

Original Research Article

Knowledge, attitude and practice of informed consent process in biomedical research among postgraduate medical students

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ABSTRACT

Background: Research is integral part of post graduate studies. Informed consent is a vital ethical and regulatory requirement for the conduct of biomedical research.

Methods: Mixed methods study was carried out from July to August 2017. Cross sectional part constitute quantitative component and forced field analysis (FFA) forms qualitative part. Approval from the institutional ethical committee was obtained. Pre-designed, validated, structured questionnaire was used to gather information from 114 participants about knowledge, attitude and practice (KAP) regarding informed consent process. FFA was employed to understand driving and restrictive forces in obtaining informed consent from the research participants.

Results: Out of the 114 study participants majority participants were males i.e. 69.3% and pursuing post-graduation in clinical subjects. There is significant association between knowledge ($p=0.008$), attitude ($p=0.032$) among postgraduates from clinical and nonclinical departments. Among clinical 51.7% and 48.3% among non-clinical have good knowledge and 67.7% among clinical and 32.3% among non-clinical have good practice. Main driving forces for informed consent process identified during FFA were ICMR guideline for biomedical research, feeling morally right to inform the participants about what the research. Main restrictive force was fear of losing the participant due to signing on informed consent.

Conclusions: There is good knowledge among postgraduates about informed consent process however there is scope of improvement in attitude and practice. Ethics training should address how to build trust with research participants and how to overcome the fear of losing the study subject.

Keywords: Informed consent, Biomedical research, Knowledge, Attitude, Practice

INTRODUCTION

Research is integral part of post graduate studies. Research will help the students to develop critical thinking, understand problem solving, generate scientific evidence and enhance self-directed learning. Every postgraduate student have to conduct research as a part of their dissertation and conference presentations and one publication which is required to appear for the examination.

Most of the colleges impart research methodology training for all postgraduates including sessions on ethical guidelines as understanding of ethical principles is critical in conducting research.

Informed consent is a vital and regulatory requirement for the conduct of biomedical research and is one of the most important benchmarks of ethical clinical research.¹ A well-constructed informed consent is foundation of one of ethically conducted research because it provides the

study participant with sufficient information to make independent decisions with understanding of risks and benefits involved in the research.

Indian council of medical research (ICMR) has laid down guidelines for informed consent process in all biomedical research involving human participants.²

In the clinical setting, the term “informed consent” was developed in the USA in 1957. It was further developed in the Declaration of Helsinki in 1964, which established worldwide ethical principles for medical research involving human participants.³

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.⁴ 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. In India, legal suits on doctors have increased in recent years; this can be largely attributed to lack of knowledge and practice of medical ethics.⁵

In many countries informed consent for medical procedures is a standard procedure for providing the patients with the information on diagnostic and treatment procedures, risks, complications, and alternative treatment options in non-emergency cases.⁶ Informed consent can lead to better patient–physician relationships, better physician understanding of the patient’s illness, and better patient adherence to treatment recommendations.

The principles of informed consent are often neglected during research. The primary objective of informed consent is ensuring safety and protecting rights of patient/participant in both clinical care and research hence the patient-physician relationship, as well as the research subject-investigator relationship, should be seen in the same manner. Informed Consent should not be different regarding both clinical as well as research activities. The present study was conducted with objectives of identifying the knowledge, attitude and practice of postgraduates about informed consent process in research activities and understanding the nurturing and hindering factors for practicing informed consent.

METHODS

Mixed methods study design was used to fulfil the study objectives. Quantitative part includes cross-sectional study design and forced field analysis formed the qualitative component of the study. Study was undertaken in a private medical college in coastal Karnataka from July to August 2017. Postgraduate medical students who have undergone research methodology training and have

collected their dissertation data from minimum 10 research participants and willing to participate in the study were considered eligible for the study.

Assuming that 50% of the subjects in the population have the factor of interest, and an expected response rate of 80%, the study would require a sample size of 121 for estimating the expected proportion with 20% precision relative to the expected proportion and 95% confidence. Accordingly postgraduate students were enrolled from clinical and nonclinical departments with probability proportional to size (PPS) method. Out of the 121 participants enrolled for study 114 participated throughout the study with response rate of 94.3%.

After obtaining clearance from the Institutional Ethics Committee, Knowledge, Attitude and Practices (KAP) were studied by using questionnaire comprised of 40 multiple choice questions and fixed-response type (yes/no). There were 16 questions on knowledge 08 on attitude and 16 on practice. Correct responses were given 2 score and incorrect responses were given 1 score. Postgraduates who scored <26 were considered having average knowledge and practice about informed consent process. Those with 26-30 and >30 scores were grouped with good and very good category. With respect to attitude participants having <11 score were grouped in average grade, 11-14 in good and >14 score were grouped in very good category.

Force field analysis (FFA) is a technique employed to identify and analyze the force affecting a problem situation, so as to bring about a change.⁷ In this study 2 sessions of FFA having 10-12 participants in each session were employed.

Data was analysed using statistical package for social science (SPSS 23). Descriptive statistic was reported as median and interquartile range (IQR) for continuous variables and frequency and proportion for categorical variable. Mann Whitney and chi square test were used to study the mean scores across the various disciplines, gender, nature of study and type of study participants. Descriptive content analysis was done for the data gathered by forced field analysis.

RESULTS

Total of 114 study participants were enrolled. Majority of participants were males i.e. 69.3% and pursuing post-graduation in clinical subjects. Mean age of participants from clinical department was 28.71 years and from non-clinical department was 28.33 years (Table 1).

Proportion of participants with good knowledge, attitude and practices with respect to informed consent practices were more among postgraduates in clinical subjects than those perusing post graduations in non-clinical subjects. The difference was found to be statistically significant with respect to knowledge and attitude with chi square

value of 7.065 and 6.890 respectively as shown in Table 2.

Table 1: Gender and discipline wise distribution of participants (N=114).

Variables	Gender		Mean age
	Male	Female	
Clinical	65	16	28.71
Non clinical	14	19	28.33

However when compared with respect to median score and Interquartile range there is no statistical difference

Table 2: Association between knowledge, attitude and practice among clinical and nonclinical post graduate.

Variables		Clinical (n=81)	Non clinical (n=33)	Chi square	P value
Knowledge	Good	15 (51.7%)	14 (48.3%)	7.065	0.008
	Very good	66 (77.6%)	19 (22.4%)		
Attitude	Average	15 (93.8%)	1 (6.3%)	6.890	0.032
	Good	66 (68.0%)	31 (32.0%)		
	Very good	0 (0.0%)	1 (100.0%)		
Practice	Average	12 (70.6%)	5 (29.4%)	1.137	0.566
	Good	44 (67.7%)	21 (32.3%)		
	Very good	25 (78.1%)	7 (21.9%)		

Table 3: Median and inter-quartile range (IQR) of knowledge, attitude and practice.

	Department	N=114	Median	IQR	P Value
Knowledge	Clinical	81	31	31.75-31	.072
	Non clinical	33	31	31-30	
Attitude	Clinical	81	13	13-12	.121
	Non clinical	33	13	13-12	
Practice	Clinical	81	29.5	31-27	.777
	Non clinical	33	29	30-28	

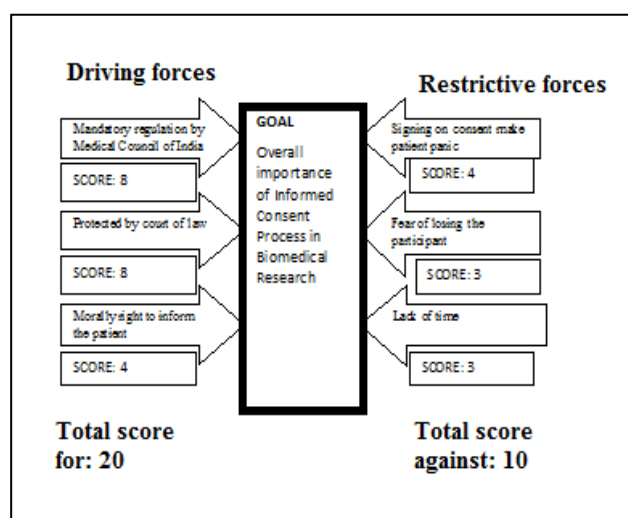


Figure 1: Force field analysis of factors influencing informed consent process.

between the knowledge, attitude and practices scores of participants from clinical and non-clinical departments. Mann Whitney test was used to study the difference between the median scores among the postgraduates of clinical and non-clinical departments.

Median score and interquartile range for knowledge among clinical and non-clinical postgraduates was 31 (IQR=31.75-31) and 31 (IQR=31-30) respectively. With respect to attitude it was 13 (13-12) and 13 (IQR=13-12). Regarding practice it was found to be 29.5 (IQR=31-27) and 29 (IQR=30-28) among clinical and non-clinical department postgraduates (Table 3).

Force field analysis was done to know about the driving forces and restrictive forces for the informed consent process and main driving forces with highest driving force with 8 score were found to be mandatory regulation by Medical Council of India and protected by court of law. Morally right to inform the patient was found to be the second highest driving force with 4 score.

And main restrictive forces perceived by the participants were found to be panic reaction of study participants when asked to sign on the consent form, make patient panic, fear of losing the participant and lack of time (Figure 1).

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.⁸

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. All the participants were trained in research methodology and ethical principles in biomedical research. Study done in Pakistan by Humayun et al, suggested incorporating formal training of bioethics in the undergraduate and postgraduate medical curriculum.⁹ The moral and legal acceptability of consent depends upon more than the transmission of appropriate information to patients. Equally, patients must be competent to consent: to be able to understand, remember, deliberate about, and believe clinical information given to them about their specific treatment options. Otherwise, consent would lack autonomy since it was made while patients were not in control of their cognitive or emotional capacities.¹⁰ Morally right to inform the patient was found to be the second highest driving force with 4 score in our study.

A study done by Yousaf et al, at Hospital Tengku Ampuan Afzan (HTAA), Kuantan, Malaysia and Sri Maharaja Hari Singh Hospital (SMHS), Srinagar found in their study that there are limited hospitals in Srinagar, the work load on these hospitals is very heavy and the doctors are taxed beyond their capabilities. The doctors have to work very hard and therefore spend less time with details. Informed consent requires time and patience, both of which are deficient in such busy clinics and these are reflected in the results. A lack of education among patients is another hindrance in achieving this goal.¹¹ In our study also its been found that lack of time was one of the major restrictive forces for proper informed consent.

CONCLUSION

Knowledge about informed consent process is very good among the disciplines. Relatively lower scores seen with respect to attitude and practice. There is scope for improvement in attitude and practice areas. Fear of losing the study participants and lack of time were reported to be the challenges in obtaining informed consent from research participants. Further training in research methodology and ethics should address the challenges reported by the participants.

Recommendations

All post graduate as a part of their training were trained in research methodology including ethical issues during first year. There is need to re-inforce the importance of research ethics during second year and there should be

student-faculty forum to discuss the challenges faced in conducting biomedical research and to find solution to problem in practicing informed consent process in biomedical research.

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REFERENCES

1. Emanuel FJ, Wendler D, Killen J, Grady C. What makes clinical research in developing countries ethical. The benchmarks of ethical research? *J Infect Dis*. 2004;189:930–7.
2. Ethical Guideline for Biomedical Research on Human Participants. New Delhi: Director-General Indian Council of Medical Research, 2006.
3. World Medical Association. declaration of helsinki – ethical principles for medical research involving human subjects. Seoul: 59th WMA General Assembly, 2008.
4. The Consumer Protection Act 1986. Available at: <http://chdconsumercourt.gov.in/consumerProtectionAct1986.pdf>. Accessed on 15.01.2014
5. Snyder L. American College of Physicians Ethics, Professionalism, and Human Rights Committee. American college of physicians ethics manual: Sixth edition. *Ann Intern Med*. 2012;156(1):73–104.
6. Paterick TJ, carson GV, Allen Mc, Paterick Te. Medical informed consent: general considerations for physicians. *Mayo clin Proc*. 2008;83:313–9.
7. Kaminski J. Theory applied to informatics–Lewin’s Change Theory. *Canadian Journal of Nursing Informatics* 2011;6(1):1251.
8. Faden RR, Beauchamp TL. *A History and Theory of Informed Consent*. New York: Oxford University Press; 1986.
9. Humayun A, Fatima N, Naqqash S, Hussain S, Rasheed A, Imtiaz H, Imam SZ. Patients' perception and actual practice of informed consent, privacy and confidentiality in general medical outpatient departments of two tertiary care hospitals of Lahore. *BMC Medical Ethics*. 2008;9:14.
10. Doyal L. Good clinical practice and informed consent are inseparable. *Heart*. 2002;87(2):103–5.
11. Yousaf RM, Fauzi ARM, How SH, Rasool AG, Rohana K. Awareness, knowledge and attitude towards informed consent among doctors in two different cultures in Asia: a cross sectional comparative study in Malaysia and Kashmir, India. *Singapore Med J*. 2007;48:559–65.

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