## Original Research Paper

# Written Informed Consent: Is It Practiced What Is Being Preached?

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## Abstract

The principles of informed consent are often neglected during clinical practice in developing countries. We tried to assess the level of knowledge of doctors with regards to informed consent and whether they adhere to the principles of informed consent in actual practice. Questionnaire based cross-sectional survey was conducted among 150 randomly selected clinical practitioners of various specialty and super-specialty working at Bhopal City of India. The questionnaire comprised of 30 items of fixed-response type (yes/no/can't say) testing mainly three attributes – knowledge, attitude and practice. Out of 150 clinical practitioners selected to participate in the survey, 115 completed the survey (Response rate=76.66%). Majority of respondents answered correctly when asked about the fundamental principles of obtaining a valid consent (correct response rate varying from 97.4% to 83.4%). However there was marked disparity between level of knowledge and actual practice with regards to informed consent. Study provides valuable insight into how doctors approach informed consent during their practice. It seems that doctors meet many, but not all, of the legal requirements for informed consent. We recommend regular workshops for doctors, on this important issue.

**Key Words:** Written Informed Consent, Medical Ethics, Consumer Protection Act

## Introduction:

In India, last two and half decades have witnessed a drastic rise in the sphere of patients' autonomy. In the past, doctors' attitude towards patients was predominated by the paternalism- "The doctor knows best, what is good for his patient".

However with enactment of legislations such as consumer protection act and after the inclusion of medical services under this act, this era of paternalism in clinical practice is long gone. [1] It is now widely accepted that clinicians should negotiate rather than dictate what is in the best interest of the patients. The idea of "Doctor knows best" has given way to "Partnership in care". [2]

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Consent in the context of a doctor-patient relationship, means the grant of permission by the patient for an act to be carried out by the doctor such as a diagnostic, surgical or therapeutic procedure. In UK, the elements of consent are defined with reference to the patient and a consent is considered to be valid and 'real' when

1. The patient gives it voluntarily without any coercion;
2. The patient has the capacity and competence to give consent; and
3. The patient has the minimum of adequate level of information about the nature of the procedure to which he is consenting to. [3]

In a landmark judgment in case of *Samira Kohli v/s Prabha Manchanda*, the Supreme Court of India reiterated the importance of informed consent in patient care. In above case, Supreme Court did a comprehensive analysis of concept of informed consent in clinical practice and its applicability in a developing country like India. [3]

In spite of strict legislations and examples set by the orders of apex court, it is commonly observed that the principle of informed consent during patient care is often neglected in our country.

Various factors may be responsible for this situation like lack of knowledge among clinicians, or it is difficult for them to change their

attitude and practice according to demands of the time. The present research tries to find out knowledge of the clinicians regarding informed consent, and how they apply it during their practice and; also to find out the ways by which we can improve the procedure of obtaining consent from patients in compliance with various rules and acts of this country.

## Material and Methods:

The present study is a Questionnaire based cross-sectional survey similar to Knowledge, attitude, practice (KAP) survey.

Study population comprised of clinical practitioners of various medical specialty and super-specialty, working in Government and Private hospitals in the Bhopal city of India.

A total 150 respondents were randomly selected to participate in the study. The study team designed a questionnaire after taking into the account of, the observations made by Honorable Supreme Court in *Samira Kohli v/s Prabha Manchanda* case and, also the guidelines prescribed by WHO and ICMR for obtaining written informed consent from patients participating in clinical research.

The questionnaire comprised of 30 items of fixed-response type (yes/no/can't say) testing mainly three attributes knowledge, attitude and practice. Complete information about the study was provided to the participants in the form of printed information sheets, highlighting objectives, methodology and policy regarding the confidentiality of data.

After obtaining written informed consent from the respondents, questionnaire was administered, both in printed form and web form using Google docs as online tool. Online tool was selected to enhance the response rate.

## Observations and Results:

Out of 150 clinical practitioners selected to participate in the survey, 115 completed the survey by answering all 30 questions provided to them in questionnaire. Response rate was 76.66%. Regarding knowledge of respondents about the written informed consent, majority of private clinical practitioners (76 out of 86, 88.4%) were aware that medical services are covered under the ambit of Consumer Protection Act.

But only few (12.2%) had any knowledge about the landmark judgment of honorable Supreme Court in case of *Samira Kohli Vs Dr. Prabha Manchanda*.

All the respondents knew that written informed consent of the patient is compulsory before any diagnostic and therapeutic procedure, which extends beyond the routine clinical check-up where only, implied consent suffice.

Most respondents answered correctly when asked about the fundamental principles of obtaining a valid consent, such as consent must be obtained voluntarily from patient without any force or fear (97.4%), after providing complete information about the planned procedure explaining all the benefits and risks (correct response=97.4%), must be obtained from the patient himself (correct response=96.5%), in his own language or in a language that he understands (correct response=97.4%) and he must be given sufficient time to make his decision (correct response=88.6%) unless it is an emergency.

Most of the respondents also knew that patients have right to second opinion and informed refusal (correct response=83.4%). (Table 1)

But do the clinicians actually practice what they know? Second part of the questionnaire was focused on this aspect, and various questions along with responses pertaining to this aspect are summarized in Tabular form. (Table 2)

Although most respondents know that consent is a voluntary agreement between patient and themselves, almost half of them (49.6%) leave the responsibility of obtaining consent to their subordinate staff such as nursing staff, resident doctors or even clerical staff. Majority of respondents (67.8%) prefer hand written format over printed proforma for obtaining consent. A sizeable chunk of respondents (26.9%) use English language for taking written consent.

Most of them admit that they provide complete information about the planned procedure to the patients including risks and side effects and alternative procedures if available. But about half of them (44.4%) do not provide separate information sheet to the patient. 68.7% respondents also provide cost estimate of planned procedure.

About half of doctors (53.9%) do not mention their name in the consent sheet and overwhelming majority of doctors (78.3%) do not put their signature on the consent form, so consent form looks more like a surrender letter by patient. In about 39.1% cases patient's attendants sign the consent form on patient's behalf. 86.1% doctors do not provide a copy of consent sheet to patient.

As far as time of obtaining consent is concerned, about 90% respondents take consent at the time of admission or a night before the planned procedure. If there is any

deviation from the planned procedure, when the operation is underway and patient is anesthetized, 66.1% doctors take consent midway from the patient's attendant and only 12.2% wait for the patient to come out of anesthesia. We also tried to identify reasons behind the ineffective implementation of informed consent in clinical practice.

About 50% respondents believe that they cannot provide complete information to patients due to lack of time and excessive workload. Even more respondents feel that revealing too much information about the risks may scare the patient and he may become averse to undergo surgery.

Majority of respondents fear Indian legal system because of its slow and costly nature. They do not want to get involved in any litigation due to lack of valid consent. Therefore almost all of them agree that there is need for regular workshop on this issue. (Table 3)

## Discussion:

Informed consent can be sought and obtained in two different senses, each with different implications." The first is the legal sense in which authorization for the professional to act implies that the patient has a reasonable understanding of the procedure and its consequences. The second and more important moral sense of informed consent is based on a true commitment to patient autonomy and the need for shared decision-making. [4]

To make an informed consent really valid, it needs to fulfill both the above stated objectives. In this context it is pertinent to cite the case of *Samira Kohli v/s Prabha Manchanda*, in which doctor obtained the consent for "laparoscopy and laparotomy if needed" but after finding extensive endometriosis during laparoscopy, doctor just informed the mother of the patient about her condition, and proceeded with hysterectomy, without waiting for the patient to come out of anesthesia. Supreme Court of India held consent to be both legally and morally invalid as it was not truly informed. [3]

This case exemplifies the paternalistic attitude of doctors to make decisions on patient's behalf. Most doctors in developing country like India still view informed consent to be just a legal formality and not an ethical issue, related to patient's autonomy.

Based on above pretext, present study attempts to find out factors affecting the informed consent. Our study shows clear-cut discordance between the knowledge of doctors and their actual practice with regards to informed consent. Results clearly showed that doctors, who participated in the survey, have adequate knowledge about the fundamental principles of written informed consent. So it is not the medical education system of the country that is at fault.

This is contrary to the study done in Pakistan by Humayun A et al, who suggested incorporating formal training of Bio-Ethics in the undergraduate and postgraduate medical curriculum. [5] In present study, about half the doctors, despite knowing very well that it is their legal responsibility to obtain the consent from patient, leave this important task to be performed by their subordinate staff, such as resident doctors and nursing staff. Such consent may not be truly informed and legally valid.

This observation highlights the fact that, for most doctors informed consent is not a moral obligation towards the patient but a legal ritual that has to be complied with.

About 39.1% doctors, who were surveyed, do not take consent directly from the patient but from their relatives and family members. This may be a "cultural artefact", because in India, individuals prefer to make important decisions after consulting with the family members. And during sickness, it is the views of family members that take precedence over individual decision.

Moreover during sickness, patient may not want to listen about the risks and cost of the procedure. Thereby doctors prefer to disclose information to attendants and seek consent from them although it may have serious legal repercussions. Study done in various Asian countries like, Pakistan, Japan, Hong Kong also point out this cultural artefact. [5-7]

Most doctors take consent in hand-written format, which may be written in haste and handwriting may not be legible. Also it is difficult to provide complete information to the patient in such format. A sizeable chunk of respondents (26.9%) still use English language for taking consent, which is neither first nor even second language for most of their patients.

Linguistic barrier has been identified as a major obstacle in obtaining a proper informed consent by several authors. [8, 9]

Results show majority of doctors disclose complete information about planned procedure to their patients, which is in contrast to studies conducted in Pakistan and Japan, where doctors still follow paternalistic model of healthcare decision making Doctor knows best what is good for their patients. [5, 6]

Application of Consumer protection Act in healthcare field necessitates the revealing of the cost to the patients, otherwise it may be

regarded as deficiency in service. In our study 68.7% doctors said, they provide cost estimate of planned procedure to their patients. In contrast a study conducted at South Africa by Henley L et al shows, 75% doctors do not reveal the cost of the procedure to the patient. [10]

Shortage of time and excessive workload is often cited as a major obstacle in obtaining proper informed consent. This fact is reiterated once more in our study. Many doctors believe that full disclosure about the risks associated with procedure may unnecessary scare the patient and he may be devoid of potentially lifesaving measure. This view is also echoed by Yousaf RM et al. [11]

## Limitations of the Study:

The study findings must be viewed in the light of the following limitations. A questionnaire based survey cannot expose the process of consent taking in real world situation.

Study would have been more meaningful, if it had been supplemented with the auditing of the consent form. This study reflects doctor's perspective only. Patient, who represents the other side of the coin in the whole process of informed consent, has not been taken into account. We recommend a patient centric survey on the same topic to have a holistic view.

## Conclusion:

To the best of our knowledge, this is first attempt to identify the gap between the knowledge and practice among clinical practitioners with regards to written informed consent. Despite its limitations, the study provides valuable insight into how doctors approach informed consent during their practice. It seems that doctors meet many, but not all, of the legal requirements for informed consent. We recommend regular workshops for doctors, on this important issue and also on various other aspects of medical ethics, not only to refresh the knowledge but also bring about change in attitude according to the demands of time.

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**Table 1: Questionnaire Part-1**

| Question | Response | N (%) |
|---|---|---|
| Do you know your services are covered under Consumer Protection Act? | Yes | 76 (66.1%) |
| | No | 10 (8.1%) |
| | N.A. | 29 (25.2%) |
| Have you heard about Honorable Supreme Court's decision on Samira Kohli Vs. Dr. Prabha Manchanda case? | Yes | 14 (12.2%) |
| | No | 101 (87.8%) |
| Do you know Written Informed Consent is necessary before any therapeutic or diagnostic procedure which is beyond the ordinary clinical check-up | Yes | 100 (100%) |
| | No | 0 (0%) |
| Do you know consent without adequate information is no consent at all | Yes | 112 (97.4%) |
| | No | 3 (2.6%) |
| Do you know a written informed consent is a voluntary agreement between you and your patient | Yes | 112 (97.4%) |
| | No | 3 (2.6%) |
| Do you know written informed consent should be taken from the patient himself / herself, unless he / she is incapable of doing so due to any reason (such as minors, unconsciousness, emergency etc.) | Yes | 111 (96.5%) |
| | No | 4 (3.5%) |
| Do you know the consent should be taken in patients' own language or in the language the patient understands | Yes | 112 (97.4%) |
| | No | 3 (2.6%) |
| Do you know it is necessary to give sufficient time to patient to make the decision about the proposed procedure | Yes | 102 (88.6%) |
| | No | 13 (11.4%) |
| Do you know the patient has right to second opinion before consenting to any procedure | Yes | 96 (83.4%) |
| | No | 19 (16.6%) |
| Do you know that patient has right to informed refusal | Yes | 96 (83.4%) |
| | No | 19 (16.6%) |

**Table 2: Questionnaire Part-2**

| Question | Response | N (%) |
|---|---|---|
| Who takes the consent in your setup | Yourself | 58 (50.4%) |
| | Subordinate | 57 (49.6%) |
| Which type of consent proforma do you use for written informed consent | Handwritten | 78 (67.8%) |
| | Printed | 37 (32.2%) |
| In which language do you prefer to take consent | English | 31 (26.9%) |
| | Hindi | 84 (73.1%) |
| Do you use separate information sheet and consent sheet | Yes | 64 (55.6%) |
| | No | 51 (44.4%) |
| Do you provide complete information about the planned procedure | Yes | 100 (86.9%) |
| | No | 15 (13.1%) |
| Do you provide complete information about alternatives | Yes | 88 (76.5%) |
| | No | 27 (23.5%) |
| Do you provide complete information about risks and side-effects | Yes | 105 (91.3%) |
| | No | 10 (8.7%) |
| Do you provide rough estimate of cost involved in the procedure and cost escalation, if any complication arises | Yes, written | 12 (10.4%) |
| | | 67 (58.3%) |
| | No | 36 (31.3%) |
| Who signs the consent on patient's behalf, in majority of elective procedures in your setup | Attendant | 45 (39.1%) |
| | Patient | 70 (59.9%) |
| Does the name of Primary physician (treating doctor) features in the written informed consent sheet | Yes | 62 (53.9%) |
| | No | 53 (46.1%) |
| Do you also sign the consent yourself | Yes | 25 (21.7%) |
| | No | 90 (78.3%) |
| When do you take the consent in elective procedures | On admission | 43(37.4%) |
| | Night before procedure | 61(53%) |
| | Just before procedure | 11(9.6%) |
| Do you take consent midway if there is any deviation in the planned procedure (when the operation is underway and patient is anaesthetized) | Yes | 82 (71.3%) |
| | No | 8 (7%) |
| | N. A. | 25 (21.7%) |
| If the answer of the above question is Yes, then time of taking such consent | During the procedure from attendant | 76 (66.1%) |
| | Wait for patient to recover from anesthesia | 14 (12.2%) |
| | N. A. | 25 (21.7%) |
| Do you provide a copy of informed consent sheet to the patient | Yes | 16 (13.9%) |
| | No | 99 (86.1%) |

**N.A.=Not Applicable**

**Table 3: Questionnaire Part -3**

| Question | Response | N (%) |
|---|---|---|
| Do you feel you cannot provide complete information to the patient due to shortage of time | Yes | 58 (50.4%) |
| | No | 57 (49.6%) |
| Do you feel it will be more time consuming and costlier if you happen to run into a court case due to lack of a valid consent, considering the Indian legal system | Yes | 99 (86.1%) |
| | No | 16 (13.9%) |
| Do you feel revealing too much information about risks and complications may scare the patient and he may be devoid of any life-saving procedure | Yes | 74 (64.3%) |
| | No | 41 (35.7%) |
| Do you feel revealing the cost may cause you to lose your patient to some other doctor | Yes | 31(27%) |
| | No | 84 (73%) |
| Do you feel a need of a workshop or conference on this topic that is “Informed Consent in Clinical Practice” to improve the quality of your services | Yes | 108 (93.9%) |
| | No | 7 (6.1%) |