunderstanding, and that they have all the information they need to make rational choices about their care.

Another challenge is ensuring that consent is continuously sought throughout the cancer treatment process. As treatments evolve, new decisions must be made, and doctors must ensure that they obtain renewed consent for each major intervention. In some instances, this can lead to delays in treatment as patients or their families seek second opinions or further clarification, creating a tension between the need for timely medical intervention and the legal obligation to respect patient autonomy.

## 6. Role of the medical council of India (MCI) in regulating consent

The Medical Council of India (MCI) plays a critical role in regulating consent practices within the healthcare system. MCI guidelines mandate that written informed consent must be obtained for all invasive and high-risk procedures, particularly those involving anaesthesia or surgery. In cancer care, where such procedures are common, MCI regulations provide a framework for doctors to follow, ensuring that they meet the legal requirements for obtaining valid consent.

The MCI also emphasises the need for proper documentation of the consent process. This includes maintaining detailed records of the information provided to the patient, the patient's understanding of the treatment, and any questions or concerns raised by the patient or their family. These records serve as legal protection for doctors in the event of disputes or allegations of malpractice.

The Indian judiciary has been instrumental in defining the role of informed consent in cancer treatment practices, reinforcing the principle of patient autonomy and setting strict guidelines for medical practitioners. The courts have clarified that consent must be prior, informed, specific, and voluntary, and have placed limits on the use of proxy consent. While emergency situations allow for exceptions to this rule, these cases are narrowly defined to prevent misuse.

For cancer patients, the judiciary's rulings have ensured that their rights are protected and that they are given the opportunity to make informed decisions about their treatment. For healthcare providers, these rulings have established clear legal and ethical standards that must be followed to avoid liability. Despite challenges in implementation, the judicial framework for informed consent in India has significantly improved the transparency and accountability of cancer care practices.

## 7. Landmark Judgments on Informed Consent in Indian Judiciary (Figure 1)

The Indian judiciary has made several landmark judgments that have defined the contours of informed consent in medical settings. These rulings reinforce the rights of patients to make informed decisions about their medical treatments, particularly in high-stakes fields like oncology. Key cases include:

1. **Samira Kohli vs. Dr. Prabha Manchanda & Anr. (2008)**: This pivotal Supreme Court judgment highlighted the importance of prior informed consent in medical procedures. Here, the court ruled that consent for a diagnostic procedure does not extend to therapeutic interventions without the patient's explicit approval. This principle is especially relevant in oncology, where diagnostic tests are often followed by more invasive treatments. The case clarified that each procedure requires distinct consent, reinforcing patient autonomy in medical decision-making.
2. **Dr. Dhananjaya Y Chandrachud, J. - Supreme Court of India (2020)**: In this case, Justice Chandrachud underscored the principles of patient autonomy and informed consent, emphasising that patients have a fundamental right to make their own medical decisions. The ruling affirmed that healthcare providers must fully inform patients about risks and alternatives before proceeding with treatment. This judgment contributes to a broader understanding of consent, beyond simple agreement to a procedure, and affirms the need for comprehensive patient education.
3. **Landmark Judgment on Informed Consent (2022)**: In 2022, a special bench of the Supreme Court laid down guiding principles that strengthened the legal framework for informed consent in medical procedures. The court mandated that all healthcare

providers must thoroughly explain the potential risks, benefits, and alternatives to patients before obtaining their consent. This ruling is a significant step towards a more standardised and transparent consent process in India.

4. **Jaiveer Singh vs. Sunita Chaudhary (2021)**: This case revolved around consent and personal autonomy in medical treatment. The court held that valid consent must be voluntary and informed, setting a precedent for respecting patient rights in all medical interventions. For cancer treatment, where decisions carry profound implications, this case highlights the necessity of a fully informed and autonomous patient.
5. **Rajesh Kumar vs. State of Haryana (2020)**: This judgment addressed the responsibilities of healthcare providers in securing informed consent. The court reinforced that consent is not merely a formality but a fundamental right that must be respected to protect patients from involuntary or uninformed medical decisions.
6. S**unita Devi vs. State of Bihar (2022)**: This recent ruling expanded on the need for explicit patient consent, particularly in situations where patients may lack comprehensive understanding due to language or literacy barriers. It highlighted the judiciary's commitment to ensuring that all patients, regardless of background, are adequately informed about their treatment options.
7. **Anita Sharma vs. Dr. Rajesh Kumar (2023)**: This case further reinforced the necessity of obtaining detailed consent, especially in cases involving complex and potentially life-altering procedures. The ruling mandated that patients should be informed not only about the primary procedure but also about any foreseeable secondary outcomes.

## 8. Blanket Consent - Its Role and Implications

Blanket consent refers to a general consent provided by a patient for the use of their biological samples or health data in multiple research studies, often with the understanding that specific details of each study may not be disclosed at the time of consent. This type of consent offers logistical efficiency in medical research, enabling researchers to use samples without repeatedly seeking individual consent. However, blanket consent raises ethical considerations, especially around patient autonomy and data privacy. Unlike specific consent, which is limited to a particular study, blanket consent may lead to patients' data being used in ways they did not anticipate or fully understand, raising concerns over transparency and trust.

The implications of blanket consent in medical ethics are profound. While it can facilitate valuable scientific discoveries by simplifying consent processes, it may challenge the patient's right to be informed of each use of their data. Hence, researchers and institutions are encouraged to clearly communicate potential uses, ensure robust privacy protections, and consider implementing a system that allows patients to withdraw consent if desired. This approach balances the benefits of broad consent with respect for patient autonomy and fosters an ethical framework that aligns with evolving consent standards in medical research.

These judgments collectively reinforce the Indian judiciary's emphasis on patient rights and informed consent, creating a legal framework that aligns with international ethical standards in medical practice. In oncology, where patient understanding and choice are critical due to the high-risk nature of treatments, these cases underscore the need for clear, compassionate, and thorough communication between healthcare providers and patients.

## 9. COVID-19 Impact on Consent Practices in Oncology (Figure 2)

The COVID-19 pandemic introduced unprecedented challenges in oncology, significantly impacting informed consent practices and the ethical principles governing patient care. Various dimensions of oncology care experienced disruptions and adaptations as healthcare providers balanced patient safety with ethical and procedural rigor in consent practices.

1. **Bioethical and human rights considerations**: The pandemic imposed substantial obstacles to upholding bioethical standards in oncology care. Many patients faced delays in diagnosis and treatment, with ethical principles such as beneficence (promoting well-being) and non-maleficence (avoiding harm) being compromised. These challenges highlighted the tension between immediate public health priorities and the ethical obligation to provide timely cancer care. In many cases, the pandemic created conditions where standard protocols had to be re-evaluated to protect patient and provider safety, sometimes leading to ethical compromises.
2. **Impact on radiotherapy practices**: A study conducted at Tata Memorial Centre in Mumbai revealed a significant reduction in new patient registrations, radiotherapy consultations, and referrals during the pandemic. In response, the institution adopted hypo-fractionated radiotherapy regimens—treatment schedules that deliver higher doses in fewer sessions—to reduce patient visits and potential COVID-19 exposure. This adaptation exemplifies how pandemic-induced constraints on patient access led to modified treatment protocols in radiation oncology.
3. **Informed consent challenges**: The pandemic introduced unique hurdles in obtaining informed

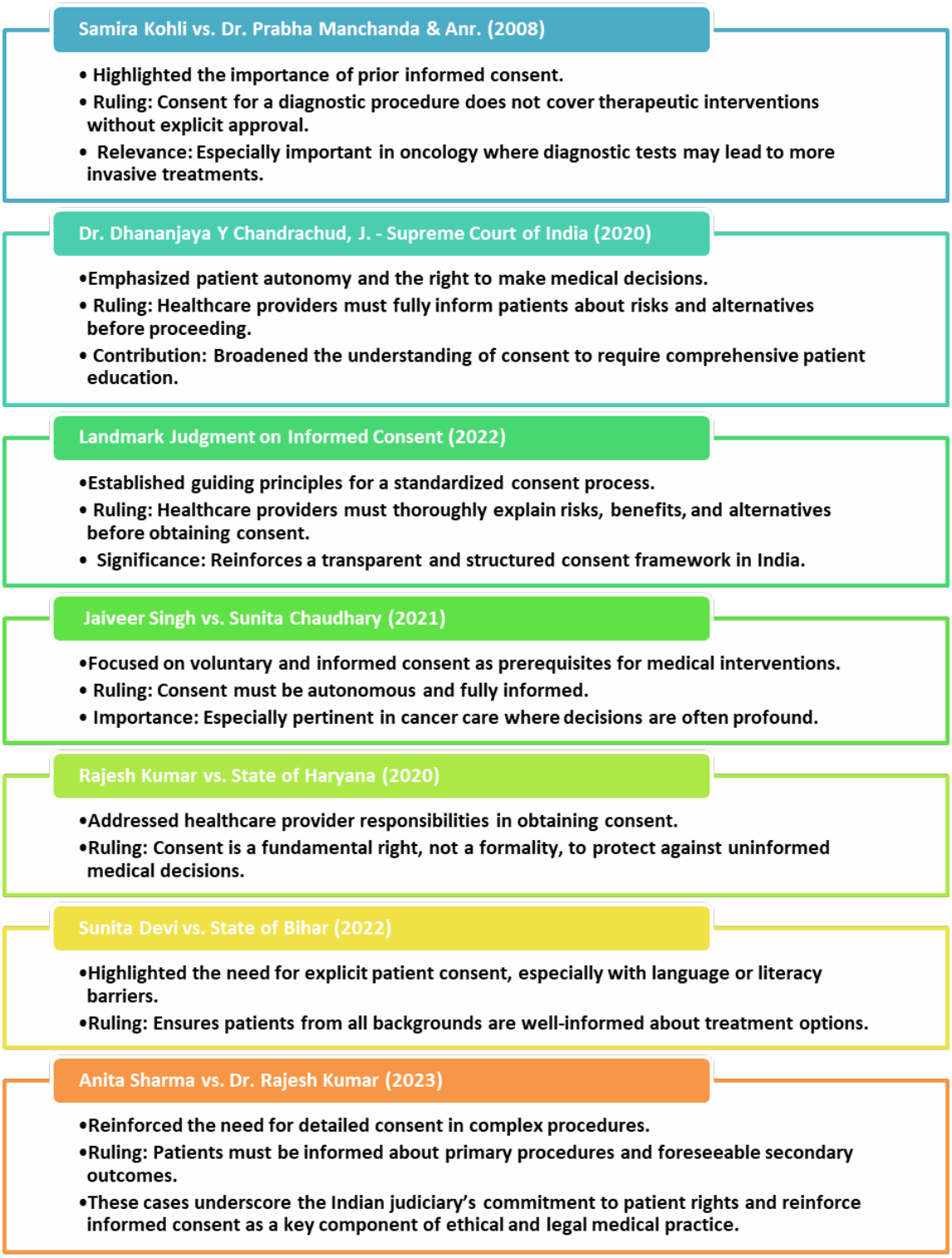


**Figure 1:** Landmark trials on informed consent

consent, especially for clinical research. Restrictions on in-person interactions necessitated innovative consent methods, including the use of electronic consent forms and telemedicine consultations. These modifications allowed the consent process to continue despite physical distancing requirements, though they also raised concerns about ensuring comprehensive patient understanding in a virtual environment. The shift to electronic consent highlighted the need for flexibility in consent procedures to adapt to public health crises while maintaining ethical standards.

4. **Gynaecological oncology care**: COVID-19 significantly affected all aspects of gynaecological oncology, as treatment delays and procedural adjustments became common. Many oncologists adopted virtual platforms for patient education and follow-up care, incorporating telemedicine and online resources into their practice. These technological adaptations provided continuity in patient care and education, though they also presented challenges in ensuring that patients received the same quality of communication and understanding as in-person interactions.

## 10. Telemedicine and Digital Consent in Oncology

The integration of telemedicine and digital consent in oncology has marked a significant shift in the way cancer care is delivered, especially highlighted during the COVID-19 pandemic. These technological advancements have enabled healthcare providers to maintain continuity of care remotely, while also addressing the practical and ethical challenges of informed consent in a digital setting.

1. **Telemedicine in cancer care**: Telemedicine has fundamentally transformed cancer care in India, proving especially beneficial during the pandemic. It has facilitated remote consultations, follow-up appointments, and even multidisciplinary team discussions, thus ensuring that patients continue to receive critical care despite mobility restrictions. This shift has made cancer care more accessible and efficient, allowing patients to consult with specialists from distant locations and reducing the need for frequent hospital visits. By enabling remote access to cancer care, telemedicine has also contributed to improved outcomes in regions with limited healthcare infrastructure.
2. **Digital consent:** The COVID-19 pandemic accelerated the adoption of digital consent processes, commonly referred to as electronic consent (e-consent). E-consent allows patients to provide informed consent remotely, through digital platforms, thus enabling healthcare providers to uphold the principles of autonomy and informed decision-making. This digital approach has proven invaluable in situations where face-to-face interactions are limited or risky, such as during infectious disease outbreaks. E-consent platforms are designed to be secure, protecting patient data privacy while allowing for seamless, transparent communication between patients and healthcare providers.
3. **Challenges and opportunities**: While telemedicine and digital consent have introduced many benefits to cancer care, they also come with specific challenges. Technological infrastructure remains a significant barrier, particularly in rural and remote areas where internet access is inconsistent. Additionally, digital literacy varies widely among patients, making it crucial to provide guidance to ensure that patients understand how to use these platforms effectively. Security concerns also play a critical role, as digital consent processes must protect sensitive patient information to maintain trust and comply with data protection regulations. Addressing these challenges is essential to successfully implement telemedicine and e-consent, thereby enhancing the accessibility and efficiency of cancer care in India.

Telemedicine and digital consent have not only made cancer care more flexible and resilient but also raised important considerations for the future of oncology practice. As these technologies continue to evolve, they hold the potential to reshape consent practices, making healthcare both patient-centered and digitally integrated.

## 11. Foundational Principles of Biomedical Ethics in Cancer Care

Ethical decision-making in cancer care rests on the foundational principles of biomedical ethics: autonomy, beneficence, non-maleficence, and justice. These principles, developed by Beauchamp and Childress, serve as the cornerstone of ethical medical practice, particularly in oncology where complex treatment choices and ethical dilemmas often arise. Understanding and applying these principles within the framework of natural law and medical ethics enhances the ability of healthcare providers to make decisions that prioritise patient welfare and uphold societal trust.

1. **A natural law approach to biomedical ethics**: In "A Natural Law Approach to Biomedical Ethics," Melissa Moschella (2020) explores how natural law theory offers a deeper interpretation of the four principles of biomedical ethics, facilitating a more cohesive approach to medical ethics. By integrating natural law theory with autonomy, beneficence, non-maleficence, and justice, healthcare providers can attain a more holistic view of patient care that aligns with both moral obligations and ethical standards. This approach

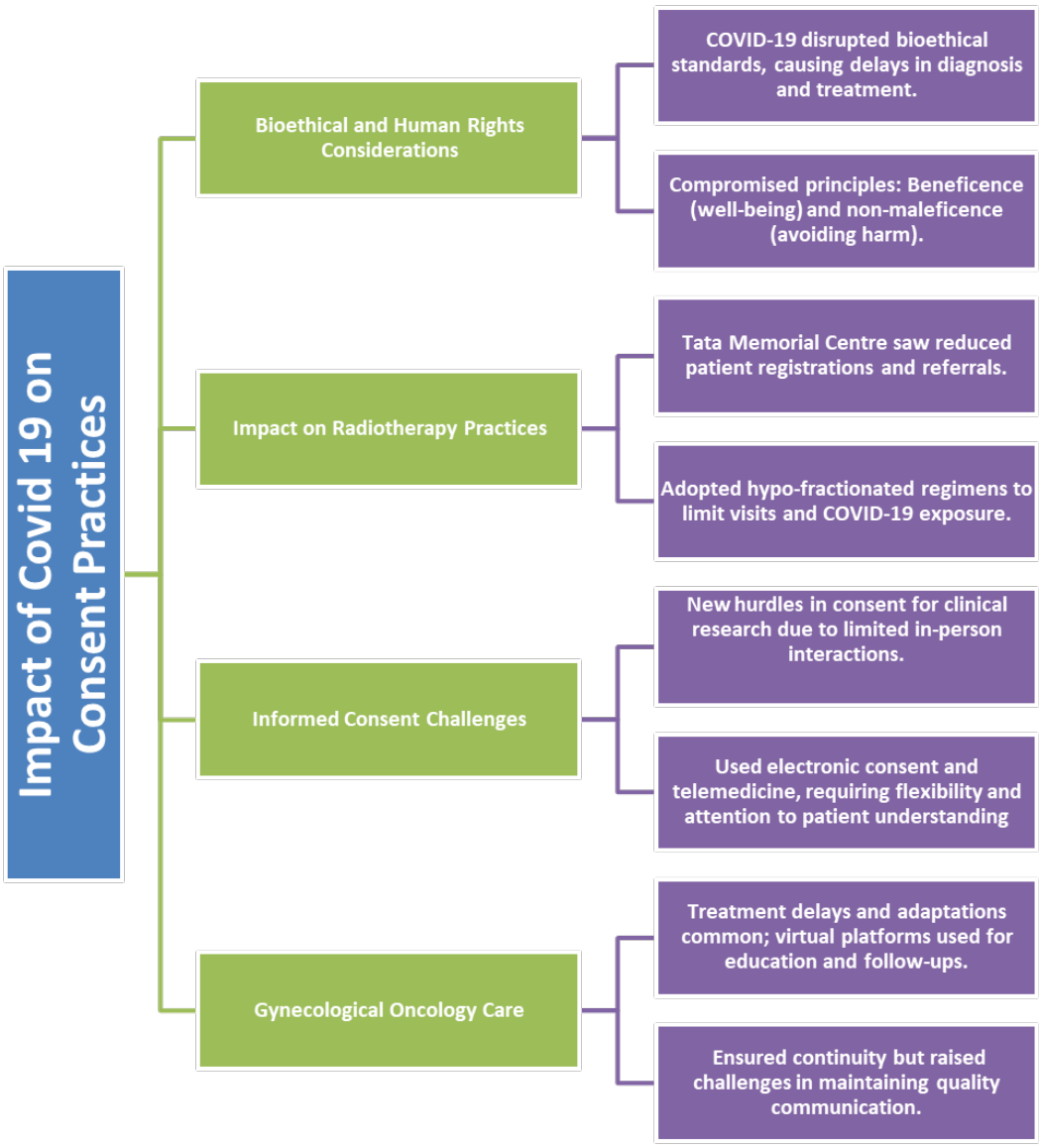


**Figure 2:** Impact of Covid 19 on consent practices in oncology

is particularly relevant in oncology, where ethical considerations are intertwined with the patient's physical and emotional well-being.

2. **Medical ethics and law**: Naresh Shetty's (2023) article in the Indian Journal of Orthopaedics underscores the essential link between medical ethics and legal frameworks, arguing that ethical principles enhance the trustworthiness and accountability of healthcare providers. This symbiosis between law and ethics is crucial in fields like oncology, where decisions may have life-altering implications. By upholding ethical principles alongside legal requirements, healthcare professionals can foster a medical environment that is both legally compliant and ethically sound, thus reinforcing public trust in medical institutions..
3. **Defending the four principles approach**: Raanan Gillon (2014) defends the four-principles framework as a robust foundation for medical ethics in his paper, "Defending the Four Principles Approach as a Good Basis for Good Medical Practice and Therefore for Good Medical Ethics." Gillon argues that

beneficence, non-maleficence, respect for autonomy, and justice collectively provide a comprehensive guide for ethical medical practice. By addressing criticisms of this approach, Gillon reaffirms its relevance, suggesting that these principles support decision-making processes that are adaptable yet firmly grounded in ethical norms. In oncology, this framework helps navigate challenging treatment decisions, balancing the need to do good (beneficence) with the imperative to avoid harm (non-maleficence) while respecting patient autonomy and ensuring fairness in treatment access.

## 12. Legal Standards and Evolving Perspectives on Informed Consent in India

The importance of informed consent in medical practice has been reinforced through judicial rulings and academic analyses, which highlight the necessity for patient autonomy and detailed disclosure by medical practitioners. These developments in the Indian legal landscape emphasise that valid consent is a crucial safeguard in healthcare, protecting patients' rights and guiding ethical medical practices.

1. **Sabiha Hamid vs. Dr. M Khan Hospital (2021)**: In this landmark case, the court ruled in favour of the patient, Sabiha Hamid, who had undergone a medical procedure without appropriate informed consent. The judgment highlighted the obligation of healthcare providers to obtain explicit consent prior to any medical intervention, regardless of the procedure's complexity. The ruling underscored that the lack of proper consent not only violates patient autonomy but also constitutes medical negligence, affirming the judiciary's commitment to patient rights.
2. **Prahalad Sriram's analysis on consent in medical negligence cases (2020)**: Prahalad Sriram's analysis provides an in-depth look at the evolving standards of informed consent in cases of medical negligence in India. Sriram advocates for greater emphasis on patient autonomy, proposing that healthcare providers should enhance disclosure practices to align with international standards. This analysis argues that India's medical consent practices require reform to prioritise patient understanding, address power imbalances in doctor-patient relationships, and minimise incidences of negligence due to inadequate information..
3. **Informed consent to clinical research in India (2020)**: The legal framework surrounding informed consent in clinical research is still developing in India, as highlighted in a 2020 analysis. The article notes that while clinical research is increasingly common, a robust doctrine for information disclosure in research settings has yet to be established. The lack of clear guidelines often leaves participants inadequately informed about the risks, benefits, and purpose of research trials. This gap underscores the need for regulatory advancements to ensure that research participants receive comprehensive information, thereby protecting their rights and well-being within the clinical research context.

## 13. Socioeconomic and Cultural Barriers to Informed Consent in Cancer Care

Informed consent in cancer care is complex and influenced by a range of socioeconomic, cultural, and geographic factors. These barriers can hinder effective communication and impact patients' understanding of their treatment options, ultimately affecting their autonomy and the quality of care they receive.

1. **Rural-urban disparity**: A study published in BMC Cancer highlights the significant disparities in cancer burden and healthcare access between rural and urban populations in India. Rural patients often face challenges such as lower literacy rates, limited access to healthcare facilities, and a higher likelihood of being engaged in unskilled or semi-skilled professions. These factors affect their understanding of medical procedures and limit their ability to give informed consent. For healthcare providers, addressing these disparities is essential to ensure that all patients, regardless of background, have the necessary information to make informed decisions about their care.
2. **Economic burden of cancer treatment:** Research from the Journal of Social and Economic Development-examines the high out-of-pocket (OOP) expenses associated with cancer treatment in India. These expenditures can create inequities in access to care, with lower-income and non-schedule caste/tribe (SC/ST) populations disproportionately affected. Financial strain may compel patients to make decisions based on affordability rather than medical suitability, affecting the quality of their consent. The economic burden can thus undermine patient autonomy by limiting the feasible treatment options, as patients may prioritise cost over efficacy..
3. **Socioeconomic gradient in cancer prevalence**: A study published in PLOS ONE found that cancer-related OOP spending is among the highest for any medical condition, and many households resort to borrowing or selling assets to afford treatment. The financial sacrifices required for cancer care can weigh heavily on patients' decision-making processes, impacting their ability to provide genuine, informed consent. This economic pressure exacerbates the vulnerability of cancer patients, particularly those from lower-income backgrounds, as financial concerns can

overshadow medical advice in their decision-making.

4. **Socio-cultural barriers**: Additional research in BMC Cancer identifies socio-cultural factors, such as joint family structures, lower levels of education and awareness, and a lack of trust in healthcare professionals, as barriers to early detection and informed consent. These cultural dynamics can complicate the communication process, as patients may rely on family members for decisions or feel uncertain about questioning medical advice. The presence of socio-cultural barriers underscores the need for culturally sensitive communication strategies to ensure that consent is not only informed but also aligns with the patient's personal and family context.

## 14. Discussion

The doctrine of informed consent is founded on the principle of patient autonomy. However, the the concept of informed consent plays a central role in cancer care, particularly in India where the legal and ethical framework surrounding medical consent has seen significant development. The discussion on informed consent in oncology is multifaceted, involving legal mandates, ethical principles, and practical challenges. In cancer treatment, where interventions are often invasive and outcomes uncertain, obtaining informed consent is not just a legal obligation but an ethical necessity to respect patient autonomy, ensure transparency, and foster trust between healthcare providers and patients.

### *14.1. Legal and ethical foundations of informed consent in cancer care*

At its core, informed consent is built upon the ethical principle of patient autonomy, which allows individuals to make decisions about their own bodies and medical treatments. In India, this principle is enshrined in Article 21 of the Constitution, which guarantees the right to life and personal liberty. The Indian judiciary has interpreted this right to include the right to make informed decisions about medical treatment, particularly in life-threatening situations such as cancer. This judicial interpretation aligns with the ethical frameworks set by international declarations like the Nuremberg Code (1947) and the Declaration of Helsinki (1964), both of which emphasise the importance of voluntary and informed consent in medical practice

Cancer treatments often involve a series of high-risk, invasive procedures, such as chemotherapy, radiation, and surgical interventions, all of which carry significant risks of side effects, complications, and long-term health impacts. Ensuring that patients understand these risks and provide their voluntary, informed consent is critical to respecting their autonomy. The Supreme Court of India has reinforced the necessity of prior informed consent in its rulings, establishing that patients must be made fully aware of the risks, benefits, alternatives, and consequences of the treatment they are consenting to.

Ethically, informed consent serves not only to protect the patient's right to autonomy but also to ensure that healthcare providers engage in beneficence, acting in the best interest of the patient while respecting their right to make decisions that affect their well-being. Balancing these ethical obligations becomes particularly challenging in oncology, where patients may be required to make complex, high-stakes decisions about treatments that could potentially save their lives or significantly impact their quality of life.

### *14.2. Judicial rulings shaping the consent process in oncology*

The Indian judiciary has made significant contributions to the legal framework surrounding informed consent, particularly in cancer care. Through a series of landmark rulings, the courts have clarified the requirements for valid consent, distinguishing between diagnostic and therapeutic consent and underscoring the need for specificity in consent forms.

One of the key rulings that shaped the landscape of medical consent in India is the Samira Kohli v. Dr. Prabha Manchanda case, where the Supreme Court ruled that consent given for diagnostic purposes does not automatically extend to therapeutic procedures. In this case, the patient had consented to a diagnostic laparoscopy, but the surgeon proceeded with a hysterectomy based on intraoperative findings without obtaining further consent. The court ruled that the surgeon had violated the patient's autonomy, as the consent for diagnostic surgery did not encompass therapeutic intervention. This ruling set a crucial precedent in Indian medical law, emphasising that broad or blanket consent is not sufficient for invasive procedures and that separate, explicit consent is required for each stage of treatment

This judicial stance is particularly important in oncology, where diagnostic procedures such as biopsies or exploratory surgeries often lead to further therapeutic interventions. The court's ruling ensures that patients have the right to be informed at each step of the treatment process and that their consent is not presumed to extend beyond the specific procedure for which it was obtained. This case law also highlights the judiciary's role in curbing medical paternalism, reinforcing that doctors cannot make unilateral decisions about a patient's treatment, even if they believe it to be in the patient's best interest.

The judiciary has also clarified that in emergency situations, where delaying treatment could result in the patient's death or serious harm, doctors may proceed without consent. However, the courts have limited this exception to true medical emergencies, ensuring that it is not used to bypass the need for consent in non-

emergency situations. This limitation is particularly relevant in oncology, where patients often face critical and time-sensitive decisions about their care.

### *14.3. Practical challenges in securing informed consent in cancer care*

Despite the clear legal and ethical guidelines surrounding informed consent, healthcare providers face numerous challenges in implementing these standards in practice, especially in the context of cancer care. One of the most significant challenges is ensuring that patients fully understand the complex and often technical information provided to them about their treatment options.

Cancer treatments typically involve a range of highly specialised procedures, each with its own risks, benefits, and potential outcomes. Communicating this information in a way that patients can comprehend is crucial for obtaining valid informed consent. In India, where literacy levels and access to healthcare education vary widely, ensuring that patients understand their treatment options is a significant hurdle. Additionally, language barriers and cultural differences can further complicate the consent process, particularly when patients come from diverse backgrounds or have limited understanding of medical terminology.

Patients facing cancer diagnoses are often in a vulnerable emotional and psychological state, which can impact their ability to make fully informed decisions. The psychological burden of a cancer diagnosis can lead to decision-making that is influenced by fear, anxiety, or a sense of urgency, rather than a clear understanding of the medical information provided. In such cases, healthcare providers have an ethical obligation to ensure that patients are not making decisions under duress and that they fully comprehend the implications of their treatment choices.

Another practical challenge is the need for ongoing consent throughout the cancer treatment process. Cancer care is typically a prolonged and multi-stage process, involving initial diagnostic tests, primary treatment (such as surgery, chemotherapy, or radiation), and post-treatment care. Each of these stages may require separate consent, and the patient's condition or treatment plan may evolve over time. Ensuring that consent is obtained at every stage, and that patients are kept fully informed of any changes to their treatment plan, is a complex but necessary aspect of ethical cancer care.

### *14.4. Role of proxy consent and family involvement*

In cases where cancer patients are incapacitated or otherwise unable to give informed consent, Indian law allows for proxy consent to be obtained from a legally authorised representative, such as a family member or guardian. This provision is particularly relevant in cancer care, where patients may be rendered unconscious or cognitively impaired due to the severity of their illness or the effects of treatment.

While proxy consent provides a legal mechanism for ensuring that incapacitated patients receive necessary care, the Indian judiciary has been cautious in its application. Courts have ruled that proxy consent should only be used when absolutely necessary and must be exercised in the best interest of the patient. For instance, in cases where non-emergency procedures are proposed, the courts have required that healthcare providers make every effort to obtain direct consent from the patient, if possible, before relying on proxy consent.

Furthermore, the courts have limited the scope of proxy consent for procedures that are not lifesaving. In cases such as Samira Kohli, the judiciary has ruled that proxy consent cannot justify procedures that go beyond the scope of the patient's original consent, even if a family member consents to the additional treatment. This ensures that family members cannot override a patient previously expressed wishes, thereby protecting the patient's autonomy.

### *14.5. Balancing medical paternalism and patient autonomy*

One of the key ethical debates in the context of informed consent in cancer care is the balance between medical paternalism and patient autonomy. Medical paternalism refers to the practice of doctors making decisions on behalf of their patients, often based on the belief that they know what is best for the patient. While well-intentioned, medical paternalism can undermine patient autonomy, particularly in situations where the patient's preferences and values are not fully considered.

The Indian judiciary has consistently favoured patient autonomy over medical paternalism, as reflected in rulings that require specific and explicit consent for each stage of treatment. The courts have made it clear that doctors cannot unilaterally decide to perform additional procedures without the patient's informed consent, even if the doctor believes that the additional procedure would benefit the patient. This legal stance reinforces the ethical principle that patients have the right to make decisions about their own bodies, even if those decisions may not align with the doctor's professional judgment.

However, the practical application of this principle can be challenging, particularly in cancer care, where treatment decisions are often time-sensitive and complex. Healthcare providers must strike a delicate balance between respecting the patient's right to autonomy and providing guidance based on their medical expertise. The challenge lies in ensuring that patients are fully informed and empowered to make decisions, while also ensuring that they receive the best possible care.

## 15. Conclusion

Informed consent is a critical component of cancer treatment, ensuring that patients have the right to make decisions about their medical care based on a full understanding of their treatment options. The Indian judiciary has played a key role in shaping the legal framework for informed consent, emphasising the importance of patient autonomy and the need for specific, prior, and informed consent for every stage of treatment. While challenges remain in implementing these standards, particularly in the context of patient comprehension, cultural barriers, and ongoing consent, the legal and ethical principles established by the courts provide a robust foundation for protecting patient rights in cancer care.

Healthcare providers must continue to navigate the complexities of informed consent with sensitivity and diligence, ensuring that patients are fully informed, supported, and empowered to make decisions about their care. By adhering to the legal and ethical guidelines surrounding informed consent, doctors can not only protect themselves from legal liability but also foster trust and transparency in the patient-doctor relationship, ultimately improving the quality of care for cancer patients.

## 16. Source of Funding

None.

## 17. Conflict of Interest

None.

## References

1. Pugh J. Informed consent, autonomy, and beliefs. London, England: Oxford University Press; 2020.
2. Goodyear MDE, Krleza-Jeric K, Lemmens T. The Declaration of Helsinki. *BMJ*. 2007;335(7621):624–5.
3. Zequi S, Silva I, Duprat JP, Coimbra FJF, Gross JL, Vartanian JG. Informed consent and a risk-based approach to oncologic surgery in a cancer center during the COVID-19 pandemic. *J Surg Oncol*. 2021;123(8):1659–68.
4. Nandimath O. Consent and medical treatment: The legal paradigm in India. *Indian J Urol*. 2009;25(3):343–7.
5. Mani RK. Constitutional and legal protection for life support limitation in India. *Indian J Palliat Care*. 2015;21(3):258–61.
6. Neilson G, Chaimowitz G. Informed Consent to Treatment in Psychiatry. *Can J Psychiatry*. 2015;60(4):1–11.
7. Schwaegermann MK, Schranz M, Moehler M, Labenz C, Moringlane A, Schmidt M, et al. Any progress in informed consenting for cancer treatment? Results from a cross-sectional analysis at a comprehensive cancer center. *J Cancer Res Clin Oncol*. 2021;147(7):2117–26.
8. Mullick P, Kumar A, Prakash S, Bharadwaj A. Consent and the Indian medical practitioner. *Indian J Anaesth*. 2015;59(11):695.
9. Olejarczyk JP, Young M. Patient rights and ethics (Internet). Treasure Island (FL): StatPearls Publishing; 2024.
10. Bal A. Informed consent — legal and ethical aspects. *Indian J Med Ethics*. 2016;7(2):56–7.
11. Pai SN, Jeyaraman M, Jeyaraman N, Shyam A. The witness to an informed consent for surgery/invasive procedure: The ethical and legal aspects. *J Orthop Case Rep*. 2023;13(10):1–5.
12. Kohli Vs Dr S. Prabha Manchanda & Anr on 16 January. AIR 2008 Supreme Court 1385, 2008 AIR SCW 855. 2008;855:5–373. Available from: https://indiankanoon.org/doc/438423/.
13. Shah P, Thornton I, Turrin D, Hipskind JE. Informed Consent. Treasure Island (FL): StatPearls Publishing; 2024.
14. The Association of Surgeons of India. Medical negligence – the judicial approach by Indian courts – the association of surgeons of India [Internet]. [cited 2024 Sep 24]. Available from: https://asiindia.org/medical-negligence-the-judicial-approach-by-indian-courts/.
15. Jain R. Article 21: Understanding The Right to Life and Personal Liberty from Case Laws-Academike Explainer; 2023. Available from: https://www.lawctopus.com/academike/article-21-of-the-constitution-of-india-right-to-life-and-personal-liberty/.
16. Misra N. Informed consent: a case analysis of Samira Kohli vs. Prabha Manchanda [Internet]; 2020. [cited 2024 Sep 24]. Available from: https://blog.ipleaders.in/informed-consent-case-analysis-samira-kohli-vs-prabha-manchanda/.
17. Marron JM, Kyi K, Appelbaum PS, Magnuson A. Medical decision-making in oncology for patients lacking capacity. *Am Soc Clin Oncol Educ Book*. 2020;40:186–96.
18. Hall DE, Prochazka AV, Fink AS. Informed consent for clinical treatment. *CMAJ*. 2012;184(5):533–40.
19. and KHSR. Informed consent: An ethical obligation or legal compulsion? *J Cutan Aesthet Surg*. 2008;1(1):33–5.
20. Epstein RM, Street RL. Patient-Centered Communication in Cancer Care: Promoting Healing and Reducing Suffering. Bethesda: National Cancer Institute; 2007. Available from: https://cancercontrol.cancer.gov/sites/default/files/2020-06/pcc_monograph.pdf.
21. Wendler D. Broad versus blanket consent for research with human biological samples. *Hastings Cent Rep*. 2013;43(5):3–4.
22. Bleiberg H, Decoster G, deGramont A, Rougier P, Sobrero A, Benson A, et al. A need to simplify informed consent documents in cancer clinical trials. A position paper of the ARCAD Group. *Ann Oncol*. 2017;28(5):922–30.
23. Avci E. Protecting incapacitated patients' rights and best interests. *Indian J Palliat Care*. 2023;29(4):343–350.

## Author's biography

**Anmol Mahani,** Assistant Professor (Radiation Oncology) https://orcid.org/0000-0001-9786-3731

**Rudranath Zadu,** Advocate, LL.B, LL.M (Corporate and Financial Laws)

**Cite this article:** Mahani A, Zadu R. The role of consent in Indian judiciary: Implications for cancer treatment practices. *Indian J Forensic Community Med* 2024;11(4):159-172.