

Knowledge, Attitude and Practice Regarding Informed Consent in Medical Research among Resident Doctors of a Medical College of Eastern India.

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ABSTRACT

Background: Informed consent remains an important ethical and legal document ensuring autonomy of the research participants. **Objective:** The present study was undertaken with the idea to find out the gap in respect to knowledge, attitude and practice in acquiring Informed Consent so that we can improve the procedure of acquiring consent in accordance with the present regulations. **Methods:** Questionnaire based close ended cross sectional study within 1 week time frame in Bankura Sammilani Medical college involving the resident doctors pursuing their post graduate degrees. **Results:** Though 83.4% had the knowledge but 68% do not feel necessary to take consent. The major limitation being excessive work load and lack of time. **Conclusion:** The study revealed that there was lot of lacunae in their knowledge giving rise to improper attitude and practice regarding Informed consent procedure in a research project.

Keywords: Informed consent, clinical research, resident doctor.

INTRODUCTION

Informed consent remains an important ethical and legal document ensuring autonomy of the research participants. In the present scenario where a research project submission is mandatory for obtaining desired post graduate and post doctorate qualification it is presumed that the resident doctors are familiar with different aspects of research projects including detailed about informed consent process. About 80 residents are admitted in various disciplines in this institution every year and the number of which is increasing per year with a nod from MCI. Bankura Sammilani Medical College caters a major population of patients from surrounding district as well for which the patient turnover is high in this institution. The residents remained occupied mostly in patient care giving apart from ensuing various researches under the able guidance of their guides. To undertake a proper

research in medical field in this institution within a stipulated time frame with huge patient turnover is posing a real challenge. Especially when the research data is to be taken from the outpatient departments. Lack of emphasis regarding bioethics in the present curriculum has resulted in proper attitude development.^[1] A research subject should always be given an opportunity to read the consent document, to ask questions about anything they are unable to understand about the research. Moreover enough time is to be provided to ensure that the research participants get enough time to consider their participation and that too without the influence of the investigator or the stakeholders having doubt of interest. The language should also be easily perceived by them to avoid their misunderstandings regarding medical research. There is strict regulations regarding informed consent process involving human participants.^[2] But it has been seen that there is lack of adherence to the guided protocol for obtaining Informed Consent due to lack of clear understanding. The present study was undertaken with the idea to find out the lacunae in acquiring Informed Consent so that we can improve the procedure of acquiring consent in accordance with the present regulations.

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MATERIALS AND METHODS

The present study is a questionnaire based observational, cross sectional one involving the students pursuing postgraduate degrees assessing the knowledge, attitude and practice regarding Informed Consent while undergoing their research work. The study was conducted in Bankura Sammilani Medical College within a period of 1 week. A total of 90 respondents who were post graduate students were selected randomly from three years. The resident doctors who were absent during the study period were excluded.

The study was undertaken after receiving Institutional Ethical Clearance. A predesigned structured and validated questionnaire were applied. The questionnaire comprised of a set of ten questions of fixed response type (yes/no/can't say) covering three domains of Knowledge, Attitude and Practice regarding informed consent. The study participants were provided complete information of the study highlighting the objectives, methodology and confidentiality of the data. The questionnaire was placed after taking Informed Consent from the respondents. They were asked to fill the questionnaire anonymously within 15 minutes and to hand it over to the investigator.

The data was streamlined in Microsoft excel and descriptive statistics were applied for analysis of the data. The confidentiality of the respondents were maintained.

RESULTS & DISCUSSION

103 postgraduate students were approached among which 90 students consented to participate in the study. 36 respondents were from 1st year, while 34 from 2nd year and only 20 students from 3rd year participated.

When asked about the fundamental principles of obtaining informed consent like voluntary participation of study subjects almost 83.4% had the knowledge. Informed consent is an ongoing dynamic process where the study participants has not only the right to give voluntary consent but also has the right to withdraw at any phase of the study. And it is the responsibility of the researchers to share all the relevant new information to the study subjects. Moreover a biased information transmission to study subjects with deliberate intention of the researchers to obtain consent makes it invalid. Unfortunately 68% of the respondents supported to share complete information to the research subjects regarding the study. They feel that revelation of the information related to the study may drive away the research subjects from participating resulting an inadequate sample size. Similar information have been shared by other studies.^[5,6] Though 72% responded that the informed consent must be obtained from the subject himself or herself but only

45% answered correctly regarding the situations where other than the study subjects may give the consent like legal heirs in case of mentally challenged and children reflecting the need for more awareness regarding undertaking of research through CME and workshops.^[7,9] Proper informed consent should be ensured by the seniors strengthen up the essential elements like voluntarism, information disclosure, and decision-making capacity of the participants. When asked about the presenting language 85% of respondents think that informed consent document should be in a language that will be easily understandable by the study subject to overcome linguistic barrier in obtaining proper informed consent.^[3,4]

Considerable percentage of respondents 68% that they don't feel necessary to take consent in every research especially those involving the inpatients whose data can be procured from the bedhead tickets.

It was disheartening to find that 23% opined that Informed consent should be obtained before allocating for study groups. The present practice of first subgrouping the subjects and then taking Informed consent leads to the failure of the very purpose of informed consent that is the autonomy of the Patient is not rightly addressed. Classes on ethical issues in medical research and informed consent should be incorporated in their PG curriculum so that along with their dissertation preparation they have a proper knowledge on ICH Guidelines to undertake such research. Excessive patient turn over and lack of time may pose a major limitation for obtaining a proper informed consent. Majority feel that revelation of the information related to the study may drive away the research subjects from participating resulting an inadequate sample size. Similar information have been shared by other studies.^[5]

Only 44% have the attitude of clearing the doubts after giving enough time for the understanding of the research participants.

Almost 98% of the respondents expressed that lack of time is the main reason for not adhering to the proper informed consent procedure.

CONCLUSION

The present study involving the resident doctors of Bankura Sammilani Medical College revealed that there was lot of lacunae in their knowledge giving rise to improper attitude and practice regarding Informed consent procedure in a research project.

So it can be concluded that there is enough scope of improvement by regular sensitization by continued medical education and workshop. Inclusion bioethics in recent curriculum will prove to bridge the gap further.

Limitations of the study was that it was conducted with a limited number of residents of only one

Medical College which cannot be generalised. We included questions that reflected major issues keeping aside more intricate aspects.

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