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Research Article

Consent & Healthcare – A Few Core Legal Considerations

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Abstract

Practicing doctors often face considerable dilemma regarding consent, while treating patients, which is arising out of misplaced notions on the legal aspects of consent vis-à-vis medical treatment. This often results into overinvestment in the process of consent, diverting the attention from medical care. The literature often focuses upon explaining consent and related ingredients, but not providing jurisprudential clarity regards the same. This paper attempts to address a few core legal issues – which might help the doctor to self-evaluate practical issues faced on day-to-day basis and concludes that overemphasis or glorification of consent would not necessarily be favorable for the doctor.

Key Terms: Consent, Consent in medical treatment, Informed consent, Written consent, Real-consent, Format of consenting, Common law consent.

Prologue

Unfortunately, the health-law literature in India does not elaborate on a few core jurisprudential issues on 'consent' in healthcare provisioning [1]. These aspects were probably taken for granted or not thought through. Whatever might be the reason, the absence of it has increased confusion among the caregivers. An attempt is made in this article to clarity upon these much-needed aspects and argues that overemphasis or glorification of consent would not necessarily produce the desired outcome in favour of the medical practitioner. All these issues may be divided as follows viz.,

Science Academique
ISSN 2583-6889
Veerayya NO.
Pages: 112-118

Substantive legal issues

- The variation between consent in 'common law' and consent in specific statutes.
- Whether consent is a document detailing the contract between the patient and the doctor?
- How much in detail does the doctor explain or document the adversities of the treatment?

Procedural legal issues

- Whether documented consent shall have witnesses and who are these witnesses.
- Whether it is fine to use a pre-printed consent form?
- Whether the use of video graphing for the consent procedure beneficial?

Introduction

There is no harm in repeating that the element of consent is one of the critical issues in medical treatment today. Doctors must seek the patient's consent, except for a few situations specifically recognised as exceptions [2]. Consent indicates the legal recognition of the bodily autonomy of able-minded patients. A doctor treating the patient successfully but without consent would still be held liable, despite his success in dragging the patient out of her morbid conditions [3]. The liability for treating the patient without proper consent would attract liability under civil and criminal law as well, as the doctor would have violated the bodily autonomy of the patient recognised under Art. 21 of the Indian Constitution. Multiple documents like the Nuremberg Code, 1947, the Declaration of Helsinki adopted by the World Medical Association, 1964, the latest ethical regulations of NMC emphasize the importance and inevitability of consent while provisioning healthcare.

The doctrine of consent (in healthcare provisioning) is still elusive. Neither is it possible to frame one format for all the cases as a prototype template nor is it expected. This would be neither patient-specific nor procedure-specific. The ambiguities of interpretation and inadequate disclosures can become a source of debate and dissent. Therefore, making the legal quest a perineal one [4].

Common Law Consent V Consent Under Specific Law

The consent got into the mainstream of clinical practice, after the Nuremberg Code, 1947 post the infamous Nazi trials during the World War II, which drew many ethical debates to sharp focus. However, the concept of consent was recognised in common law from time immemorial. The theory on tort of 'battery' testifies to this [5].

The common law consent (or generic prescription of the consent) is applicable to all cases of healthcare provisioning as the bare minimum necessity of law. The 2023 ethics regulations [6] emphasize the common law requirement of 'informed' consent under Sec. 19.

However, if the treatment is specifically regulated by any of the specialised statutes – then additional consenting procedures might get attracted, as the statutes may prescribe. Clinical

Science Academique
ISSN 2583-6889
Veerayya NO.
Pages: 112-118

trials, artificial reproductive technologies (ARTs), human organs and tissue transplantation, medical termination of pregnancy etc., are the areas dealt with under special statutes, which indicate more emphasis on the consenting procedure. It is imminent for the doctor to understand both – (i) the general demand of the common law *vis-à-vis* consent and (ii) any specific procedural requirements prescribed by any specific statutes; and must comply with both of them in the letter and spirit.

Consenting Document – Whether Indicates A Contract for Healthcare Provisioning?

Before answering the question, it is productive to understand why we must answer this question?

Let us say a doctor has explained the consequences or side effects of the impending treatment to the patient. Subsequently, can the doctor take this as a defence if that side effect in fact occurs? Obviously, the answer is in negative. It must be explained that it is the demand and requirement of the consenting procedure that, while seeking the mandated consent for the treatment, the patient should be provided with the necessary information to enable him to give real consent (also known as informed consent).

Therefore, if the explained side effect occurs in the patient, the law investigates independently – whether the same has happened as an unfortunate event or due to the inadvertence of the doctor. If the same is due to the latter, the doctor is held liable. It is irrespective of the fact that the same was explained to the patient while seeking consent. Moving further, doctors are often confused about how much documentation is needed regarding explaining the side effects or consequences of the medical treatment, especially in the case of written consent.

Hypothetically, if the consenting document is taken as a contract between a doctor and a patient then, we are justified in beating the situations explained above. Unfortunately, that is however, not the case. Whether in writing or otherwise, it has a very limited legal purpose to serve. That is to demonstrate the respect for individual autonomy and choice. This is to simply state that the patient is treated after seeking her consent. Had the consenting document been a contractual document, then the medical practitioner could even have limited his liability by inserting an additional clause [7].

Can the documented consent (or otherwise) can be taken as part of the contractual arrangement existing between a medical practitioner and the doctor? The answer is again in negative. The need to seek consent for treatment is the mandate of law (be it common law or arising out of any specific statute). The doctor, therefore, is merely complying with the law. In some hard cases, where the patient is anaesthetized, or the assessment of the situation demands, the doctor would document the consent taken. Hence, it can’t be even taken as an indicator of partial documentation.

Science Academique
ISSN 2583-6889
Veerayya NO.
Pages: 112-118

Details of Adversities or Side-Effects of the Treatment

Consent, unless informed is not valid one [8]. The doctor shall provide all such information, which would enable the patient to evaluate the pros and cons of the treatment and provide her consent. If the consent is obtained otherwise, the same is not an informed one and not valid in the eye of the law. Doctors face considerable challenges here as well. How much information is sufficient here? And whether all that is explained as side effects is to be documented in the consent form. Are the questions.

The first of these two questions is relatively easy to answer. The doctor is bound to provide 'all such information' which is required – is the principle. There are two schools of thought viz., one originating from English writings and another dominated by Americans. The American approach believes that there is a standard packet of information to be provided to the patient, and the doctor is expected to provide such information while seeking consent. As it assumes the patient to be prudent or all average patients to make rational decisions, would be needing such an amount of information, is referred to as 'prudent-patient test' [9].

On the contrary, the English approach presupposes that every patient's appetite for information is different. Accordingly, the doctor who understands the patient's need for information would customize the information packet according to that need and communicate it to the patient while seeking consent. As the doctor is vested with discretion in this approach, the same is referred to as a 'prudent-doctor test' [10]. Indian law endorses the English approach [11]. So, in India, the doctor is in a commanding position in deciding how much information needs to be provided to make the consent a valid one.

However, the next question is a formidable one. Whether it is necessary to document all that information on the consenting document? If an unfortunate doctor has to treat a timid and touchy patient, who is demanding tons and tons of information about the impending treatment – would make the doctor's life miserable, if he were to document all such information provided. Naturally, this would make the consenting document a bulky one, clogging the limited time doctors generally have in discharge of their duty. Luckily it is not necessary to document all that. It is sufficient if the doctor endorses a statement "that all necessary information is being provided to the patient" is sufficient. To be more cautious – it can be innovated still further, in two parts. In the first part of the consenting document, the doctor affirms that all necessary information, to enable the patient to decide has been provided. In the second part, the patient affirms (by his signature on to the document) where she states that all necessary information, including her specific queries, has been answered to her satisfaction and understanding by the doctor [12]. This best practice has to be developed as the Indian approach is to vest the discretion to the doctor (in customising the information packet), and such discretion, unless glaringly unreasonable from the circumstances, the court would not sit in judgment over. There is no need to document all the information provided to the patient.

Science Academique
ISSN 2583-6889
Veerayya NO.
Pages: 112-118

Witnessing the Consenting Document

Consenting is an essential element for the medical treatment; but does not reflect the contract between doctor and patient. Therefore, witnessing the document is not really of great significance. It must be once again repeated that, if the judicial review takes place, to prove the point of consent documentation helps. Also does the witnessing of the document. Lot of debate still goes on as to who can be the witness to consenting document. It is somewhat well established that, it is ideal to have an independent party putting his hand as a witness to the document, rather than a hospital staff or the near and dear one of the parties. But practically finding such an 'independent' party is uphill task for the doctor in his working environment. Hence often he ends up taking some attendant of the patient as witness. The law is well settled that, a witnessing party to any document, testifies in the court of law that parties alone have executed the document, and not to the averments or contents of the document. He is not supposed to know the details of the terms and conditions of the document. Therefore, having multiple witnesses to the consenting document does not increase the inviolability or weightage of the consent document.

Law presupposes that among the doctor and patient, the former is the dominating party and hence warranted to take greater burden of proof in case of adducing evidence. Taking multiple evidence would place the doctor to a situation to explain why he has taken multiple witnesses. In this light, if the witness is among the staff of the hospital, or other fellow professional colleague, the court may reduce the weightage, as he stands in near-relationship to the doctor. On the other hand, if he is anyone sharing closer relationship with the patient, may attempt to testify supporting the patient's stand in the court of law, making it difficult for the doctor to overcome the situation. It is, therefore, advisable to continue with the customary practice of taking only one witness who is easily available at the time of treatment, rather than struggling to search for an independent witness or multiple of them.

Printed Formats of Consent

The judgement of the National Consumer Dispute Redressal Commission in Vinod Khanna v R. G. Stone Urology and laparoscopy Hospital & Others raised this debate [13]. Particularly the following observation made the entire medical community concerned:

"We but note that a pre-printed and fixed 'informed consent cum undertaking' form, with blank spaces for limited select handwritten entries and for the signatures has been used by the hospital. The main body of the form is pre-printed and fixed. It can fit into any procedure, any doctor and any patient, after filling up the blank spaces for the limiting select handwritten entries and getting/affixing the signatures. We note this to be administrative arbitrariness and one-sided high handedness, and to be unfair and deceptive, one the part of the opposite party No. 1 (hospital), for which, though, the complaint has not been prejudiced in this particular case".

However, on appeal this order was stayed by the supreme court providing a great relief [14]. It has to be mentioned, while we are awaiting the apex court to decide on the same, that the

Science Academique
ISSN 2583-6889
Veerayya NO.
Pages: 112-118

NCDRC's verdict, if seen in the context of its facts; and particularly the kind of shoddy consent form which was relied in that specific case, would justify its verdict. However, it can't be concluded that – (i) pre-printed consenting formats are not tenable; or (ii) the consent can't be generic one. Therefore, taking handwritten consent, or asking the patient to write in his own hand the consent is rather over-doing practices than necessary.

Videographing the Consent

Yes, technology is advancing and becoming more affordable. A video graphed consent, if possible, administratively will substitute the written consent forms. However, it is myth to take them as having greater sanctity in comparison to the written consent forms. The video graphed consent is as strong or as weak a witness as the written consenting form, for all the reasons and justifications above.

There are some specific statutes, particularly the Regulations or Rules made under the statutes, provide for video-consenting. There are more and more doctors recording video consents, as it is easy and affordable now a days. Both these practices are to be continued, solely from the practical and administrative part of it.

In conclusion, it may be worth repetition that, the doctor shall always bear in his mind that consent is an essential legal element to treat the patient; but can't be taken as comprehensive contracting document, between him and his patient. Overdoing the consenting activity would not render any defence for the doctor in case of litigation.

Conclusions

Due to lack of clarity (and literature) on the point, doctors over-emphasize (or over-glorify) the process of consent and over invest with the hope that, it would come to their rescue in case of need. This is a clear myth. The process of consent only indicates the doctors' respect towards bodily autonomy of the patient and is certainly mandated by law. Once that is established, the role of consent comes to an end; and any further enquiry of law will be independent of the consent (or consenting documentation). Therefore, it is ideal that the doctor shall not over-invest in this placebo.

References

1. Including my own popular publication on the subject, "Consent and Medical Treatment – the Legal Paradigm in India", published at Indian Journal of Urology in July-September 2009.
2. There are far and few situations recognised by law as exceptional situations. For instance, emergency treatment, where patient's life or safety is at risk, is among the most popular methods. Subjecting
3. See generally, Marjorie Maguire Shultz, Form Informed Consent to Patient Choice: A New Protected Interest, The Yale Law Journal, Volume 95, Number 2, December 1995, p. 219.

Science Academique
ISSN 2583-6889
Veerayya NO.
Pages: 112-118

4. See generally, Nandimath Omprakash V and Promod Kohli, "Law of Consent and Medical Treatment", Health Law and Practice, Critical Reflections, p. 221. Thomson Reuters, 2022.
5. The simplest way battery can be explained as when an unjustified force is used against another's person. The person using such unjustified force will be held liable for violating the bodily autonomy of the other. The volume or gravity of force is of no consequence. Mere touching a person without proper and reasonable justification would result in an actionable claim.
6. The National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023.
7. As it is done in commercial contracts today. Parties insert the 'limitation of liability clause' and limit their liability for non-performance or otherwise. Whether a medical practitioner can limit his liability by adopting such a method is keenly debated by some scholars, with no categorical conclusions.
8. This is also referred to as real consent, valid consent etc.
9. See generally, Canterbury v Spence, The District Columbia Circuit, 464 F. 2d 772 (1972).
10. See generally, Sidway v Board of Governors of the Bethlem Royal Hosptial, (1985) AC 871.
11. See generally, Sameera Kohli v Prabha Manchanda & Another, 2008(1) SCALE 442.
12. See the general consent document.
13. The judgement was pronounced on July 6, 2020.
14. By order dated November 18, 2020. The said order may be noted vide - https://main.sci.gov.in/supremecourt/2020/16143/16143_2020_41_11_24729_Order_18-Nov-2020.pdf