The International Journal of Indian Psychology
ISSN 2348-5396 (Online) | ISSN: 2349-3429 (Print)
Volume 14, Issue 2, April- June, 2026
DIP: 18.01.186.20261402, DOI: 10.25215/1402.186
https://www.ijip.in

Research Paper

Consent or Informed Consent: An Empirical Analysis of Healthcare in India

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ABSTRACT

Informed consent is a fundamental ethical principle in healthcare, and it is supposed to be taken seriously in Indian healthcare services, just as it is taken in many other parts of the world. It involves providing patients with adequate information about their medical condition, proposed treatment and its cost, potential risks and benefits, and alternative options, allowing them to make informed decisions about their healthcare. It is important to note that this "Informed Consent" comes under the ethical principle of broader domain of well-being of the client/patient and not only informing the client/patient for the sake of socio-legal implications and guidelines given. Indubitably, people in India still have great regard and respect for doctors. The members of the medical profession have also, by and large, shown care and concern for the patients. There is an atmosphere of trust and implicit faith in the advice given by the doctor. However, some questions do sometimes appear to be meaningful to ask in doctor-patient conversations: Is asking for consent informed or is it just written on papers for legal compliance? "What choice do these poor patients have? Because it is mostly observed that any treatment of whatever degree is a favor for them. The sad reality is that for a vast majority of patients in the country, the concepts of informed consent or any form of consent, and choice in treatment, have no meaning or relevance." This paper deals with the applicability of the concept of 'informed consent' at present in India, based on the critical review of legal procedure and guidelines. Through a comprehensive literature review, this research explores the multifaceted aspects of informed consent theoretically as well as practically. Keeping the above in view, data is collected from secondary resources like journals, newspapers, books, articles, reviews of law and legislation, etc. The data is also collected through interviews with people from diverse age groups to understand their experiences, attitudes, and opinions regarding this concept of "informed consent" and how they feel it is applied in real life and the challenges faced. The participants for the interview were conveniently selected, and a total of 50 interviews were conducted, of which 26 were women and 24 were men. Results show that there is indeed a vast difference between the concept and reality. Various reasons and consequences are discussed in detail in this paper. However, it is important to note that individual experiences may vary, and there may be instances where informed consent is not obtained or is inadequately implemented. Continuous efforts to raise awareness, improve training, and strengthen regulatory oversight are essential to ensure that informed consent is a meaningful and respected concept in Indian healthcare services.

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Received: March 20, 2026; Revision Received: June 04, 2026; Accepted: June 08, 2026

Keywords: *Consent, Informed Consent, Ethics, Healthcare, Well-being*

Healthcare in India is still under growing stage with a need for advances in treatments, medicines, infrastructure and much more. But it is important that with advances comes more ethical considerations that are needed to be taken care of not only in research but also in practical space like hospitals, clinics, etc. It will be a long list to talk about each and every ethical consideration in this paper, although acknowledging that each and every ethical considerations are important especially when it is for the patient's well being. But for now, we shall be focusing on one ethical consideration and that is informed consent which is often taken as “consent” rather than informed one.

Consent by definition refers to a person’s voluntary agreement to a specific treatment, action or procedure. In general terms, it implies that an individual has a right to make decisions about what concerns them. In the context of healthcare, consent is taken from the patient or his/her family before certain medical interventions which range from simple to complex procedures. It can either be taken verbally or in writing depending upon the seriousness of the case.

On the other hand, Informed Consent is very close to Consent by definition but it includes one more term “Informed” before consent which in lay man’s language means informing before taking consent for it, here inform just doesn’t mean stating the procedure, medicines and whatever is written on the page of consent but also helping the patient and his/her family to understand the pros and cons of the procedure, any alternatives, consequences, bills, medicines, etc. It is totally understandable that most of the time when the case is serious and every second is important towards saving the life of the patient, it is hard to sit with the family and talk about everything about the treatment and illness, but what about the 90% times when there’s time to inform the patient and his/her family about the it and then also only legal procedure is followed. Sometimes, even when the situation is under control, many doctors or so called marketing team of the hospital pressurize the patient and his/her family for certain treatments which are not even required at that time.

In India, the concept of informed consent is followed by legal guidelines. The Medical Council of India (MCI) has laid down rules and regulations regarding the obtaining of informed consent in the "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002." Also, the Consumer Protection Act of 2019 has provisions laid down for medical negligence and the duty of care, which are linked to obtaining informed consent. Courts in India have also mentioned the importance of Informed Consent in various judgements but mostly ends with “proof” given by the hospital where the patient has signed the consent mostly unaware of all the details. Even by definition, Consent can be easily turned to Informed Consent by telling the patient about each and every step that has been taken during his stay or visit to the hospital but we are here more focused on ethics rather than rules or some legal laws which any doctor or hospital as an organization can follow.

Ethical considerations are for doctor-patient well-being and not something which can be followed just by forming some rules and laws for it, it should come within. Though something which can’t be controlled or regulated is difficult to follow from the heart when there’s organization pressure on the doctors to see more clients in less time with suggesting more costly medicines than required and one issue that we all know about is doctor-patient ratio in India which is far less than what is required. On the other hand, patients and their families in India face the problem of time constraints when there is a long line in front of you waiting to get appointment, lack of education to understand even simple terms used by the doctors, lack of awareness, feeling totally dependent on the doctor for everything and anything without cross questioning anything, etc.

REVIEW OF LITERATURE

Informed consent is an important aspect of healthcare that ensures patients are adequately informed about the risks, benefits, and alternatives before making decisions about their treatment. Some scholars address ethical considerations surrounding informed consent, emphasizing the need for transparency, respect for autonomy, and protection of vulnerable populations in the healthcare decision-making process (Kumar, 2013). The Medical Council of India (MCI) has laid down guidelines on informed consent in the "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002." This document outlines the principles of informed consent and emphasizes its importance in medical practice. However, studies highlight the gap between the legal provisions and actual implementation, raising concerns about the protection of patient autonomy (Shetty, 2002; Kaur et al., 2013). Some research articles discussed challenges in obtaining valid informed consent in India due to issues related to comprehension, voluntariness, and the influence of family dynamics on decision-making (George, et al., 2014). Scholars and practitioners recommend interventions such as improved communication skills training for healthcare professionals, simplified consent forms, and community awareness programs to bridge the existing gaps in obtaining informed consent in India (Mishra, 2019; Srivastava & Misra, 2014).

The cultural context in India also plays a significant role in the understanding and acceptance of informed consent. Studies have explored the cultural nuances that influence patient perceptions and decision-making in the context of healthcare (Krishnamurthy & Shankar, 2015). Issues include language barriers, low health literacy, and a hierarchical doctor-patient relationship are quite common in a setting where communication is involved. The diverse cultural, linguistic, and educational backgrounds of patients also pose challenges to effective communication and understanding during the consent process (Shetty, D., 2017). Literature highlights the need for healthcare professionals to adopt culturally sensitive approaches during the informed consent process. This involves adapting communication strategies to suit the cultural context of the patient which seem difficult in a country like India which follows a diverse range of languages and cultures but is obviously not impossible (Ravindran, et al., 2015; Macklin, 1981; Jafarey & Farooqui, 2006).

Also, effective communication is only possible when the doctor follows ethical considerations and on the other hand patients and their family are well aware of the importance of informed decision making (Choudhary et al., 2017; Venkatraman et al., 2019). Some studies explore the use of technology, such as multimedia tools and mobile applications, to enhance the informed consent process and awareness in healthcare settings in India (Shukla, et al., 2016).

METHOD

Research Design

Qualitative Approach: Qualitative research focuses on in-depth understanding of people’s perspectives, experiences and behaviors. It is well suited for research where not only getting viewpoints of participants are needed but also the “how” behind those viewpoints. For this research, a qualitative approach is used to understand the experiences of people in Healthcare settings when informed consent is concerned.

Data Collection

Interviews: In qualitative research, there are three types of interviews- structured, unstructured, semi-structured. Unstructured or semi-structured interviews are mostly used as these allow for open discussion on topics/questions through open ended questions and follow-up probes, enabling people to express their experiences in their own words. To understand and go in depth to talk about people's experiences, the researcher has followed a semi-structured type of interview with open-ended questions.

Sampling Method

Convenience Sampling: Convenience sampling comes under non-probabilistic sampling technique where individuals are selected to participate in the research based on their willingness, accessibility and availability. This method is commonly used in qualitative research because of practical considerations such as resource and time constraints. For this research, convenience sampling is used because the research topic is focused on something which any and every individual has gone through in his/her lifetime.

Participants

Selection Criteria: Interviewees are approached based on their availability and accessibility. This method involves approaching participants who are ready to get interviewed and share their viewpoints and experiences as a researcher, the aim of the study is to tap on experiences in general and not based on any religion, region, age, gender, etc.

Procedure

Approaching the participants: Researcher identified and approached potential participants based on the convenience sampling method. This involved contacting individuals through social media, personal networks or by simply reaching out to strangers on road whosoever are willing to share their opinions.

Informed Consent: After confirming individuals participation in the study, a verbal informed consent was taken from each participant to record their interview for academic research and shall be deleted after the completion of the research.

Interviews: Researcher conducted one-on-one interviews with participants. Interview was semi-structured in nature, meaning that though questions were already framed before approaching the participants, there was no strict rule followed in terms of serial of questions and probes were also asked in between for better understanding of the viewpoints presented by the interviewees. The interview guide was designed to encourage individuals to share their perceptions, experiences and insights on the topic.

Data Recording: Interviews were audio-recorded after taking informed consent from the participants and then transcribed later for analysis.

Data Analysis

Thematic Analysis: Thematic analysis is a common approach in qualitative research. Researchers identified patterns, themes, and categories in the data, organizing and interpreting the information to understand the experiences and perspectives of the participants. For a more a clear picture of the analysis, tables and graphs are used.

Ethical Considerations

- Confidentiality and Privacy: Researcher ensured that participants' information is kept secure and is protected.
- Informed Consent: Researcher was transparent about the research purpose and the use of the information. Proper verbal consent was taken before recording the audio of the participants and also ensured that the data will be deleted after the completion of manuscripts and will not be shared to any second party.

Limitations

One of the main limitations was convenience sampling as it may not represent the broader aspects of the population such as issues specific to gender, age, caste and class.

RESULTS

Table 1 Following are the themes and sub-themes with necessary participant's answers verbatim.

Themes	Sub-Themes	Verbatim
Reasons for not understanding the consent taken	Time Constraints	"Itna time kaha hai to understand itna kuch? Ab jo doctors kr rhe hai sahi hi hoga" "Aapko kya lagta? Bahar itni lambi line hoti hai harr doctor ke pass aur vo mujhe ek ek chiz samajhayega?"
	Illiterate Patients	"Doctor agr samajhaye bi kuch toh samajh kisko aayega? Hum toh garib hai buss illaj krvane jaate hai doctor ke pass" "Mujhe acche se padhna, likhna bi nahi aata didi, mein kaha se doctor ki bhasha samajhungi?"
	Difficult medical terminology	"See, I tried to get information from the doctor and he explained everything to me, but the terms he used, I didn't understand a thing, so yeah he did his job I guess" "Medical world is beyond my understanding yaar"
	Blind trust on Doctors	"Doctor is like a God, why would he cheat me on something like this? And everything is written so I guess he won't do anything to harm me I believe." "Esse toh koi bi vishwash ke layak nahi hai, per ab doctor pe toh trust krna padega na"
Why Informed Consent is difficult to practice	Hospitals own expenses	"See, if I decide to go to a private hospital, I go with a mindset ki paise lagenge even if saste me ho jayega kaam" "mene kabhi cross-check toh nahi kiya about expenses that the hospital put, ek toh hospital ke khudhke kharche bi toh hoinge hi ab kya kr sakte hai"
	Low Doctor-Patient Ratio	"You know it well that doctors are way lesser than patients out there and obviously treatment is more

		important than this ethics" "For me the main concern is to get a doctor rather than thinking ki usne informed consent liya hai ki nahi"
	Culture and language barriers	"Didi, meri English acchi nahi h aur doctor sirf english ke shabad istemal krta, toh mein kya karu" "Once I went to Banglore for my treatment and there even i asked the nurse ki yeh injection kiske liye hai toh she said hindi nahi aati and ran off"
	Lack of awareness about procedures, medicines and treatment	"Accha doctor ne bata bi diya ki yeh yeh procedure follow hoga, pr mujhe kya pata?" "See, I know my field and doctor knows his field and I have to trust him" "I don't know kisse clarify karu ki sahi treatment hai bi ya galat"
Consequences of "Consent" Vs "Informed Consent"	Expensive Medications	"This happened with me, mein apni beti ka cancer ka treatment krvane gyi thi and hospital ne itna bada bill de diya mujhe without telling me before about the hidden charges" "Yaar ekbaari mein ek doctor ki prescription apne family doctor ko dikhaya he told me that there are a way better alternatives than the medicines the other doctor provide which were so expensive"
	Performed more tests on patients than required	"Legit 58 tests huye the mere pe jo required bi nahi the, I cross checked with other doctors and they told me ki itne tests kaha se krva liye fhaltu mein" "ekbaari mere samne hi hua tha yeh, I went to hospital for some brain injury and usne ek do costly tests likh diye and mene krva bi liye and baad mein uss doctor ne dekhe bi nahi? I mean fir kyu hi krvaye" "These hospitals now wait ki jb tk patient ki insurance ke saare paise khatam nahi ho jaate tb tk stupid tests krvate raho, yeh toh jaaye kisi se bi poochlo "

DISCUSSION

In India, with a large and diverse population comes various challenges especially in the Healthcare sector, though there are improvements but still a lot of issues are often ignored like the concept of Informed consent. As mentioned already, consent generally means seeking permission from the patient to administer treatment, medicines, etc while on the other hand, informed consent goes further by ensuring that patients fully understand the risks, benefits and overall nature of the treatment before making a decision. After conducting interviews on Informed Consent in India, it is very evident that the practice is deeply ingrained and widespread in the healthcare culture of the country. This discussion focuses on various aspects of informed consent, including reasons for not understanding the consent taken, difficulties and its consequences based on the results.

Reasons for Not Understanding the Consent Taken

One of the major reasons noted is time constraints, both for doctors and patients. Knowing the population of India and doctors availability, it is often difficult to give a long time to each and every patient to make him/her understand the procedure and then take the consent. And also acknowledging that some cases are very time sensitive and quick action in such cases are more beneficial for a patient's well being. On the other side, patients too have other work to do rather than sitting with the doctor for hours to understand everything.

In many cases, there is a significant power differential between healthcare providers and patients. Patients may feel pressured to agree with their doctors' recommendations without fully understanding or questioning them, leading to a lack of truly informed consent (Sudore, et al., 2009). And as mentioned by some individuals during the interview, they believe in doctors so much that they often forget or stop themselves from doubting the doctor or cross-questioning him/her. And even if they do, interviewees mentioned the difficulty in understanding the terminology doctors use to explain the illness and its treatment. Healthcare providers may struggle to convey information clearly, answer patients' questions, or navigate complex ethical dilemmas related to consent (Bala, et al., 2017). Sometimes it is the difficult terminology and sometimes it is the patient who is not educated enough to understand simpler language too. Communicating complex medical information in a language and manner understandable to patients with different literacy levels can be challenging. This can compromise the truly informed nature of consent (Reddy, et al., 2000).

Why Informed Consent is Difficult to Practice

Informed Consent is often difficult to practice when money is more important than the wellbeing of the patients, and as mentioned by the interviewees that they have faced such issues when visiting private hospitals for the treatment. Issues like expensive procedures and medications are quite common in hospitals because of their own internal expenses. And as mentioned above the population of India, not everyone can get treated in government hospitals and have to choose private hospitals with unaffordable bills. Second reason which was highlighted during the interviews was the culture and language barriers, as already talked about how diverse India is in terms of its cultures, moving from one city to another for treatment sometimes makes it difficult for the patients to interact with the healthcare providers. Few individuals have mentioned such difficulties which are mentioned in the results verbatim.

Another reason which came out for difficulty in practicing informed consent is lack of awareness among patients regarding their rights to consent and the importance of informed decision-making. Many patients may not fully understand the implications of the treatment they are receiving or the procedures they are undergoing (Kaur H, et al., 2016). Lack of resources to get the knowledge about the procedures, treatment and medicines makes it difficult for the patients to question the doctor about it. Few interviewees mentioned that they had their own family doctors with whom they cross checked and some visited more than one doctor to confirm the treatment. But this solution is not feasible for everyone.

Consequences of "Consent" vs "Informed Consent"

Consequences of not being properly informed about the procedure, treatment, medicines, etc are many but some which were highlighted during the interviews were of expensive medicines without suggesting any alternatives and additional tests which were conducted on patients unnecessarily to increase bills. Medical malpractice, including overprescription of medicines and unnecessary tests, is a concern in India. A study published in the Indian

Journal of Medical Ethics highlights the prevalence of medical malpractice and its various forms, including unnecessary surgeries, overprescription of medicines, and unnecessary investigations (Pandit, et al., 2009). Some individuals who have blind trust on hospitals and doctors didn’t even cross-checked the tests and expensive medicines with other doctors for second opinion but some did and found that there were indeed alternatives for the same.

Before concluding this paper, it is important to note that this discussion is purely based on opinions and experiences of individuals and for more accurate judgment about right and wrong of the concept of “Informed Consent” in healthcare sector in India, it is important to understand doctors side as well to come to a proper conclusion with solutions to decrease this gap between patients and doctors relation.

Limitations

Studying a small sample of India's population cannot be generalized to what the entire population thinks or does. And keeping in mind the advantages and disadvantages of interview data collecting tool, more tools could be incorporated to gather strong evidence on the topic. Using interview method also restricted the flexibility to get information from anywhere in India like through online means, that can be considered in the further studies.

Also keeping in mind the selection of interviewees through convenience sampling can put a limitation to this study further, to properly study reasons and consequences of Informed Consent in India. Also, it is important to examine the ethics followed in private vs government hospitals too for better understanding of the topic. And mentioned above in discussion, it is important to hear the doctors and hospitals point of view too to come to a detailed conclusion. Thus, generalizability of the present findings are somewhat very limited.

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Acknowledgment
The author(s) appreciates all those who participated in the study and helped to facilitate the research process.

Conflict of Interest
The author(s) declared no conflict of interest.

How to cite this article: Sachdev, P. (2026). Consent or Informed Consent: An Empirical Analysis of Healthcare in India. *International Journal of Indian Psychology*, *14*(2), 2032-2040. DIP:18.01.186.20261402, DOI:10.25215/1402.186