

## Research Paper

## Medical Science



## Perception of Informed Consent Among the Patients Coming to Radiology Department

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### ABSTRACT

*The qualitative study conducted in 2013 sought to understand the Perception of informed consent among the patient coming to Radiology Department in Indian population using purposeful sampling. A total of 6 patients who are coming to radiology department are selected for the in-depth interviews. The interviews were conducted in a large multi-specialty, private hospital in south India, wherein people from all over India come to access care. It is well known for good quality patient care at relatively low cost. The in-depth interview was audio-taped and coded according to three major themes that emerged during the interview. This study highlighted the poor awareness of informed consent obtained during the radiology procedures. The patient's poor literacy levels and language interfered with doctor's ability to help patients to understand the informed consent obtained during the radiology procedures.*

**Keywords :** Qualitative Study, Informed Consent, India, Radiology

### Introduction

The Radiology is a branch of medicine which deals with the application of radiation for diagnosing and treating patient with disease. All the radiology, radiotherapy and nuclear medicine examination use radiation which confers a long term risk of cancer but the patient who are undergoing such diagnosing examination receive inaccurate information about risk directly related to the radiology dose received(1). According to the revised International Basic Safety Standards for protecting people and the environment, patient who are undergoing radiology procedure which involves ionizing radiation should be informed clearly about the benefit and risk of radiology procedure as well as the radiation risk(2). It is anticipated that detail information on radiation dose imparted during the examination and its risk may lead into the anxiety of the patient. Many medical interventions may have the potential to cause harm instead of the good for which they are intended. As a consequence of several questionable and offensive experiments in which patients were either abused or subject to dangerous procedures without their knowledge, legal codes and government regulations concerning rights of patients have now been fairly well developed(3). In order to understand Perception of informed consent among the patient coming to Radiology Department, qualitative study among patient coming to the radiology department would help in better understanding the barriers and how to improve the awareness among the patients.

### Objective

To ascertain how patients actually perceive informed consent and how important it is to them.

### Methods

The study was carried out in the south india. Qualitative methods of in-depth interviews were carried out with patients after obtaining consent.

**Study Design:** Cross sectional study using qualitative techniques of in-depth interviews.

**Study Sample:** Consenting adult, male and female Kannada and tulu speaking patients who came to radiology department to undergo radiology procedure for computer tomography and radiology special procedure are included.

**Sample Size:** A total of 6 in-depth interviews with male and female patients selected from computer tomography section and radiology special procedure section of the department.

**Sampling Technique:** Purposive sampling a non probability sampling method was used in the recruitment of patients.

**Procedure:** Six patients who came to radiology department were approached and those who gave consent to participate were recruited for the study. Patients were approached fol-

lowing completion of their radiology procedure and only those who were physically fit enough to participate in an interview and expressed their willingness to do so were included. All interviews were carried out in the hospital campus and patients were assured of confidentiality. Semi-structured interview schedules were prepared to document the information derived from the observation of the informed consent process. All the interviews were tape-recorded after obtaining consent to enable a thorough recording of all information provided by the participants. Those interviews conducted in Kannada and Tulu were transcribed verbatim and then translated into English to facilitate the textual analysis of data. A framework analytical approach was used for data analysis.

## Results

The main emerging themes of analysis are described.

### Themes of Analysis

- Understanding Of Informed Consent
- Information provided by doctors
- Patient perception to discuss their health problems

### Understanding of informed consent

For many patients the word "Informed Consent" was an unfamiliar one. They were not aware of what it meant aside from them having to sign a form. Few patients reported that informed consent implied to a document they had to sign by which the hospital could protect them in the event of any mishap occurring during injection of contrast media to the patient. But few patients reported that informed consent is a process whereby doctors communicated all the details about the nature of radiology procedure that was to be performed on the patient, and inform them all the potential risk and benefits of the radiology procedure and the contrast injected during the procedure. Over all the informed consent is unknown the patients who are coming to radiology imaging.

### Information provided by doctors

Patients who were interviewed reported that the health care professionals do not provide sufficient information regarding the diagnostic radiology procedure. The benefit vs risk of a particular procedure is also not clearly explained to the patients. Patients also reported that in a tertiary health care set up medical doctors fail to provide valuable information about their illness and about the diagnostic procedures which will be required to diagnose their illness. Patients also confessed that the medical doctors do not have any face to face contact with them and the instructions are usually given by junior post graduate students. An in-depth interview with one of the patients revealed that he was totally unaware about the term "Informed Consent" and he added by saying that the medical doctors should briefly describe and explain about informed consent form. Some patients reported that the medical doctors told them that informed consent is a form to be signed by the patients to protect them if anything goes wrong during the diagnostic procedure. One of the patients reported that he was given a very brief explanation about informed consent and matters related to informed consent, but he admitted that he did not understand anything as the medical doctor was too fast in conversing and was using terms which the patient was totally unaware. Overall the information provided by doctors to the patients is very poor.

### Patient perception to discuss their health problems

An in-depth interview with patients revealed patients perception to discuss their health problems with the treating physician and radiologist is very poor. Patients admitted that they have inner fear and consciousness which prevents them from discussing their health related issues with their treating physicians. One of the patients reported that if they discuss their health related problem in detail it will increase the number of diagnostic procedures which is prescribed by the treating physician. Patients also stated that the radiologist who is involved in diagnostic imaging also does not discuss or inform anything about the procedure in detail. An important point which was stressed more by the patients was communica-

tion skills and literacy. Patients reported that they are not that well educated to communicate with the medical doctors and have poor communications skills. Patients admitted that this is a major cause for not discussing their health related problems with medical doctors. Patients reported that ignorance and negligence also lead to not discussing critical and crucial health problems with medical doctors. Overall the patient perception to discuss their health problems with medical doctors is very poor.

## Discussion

The findings from this study revealed that an understanding of informed consent among patients who are coming to radiology department is poor. The patients don't question their doctor about their radiology examination and its hazards. The doctors believed in communicating key issues related to the radiology examination to the patients but often found their poor literacy levels and language barriers as factors which interfered with their ability to help patients understand the biological hazards of radiation. This ineffective communication between the patient and doctors result in the significant ethical problems. Informed consent in the every radiology procedure is needed to establish a respectful in all health care centers. The US National Institutes of Health, explains the radiology risk in more straightforward to the patient who are the considered as a sample for the research project and with a radiation dose greater than 15 millisieverts [4]. The recent study reported, not only of patients but of practicing doctors from the British [5], Israeli [6], Italian [7], Canadian show substantial unawareness of doses, and risks. Since we are dealing with various kinds of patients ranging from those who are educated to those who are not literate and have poor understanding of issues regarding their rights as patients, we need to try and understand what sort of informed consent in the radiology department will work best and will be meaningful and relevant to our culture. The effective Informed consent should explain the detail of procedure use ionizing radiation and its hazards. In general, patient often do not understand radiation and its hazards, in which doses are expressed in many varied units, and simple information on doses and risks is difficult to find and hard to interpret. Currently upto our literature survey in India there is no informed consent for radiology department which explain the radiation dose and its biological hazards of the radiation used for the radiology examination. From our study, the consent form that was used usually in radiology department consisted of a printed form basically outlining that the patient was aware of the potential risks and had consented for using the contrast study in radiology examination which does not explain the biological hazards of radiation to the patient. There is thus a degree of inconsistency in the entire informed consent process in terms of the depth of information that is communicated to patients. Based on our experience, most patients do not really read the form. The reasons for these are illiterate, not interested and cannot understand. There is a need for educating patients about the consent process thereby empowering them to play a more active role in their treatment. However, the use of visual aids, certainly found to be helpful by patients to understand the type of radiology examination and its hazard. Radiology doctors will be the ideal persons to obtain consent considering they were the ones doing the procedure and have the full knowledge of the radiation dose and its biological hazards. If we believe that informed consent is more about patient understanding and involvement and less about satisfying legal requirements and hospital policy, then we also need to be more progressive, perhaps, innovative in the manner in which we approach it.

## Conclusion

This study has highlighted the poor awareness among the patient about the informed consent. Implementation of awareness programs and visual aids informed consent could be an effective method to make the informed consent to be more information to the patient. Further research on quantitative should consider to addressing these issues.

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