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Original Research Article

Knowledge and practices regarding informed consent process for research among junior doctors of a tertiary-care institution in Northeast-India: a cross sectional study

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ABSTRACT

Background: Medical research involving human participants needs to be guided by fundamental ethical principles to ensure the protection of their rights and welfare. Informed consent is one of the fundamental ethical principles. This study was conducted to assess the knowledge and practices regarding informed consent process for research among junior doctors and to determine the association between level of knowledge and their practices regarding informed consent process with certain socio-demographic variables.
Methods: A community-based cross sectional study was conducted among the junior doctors of a medical college and tertiary-care institution in Northeast-India. A pretested, peer reviewed, semi structured questionnaire was used. Descriptive and analytical statistics like chi square test and fisher exact test were generated taking a $p<0.05$ as level of significance. Ethical approval was obtained from the institutional ethics committee.
Results: Out of 350 participants, males constituted 47%. More than half of the participants (196, 56%) have good knowledge of informed consent process. Around two-fifth (148, 42.3%) of the respondents were involved with some kind of research work and out of them majority of the participants showed good practice (141, 95.3%) of research. Participants from pre and para clinical departments have significantly higher level of knowledge as compared to those from clinical department.
Conclusions: Only around 56% of the junior doctors had good knowledge of informed consent process. As part of continuing medical education program there is a need to organise seminars and workshops for the junior doctors on the informed consent process for ethical conduct of research.

Keywords: Informed consent process, Junior doctors, Knowledge, Medical college, Practices

INTRODUCTION

Medical research involving human participants needs to be guided by globally agreed fundamental ethical principles to ensure the protection of their rights, welfare and dignity such as the Belmont report and the Helsinki declaration.[1-4] One of the important principles of research involving human participants is respect for the dignity of persons.[5]

Informed consent is one of the fundamental ethical principles universally recognized as an essential safeguard to ensure the preservation of individual's rights which is based on the declaration of Helsinki and the Nuremberg code.[3,5-8] It is mandatory for a researcher to obtain voluntary informed consent from the participant for any biomedical and health research involving human participants.[9]

The informed consent process begins with a conversation between the researcher and the subject, who is presented with the option to participate in the research as well as an informed consent document (ICD).[10] Subsequently, the subject will decide to participate in the research, then they will sign the consent form.[11] Investigators should be aware that the informed consent document alone does not assure the subject's full understanding of their participation.[12] Therefore, before the subject makes a decision, the researcher should explain clearly, the study purpose and procedures, risks and benefits, and the rights and obligations to the participant.[13]

Informed consent document (ICD) has two parts- participant information sheet (PIS) and informed consent form (ICF). Information on known facts about the research, which has relevance to participation is included in the PIS. This is followed by ICF in which the participant acknowledges that he/she has understood the information given in the PIS and is volunteering to be included in that research.[14]

Since junior doctors are or will be engaged in medical research as a part of their academic career, it is necessary to understand their knowledge regarding informed consent process and ethical principles in research.[15] Also no study has been conducted regarding knowledge and practice of informed consent process in Manipur. Hence, this study was conducted to assess the knowledge and practices regarding informed consent process for research among junior doctors and to determine the association between level of knowledge and their practices regarding informed consent process with certain socio-demographic variables.

METHODS

A community-based cross-sectional study was conducted among junior doctors of a government medical college and tertiary care institution in Imphal-east, Manipur, north-east India during October to November, 2023. All the internees, non-academic junior residents, post graduate trainees in the 1st, 2nd and 3rd years currently pursuing MD/MS were included in the study. Those who were not willing to participate in the study, those who could not be contacted on 3 consecutive visits and post graduate trainees involved in the research were excluded from the study.

According to the data obtained from the college authority, a total of 383 eligible participants were included in the study, out of which 82 were internees, 93 were non-academic junior residents, 208 were post graduate trainees (1st, 2nd and 3rd year). All the questions were adapted from the 'National Ethical guidelines of Biomedical and Health research involving human participants 2017' of the Indian Council of Medical Research (ICMR).[9] The tool was peer reviewed by experts in the subjects and pre-tested on a group of doctors who were not included in the study. The finalized semi-structured questionnaire consisted of the following domains- socio-demographic profile, questions on knowledge regarding informed consent process and questions on practice of informed consent process. A total of 19 knowledge questions adapted from national ethical guidelines of biomedical and health research involving human participants 2017 of ICMR were used. Out of 19 knowledge questions, 01 score for every correct response were given except for three questions. For one question, score of 01 each for 02 correct responses while for the other two questions, a score of 01 each for 03 correct responses were given. Total score ranges from 0 to 24 and cutoff was taken as more than 50% i.e. score of 13 and above were considered as having good knowledge of informed consent process. For practice question, a total of 5 questions were used, 01 score for every correct response were given with a total score ranging from 0-5 and those who score 3 and above (i.e. more than 50%) were considered as having good practice of informed consent process.

Statistical analysis

Data were entered in MS Excel and analysed in SPSS v19. Descriptive statistics like mean, median, proportion, standard deviation were used to summarize the findings and analytical statistics i.e. chi square test and fisher exact test were used to find association between level of knowledge and practices of informed consent process with certain socio-demographic variables. P value of less than 0.05 was taken as statistically significant.

Ethical approval

Ethical approval was obtained from the Institutional Ethics Committee vide protocol No.471/84/2023 dated 18/10/2023. Informed consent was taken from the study participants and purpose of the study was clearly explained prior to data collection. Strict confidentiality of the information was maintained. All the collected data were in the custody of the investigators in password protected computers.

RESULTS

Out of the 383 eligible participants, 15 post graduate trainees were inaccessible as they were posted for the district residency program, 12 were from community medicine department where pre-test was done and 06 were non-responders so a total of 350 participated in the study. Median age of participants was 28 years with minimum age of 23 and maximum age of 46 years. Majority of the participants were in the age group less than or equal to 28 years (62.6%) and more than half were female (52.9%). Most of them were Hindu (42%) followed by Sanamahi (33.4%), Christian (18%), Islam (6%) and others (TRC, Donyi Polo) (0.6%). Majority were from surgery and allied department (46%) followed by medicine and allied department (42%) and pre and para clinical department (12%).

Table 1: Knowledge regarding informed consent process (n=350).

Questions	Frequency (n)	Percentage (%)
Informed consent comes under which Ethical Principle?		
Correct response	178	50.9
Incorrect response	172	49.1
Informed consent document has how many parts?		
Correct response	139	39.7
Incorrect response	211	60.3
What are the parts of an ICD?		
Correct response	92	26.3
Incorrect response	258	73.7
Language used throughout consent form should be at the level of local student of class?		
Correct response	172	49.1
Incorrect response	177	50.9
An informed consent is mandatory for?		
Correct response	247	70.6
Incorrect response	103	29.4
Introduction of ICD should contain?		
Correct response	249	71.1
Incorrect response	101	28.9
While explaining the purpose of research the researcher must use which language?		
Correct response	267	76.3
Incorrect response	83	23.7
At what stage of consent process should the intervention to be undertaken be stated?		
Correct response	253	72.3
Incorrect response	97	27.7
Is it necessary to explain why individual is chosen for research?		
Yes	258	73.7
No/Don't know	92	26.3
A participant can withdraw anytime even after giving valid informed consent?		
Yes	239	68.3
No/Don't know	111	31.7
Duration of research and follow up must be stated?		
Correct response	261	74.6
Incorrect response	89	25.4
Explanation about the research should include both risks and benefit?		
Correct response	294	84
Incorrect response	56	16
Assent is an agreement to participate in research given by a person aged?		
Correct response	140	40
Incorrect response	210	60
For physically and mentally incapable participants, consent can be taken from?		
Correct response	279	79.7
Incorrect response	71	20.3
ICD contains information regarding compensation for research related injury/harm?		
Yes	214	61.1
No/Don't know	136	38.9
Confidentiality of data must be maintained for all types of research?		
Yes	240	68.6
No/Don't know	110	31.4
Is it mandatory to provide name and contact details of researcher in ICD?		
Correct response	226	64.6
Incorrect response	124	35.4
The EC may grant consent waiver in which situation?		
Correct response	256	73.1
Incorrect response	94	26.9
Which part of the ICD must be handed over to participant?		
Correct response	167	47.7
Incorrect response	183	52.3

Table 2: Practices regarding informed consent process (n=148).

Questions	Frequency	Percentage
Have you ever involved in any research work?		
Yes	148	42.3
No	202	57.7
If yes, have you taken informed consent?		
Yes	148	100
No	0	0
Did you explain to the participant that they are taking part in research?		
Yes	134	90.5
No	14	9.5
Did you explain informed consent to the participant in their local language?		
Yes	126	85.1
No	22	14.9
Did you hand over the PIS to the participants?		
Yes	86	58.1
No	62	41.9
Did you explain to the participant about publication of research results in public domain?		
Yes	102	68.9
No	46	31.1

Table 3: Association between knowledge regarding informed consent process with some socio-demographic variables.

Variables	Knowledge regarding informed consent process		P value
	Good (score ≥13) n (%)	Poor (score <13) n (%)	
Age (completed years)			
≤ 28	126 (57.5)	93 (42.5)	0.455
> 28	70 (53.4)	61 (46.6)	
Gender			
Male	99 (53.5)	86 (46.5)	0.321
Female	97 (58.8)	68 (41.2)	
Department			
Pre and para clinical	32 (76.2)	10 (23.8)	0.005
Medicine and allied	71 (48.3)	76 (51.7)	
Surgery and allied	93 (57.8)	68 (42.2)	
Designation			
Internees	48 (53.9)	41 (46.1)	0.175
Non-academic JRs	41 (57.7)	30 (42.3)	
PGTs	107 (56.3)	83 (43.7)	

More than half of the participants were post graduate trainees (54.3%) followed by internees (25.4%) and non-academic junior residents (20.3%).

Only half of the participants (50.9%) knew that informed consent comes under the ethical principle of autonomy while majority (60.3%) were not aware of how many parts the informed consent document has. Only 26.3% of them know the parts of ICD and less than half of them (49.1%) knew which level of language should be used in the consent form. Around 70% of the participants knew that informed consent is mandatory for all types of study involving human participants. When ask about what should be included in the ICD, majority of the participants (71.1%) gave the correct response i.e. it should include a brief about researcher, should explain the purpose of the research and should give time for asking questions to the participants. Most of the participants (76.3%) knew that local language and simplified words should be used while explaining the purpose of the research to the participants and 72.3% of them knew that type of research intervention to be undertaken must be stated at the beginning of the consent. Majority of the participants (73.7%) knew that it is necessary to explain why the participants were chosen for research and 68.3% of them knew that they can withdraw anytime from the research even after giving valid informed consent. Most of them (74.6%) knew that

duration of the research and follow up must be stated in the ICD and four-fifth of the participants knew that both risk and benefits of the research should be explained in ICD. Majority of the participants (60%) didn't know that assent is an agreement given by participants 7-18 years to participate in research while 79.7% of them knew that consent should be taken from legally authorized representative (LAR)/parents for those participants who are physically or mentally incapable of giving consent. Most of them (61.1%) knew that ICD contains information regarding compensation for research related injury/harm and 68.6% of them knew that confidentiality of data must be maintained for all types of research. Two-third of the participants (64.6%) knew that it is mandatory to provide name and contact details of researcher in the ICD and 73.1% of them knew in which situation ethics committee may grant consent waiver while only 47.7% of the participants knew that Participant Information Sheet (PIS) must be handed over to participant as shown in Table 1.

Among the participants, only 42.3% were ever involved in any research work. Out of them, 90.5% explained to the participants that they are taking part in research and 85.1% of them explained the informed consent in their local language. Among them, 68.9% of them explained to the participants about publication of research results in public domain as shown in Table 2.

Table 4: Association between practices regarding informed consent process with some socio-demographic variables.

Variables	Practices regarding informed consent		P value
	Good (score ≥3) n (%)	Poor (score <3) n (%)	
Age group (completed years)			
≤28	90 (94.7)	5 (5.3)	0.513
>28	51 (96.2)	2 (3.8)	
Department			
Pre and para clinical	18 (90)	2 (10)	0.430
Medicine and allied	65 (97)	2 (3)	
Surgery and allied	58 (95.1)	3 (4.9)	
Designation			
Internees	39 (97.5)	1 (2.5)	0.779
Non-academic JRs	31 (93.9)	2 (6.1)	
PGTs	71 (94.7)	4 (5.3)	

Regarding association between knowledge regarding informed consent process and some socio-demographic variables, participants posted in pre and para clinical departments have significantly higher level of knowledge ($p<0.05$). Age, gender and designation were not found to be statistically associated with level of knowledge as shown in Table 3.

Table 4 shows association between practices regarding informed consent process with some socio-demographic variables.

DISCUSSION

Junior doctors are the backbone of medical research in India, and hence it is essential to ensure that their knowledge and practices regarding informed consent process is sound which can ensure adequate ethical practices. This study was mainly focused toward junior resident doctors which comprise of the internees, non-academic junior residents and post graduate trainees to assess their level of knowledge and the practices followed by them as they are involved in medical research.

In our study, majority of the participants (70.6%) responded that informed consent is mandatory for both observational and experimental studies. Similar findings were seen in a study conducted by Vyas et al where (73%) of the participants responded that informed consent is mandatory for all types of research.[15] Most of the participants knew that informed consent should include both risks and benefits of the study (84%) and is supported by a study conducted by Demour et al where (88%) of participants were aware that informed consent should explain both risk and benefit of the research.[16] Every research involved some risks and probabilities of harm involved and therefore protection of participants should be inculcated into the design of the study.[17]

Most of the participants (74.6%) knew that duration of the study must be stated in the informed consent document (ICD). Similar findings can be seen in a study conducted in Mumbai.[15] In our study, a lower level of knowledge (68.3%) was found regarding patient's right to withdraw from the research anytime even after giving informed consent and similar findings can be seen in a research conducted by Demour et al.[16]

Only 61% of the participants knew that ICD should contain information regarding compensation for research related injury or harm which is in contrast to study conducted by Demour et al, where majority (86%) of the participants knew that patient should be informed about compensation policy in case of injury or harm.[16] This may

be because less than half of our study participants were involved in the research work.

In our study, majority of the participants (76.3%) knew that they informed consent must be in a language that can be easily understandable by the participants to overcome language barrier which is supported by a study conducted by Mandal et al in Kolkata.[18] In our study, only 42.3% of the participants were ever involved in research work and all of them who were involved in research have taken informed consent from the participants.

Out of those participants who have taken informed consent, most of them (90.5%) explained to the participants that they are taking part in a research study and 85.1% of them explained the informed consent to the participants in local language. Similar findings can be seen in a study conducted by Vyas et al.[15]

The study was limited to only one medical college and tertiary care institution in the state and included only junior doctors however the study gave an insight to the knowledge and practice of informed consent process among junior doctors.

CONCLUSION

A little more than half of the participants have good knowledge, out of which non-academic junior residents have higher knowledge as compared to other junior doctors and less than half of the participants were ever involved in research work, out of which majority have good practice. Participants posted currently in pre and para clinical departments have significantly higher level of knowledge as compared to those participants in other departments. Hence from this study, it can be concluded that, the junior resident doctors have low knowledge about informed consent process and also have low practice level. There is a need to organise seminars and workshops by the concerned authority on the informed consent process and also researchers to conduct more research on informed consent process covering more institutions.

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REFERENCES

1. Normile D. The promise and pitfalls of clinical trials overseas. Science. 2008;322(5899):214-6.
2. World Health Organization. Declaration of Helsinki-Ethical principles for medical research involving human subjects. 59th WMA General Assembly. Seoul, Republic of Korea; 2008.
3. Council for International Organizations of Medical Sciences C. International Ethical Guidelines for Biomedical Research Involving Human Subjects. Geneva, Switzerland: Council for International Organizations of Medical Sciences; 2002.
4. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Bethesda, Md.: The Commission; 1978.
5. World Health Organization. Operational Guidelines for Ethics Committees that Review Biomedical Research. Geneva: WHO Special Programme for Research and Training in Tropical Diseases (TDR); 2000.
6. Zimmerman C, Watts C. WHO ethical and safety recommendations for interviewing trafficked women. Geneva: World Health Organization; 2003.
7. Grodin MA, Annas GJ. Legacies of Nuremberg: medical ethics and human rights. JAMA. 1996;276(20):1682-3.
8. Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? JAMA. 2000;283:2701-11.
9. Indian Council of Medical Research. National Ethical Guidelines for Biomedical and Health Research involving Human participants. New Delhi, 2017. Available from: https://ethics.ncdirindia.org/asset/pdf/ICMR_National_Ethical_Guidelines.pdf. Accessed on 2 October 2023.
10. Lavori PW, Sugarman J, Hays MT, Feussner JR. Improving informed consent in clinical trials: a duty to experiment. Control Clin Trials 1993;20:187-93.
11. Howard JM, DeMets D. How informed is informed consent: the BHAT experience. Control Clin Trials 1981;2:287-303.
12. Kim L, Young AJ, Neimeyer RA, Baker JN, Barfield RC. Keeping users at the center: Developing a multimedia interface for informed consent. Tech Commun Quart. 2008;17(3):335-57.
13. European Medicines Agency. ICH Topic E 6 (R1): Guideline for Good Clinical Practice. London: European Medicines Agency Press; 2006.
14. Saritha SR, Sreedevi CS. Informed consent in clinical practice and research and its awareness among under graduate medical students. Indian J Forens Med Toxicol. 2020;14(1):50-5.
15. Vyas N, Jadhav P, Sane R. Knowledge, attitude and practices regarding informed consent for research purposes among postgraduate resident doctors. Nat J Physiol Pharm Pharmacol. 2020;10(01):54-8.
16. Demour SA, Alzoubi KH, Alabsi A, Abdallat SA, Alzayed A. Knowledge, awareness, and attitudes about research ethics committees and informed consent among resident doctors. Int J Gen Med. 2019;12:141-5.

17. Raj GM, Priyadarshini R. The new Indian ethical guidelines for biomedical and health research-delving new vistas. J Pharmacol Pharmacother. 2018;9:56.
18. Mandal S, Naser SM, Das S, Karmakar A, Nahar N, Banu P. Knowledge, attitude and practice regarding informed consent in medical research among resident doctors of a medical college of eastern India. Ann Int Med Den Res. 2019;5(4):PC09-11.

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