

Human research ethics among postgraduate medical students in a medical college of south India

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ABSTRACT:

Background – Medical ethics deals with the moral values and judgment in the practice of medicine. Medical research is happening vigorously in many developing countries in the present scenario, because of the need to improve healthcare. As medical research involves human participants, it has to be guided by fundamental ethical principles to ensure the protection of their rights and welfare. There are very few medical colleges in India with a standardised ethics curriculum, and with provisions for evaluation. This study was done to assess the knowledge, attitude and practices of Medical postgraduate students regarding research ethics.

Methods - A one year Cross Sectional Study was done among 154 Postgraduate MD and MS students of medical college. An online questionnaire consisting of questions related to knowledge and attitude towards principles and practice of ethics in clinical research, informed consent, and role of the ethical committee in the institution was given to those who gave consent to participate in the study.

Results The Mean \pm SD score for Knowledge questions was $8.49 \pm 1.65(11)$ with a min and max score of (2,11). The Mean \pm SD score for attitude questions was $7.35 \pm 1.78(10)$ with a min and max score of (0,10). The Mean \pm SD score for practice questions was $14.01 \pm 2.75(18)$ with a min and max score of (1,18)

Conclusion

Integrating comprehensive ethics education into the curriculum, addressing specific concerns through targeted training programs, and providing mentorship opportunities are needed. Apart from these, efforts in development of national regulations and guidelines, establishment of relevant national bodies, capacity building, and accreditation system are required. At the institutional level necessary structured process and independence of ethical committees is required.

Introduction

The work that health professionals do is of great importance to society because it impacts the health security, and well-being of those served. Research ethics in its broadest definition encompasses the principles, standards, norms and guidelines that regulate scientific inquiry. Ethical considerations in medical research are paramount to ensuring the well-being and rights of human participants. Postgraduate medical students play a crucial role in advancing scientific knowledge, making it imperative for them to possess a strong foundation in human research ethics.

Understanding the principles and guidelines of human research ethics is fundamental for conducting ethically sound research. Postgraduate medical students need to be well-versed in concepts such as informed consent, confidentiality, and the protection of vulnerable

populations. Studies have shown that a comprehensive understanding of these ethical principles positively correlates with the quality of research conducted ¹.

Attitudes towards human research ethics can significantly influence the ethical conduct of research. Positive attitudes foster a culture of responsible research, emphasizing the importance of safeguarding the rights and well-being of participants. On the other hand, a lack of concern or negative attitudes may lead to ethical breaches.

The translation of knowledge and positive attitudes into ethical research practices is critical for upholding the integrity of the scientific community. Postgraduate medical students often encounter challenges in implementing ethical guidelines due to practical constraints and complex research scenarios.

The primary role of ethics in health research is to protect the rights, integrity, and safety of research participants ² Medical research has increased greatly in many developing countries during the recent decade, motivated by the need to improve health in these countries. Since medical research involves human participants, such research needs to be guided by fundamental ethical principles to ensure the protection of their rights and welfare.

Furthermore, international standards mandate the review of research work by research ethics committees. Healthcare ethics is not routinely taught to the medical professionals. Hence it is not surprising that the theory and application of healthcare ethics in day-to-day practice are still not well known to many healthcare providers ³ Another reason regarding less awareness is that students do not have much interest in learning about research ethics as they consider other subjects to be more important for qualifying for examinations ⁴

This study aims to investigate the knowledge, attitude, and practices of human research ethics among postgraduate medical students in a medical college of South India.

Methods

A cross-sectional study was conducted among postgraduate medical students (MD/MS) in their 1st, 2nd, and 3rd clinical years at a medical college in south India, who willingly agreed to take part in the research. An online questionnaire was developed based on our study objectives, drawing insights from existing literature on research ethics. The questionnaire encompassed inquiries pertaining to knowledge and attitudes regarding the principles and practices of ethics in clinical research, informed consent, and the role of the ethical committee within the institution.

The questionnaire was disseminated to all medical postgraduate students through their respective departments. Only those who provided consent to participate were included in the online study. Data collection was facilitated through an online questionnaire in the form of a Google Form. Subsequently, statistical analysis was performed using SPSS.

The Multiple choice questions consisted of 13 Knowledge questions, 10 Attitude and 12 Practice Questions. The correct answer for every question carried 1 mark, 0 (zero) otherwise. Total marks for all students were added. Mean, Standard deviation, Median, IQR, correlation were calculated.

Questionnaire

Knowledge of research ethics

1.Are you familiar with ethical principles that govern conducting research involving human subjects?

Agree

Disagree

Neutral

2. Are you completely aware of the functions of ethics committees?

Agree

Disagree

Neutral

3. Which of the following is/are the role of a research ethics committee according to you?
YES/NO

a. Reviewing the scientific content of the proposed research study

b. Reviewing the ethical aspects of the proposed research study

- c. Decide whether informed consent is needed
- d. Protection of rights and welfare of the participants in the research study
- e. Make research more difficult to perform
- f. Any others Specify -----

Case scenarios involving the ethics of clinical research

CASE 1 (Informed consent describing risks and benefits)

A Study was conducted on two surgical methods used for the treatment of a disease. An oral consent has been taken from the patients without full description of the risks and benefits. Which of the following best describes obligations of informed consent?

- (a) The investigators can conduct the research without written consent.
- (b) A written consent must be taken after describing the procedure briefly
- (c) complete description of the risks and benefits should be explained before taking informed consent.
- (d) There is no need for informed consent, as the patients were enrolled from the outpatient clinic

Case 2 (Research involving children).

Two techniques were evaluated among 50 children in age range of 6 to 15 years undergoing surgery and they were randomly allocated to one of two equal groups.

- (a) Details of the procedure should be explained to the child's parent/guardian thoroughly.
- (b) Assent should be taken from the children.
- (c) A written informed consent from the child's parent/guardian and assent from the child, both need to be taken
- (d) Assent / consent is not required as the children were registered in the outpatient clinic and available to receive any type of treatment.

Case 3 (Retrospective research on stored samples originally collected for clinical purposes).

Sixty patients from the outpatient clinic were diagnosed as having a certain disease. Biopsies were taken from the patients after their approval to confirm the clinical diagnosis (patients were not charged any money). A month later, a research is planned by the Faculty involving all biopsies that were previously obtained from the patients.

- (a) This study cannot be started without the approval from patients.
- (b) Patient approval is not required as, the biopsies belong to the faculty
- (c) Researchers have to decide whether to take the patient's consent or not.
- (d) Dean or head of the department has to decide what has to be done with the biopsies without patient's interference.

Case 4 (Confidentiality in medical research).

Eighty patients from the outpatient clinic were enrolled in a research. The aim of the research was to compare the effectiveness and safety of 2 doses of an experimental drug in the treatment of patients.

- (a) Case files of patients have to be coded to ensure confidentiality of the patient details.
- (b) Confidentiality is not required as the procedures are routine in practice.
- (c) Investigator has to decide about the confidentiality.
- (d) Head of the department has to decide regarding confidentiality.

Attitudes regarding Research Ethics Committee (REC) and research ethics education

Agree Disagree Neutral

(1) REC is required in each institution for ethical review of proposed research studies

(2) Ethical review of research studies is not required as there are scientific committees

(3) Research studies involving human subjects

must be reviewed by the REC

(4) Retrospective studies should be exempted for ethical consideration

(5) Ethical review of research will complicate the research process and it will be hard for the investigator

(6) Ethical review of research studies is mandatory only for international collaborative research

(7) Research ethics should be considered as a required module in postgraduate curriculum

(8) All researchers should have some training in research ethics

(9) Is it okay to fabricate data to improve outcome of research as long as there is no harm to the patients

(10) Are you aware of the composition of your institutional Research ethics committee (REC)

Practices regarding Research ethics

Your research study involves participants from vulnerable group. How will you take informed consent from them

1. Who are the individuals belonging to the vulnerable group

YES/NO

- a. Economically disadvantaged
- b. Racial and Ethnic minorities
- c. Children
- d. The elderly
- e. Those with human immunodeficiency virus (HIV)
- f. Those with other chronic health conditions
- g. Those with severe mental illness

2. Who should talk to the patient when taking consent for a clinical trial

- a. Treating doctor
- b. Researcher
- c. Nurse
- d. Family member

3. You will take informed consent in English only

YES/NO

4. You will take informed consent in local language also

5. You will give enough time for the study participant to understand the full details of research

6. You will inform them about their right to withdraw from study anytime

7. You will provide valid contact number to the participant to be contacted if needed

8. You will provide a copy of informed consent to study participant

9. You will give incentives for participation in your research study

10. You will provide for compensation for study related injury

11. You will take measures to protect confidentiality of participant details
12. Due to pandemic situation the process of submitting the research study proposal for ethical committee clearance and ethical committee meeting got delayed. Will you start your study before receiving ethical clearance?
YES/NO

Justify -----

Results

Scores obtained for knowledge, attitude and practice questions are mentioned in Tablular form (Table 1, 2 and 3) .The Mean \pm SD for Knowledge questions was $8.49 \pm 1.65(11)$ with a min and max score of (2 ,11). The Mean \pm SD for attitude questions was $7.35 \pm 1.78(10)$ with a min and max score of (0 ,10). The Mean \pm SD for practice questions was $14.01 \pm 2.75 (18)$ with a min and max score of (1,18) (TABLE 4)

The correlation between knowledge and attitude scores is as shown (Figure 1). Correlation between knowledge and practice scores (Figure 2). Correlation between attitude and practice scores (Figure 3).

TABLE 1 SCORE FOR KNOWLEDGE QUESTIONS

| KNOWLEDGE SCORES | | | |
|------------------|-----------|---------|--------------------|
| | Frequency | Percent | Cumulative Percent |
| 2 | 1 | 0.6 | 0.6 |
| 3 | 1 | 0.6 | 1.3 |
| 4 | 3 | 1.9 | 3.2 |
| 6 | 13 | 8.4 | 11.7 |
| 7 | 18 | 11.7 | 23.4 |
| 8 | 35 | 22.7 | 46.1 |
| 9 | 31 | 20.1 | 66.2 |
| 10 | 44 | 28.6 | 94.8 |
| 11 | 8 | 5.2 | 100 |
| Total | 154 | 100 | |

TABLE 2 SCORE FOR ATTITUDE QUESTIONS

| ATTITUDE SCORES | | | |
|-----------------|-----------|---------|--------------------|
| | Frequency | Percent | Cumulative Percent |
| 0 | 1 | 0.6 | 0.6 |
| 1 | 1 | 0.6 | 1.3 |
| 2 | 2 | 1.3 | 2.6 |
| 3 | 2 | 1.3 | 3.9 |
| 4 | 2 | 1.3 | 5.2 |
| 5 | 6 | 3.9 | 9.1 |
| 6 | 33 | 21.4 | 30.5 |
| 7 | 29 | 18.8 | 49.4 |
| 8 | 27 | 17.5 | 66.9 |
| 9 | 44 | 28.6 | 95.5 |
| 10 | 7 | 4.5 | 100 |
| Total | 154 | 100 | |

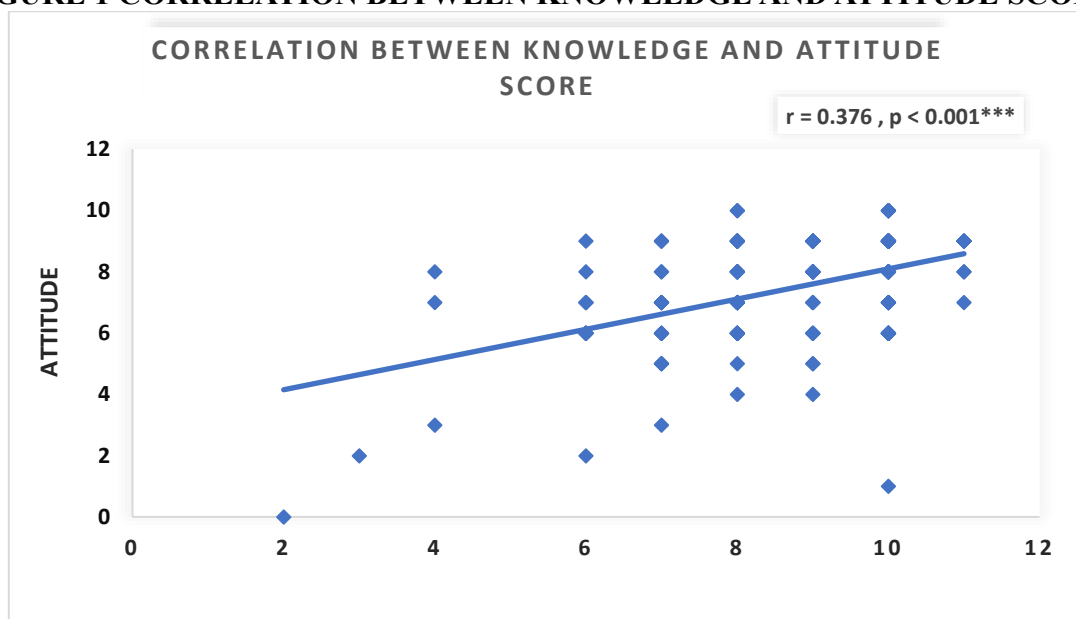
TABLE 3 SCORE FOR PRACTICE QUESTIONS

| PRACTICE SCORES | | | |
|-----------------|-----------|---------|--------------------|
| | Frequency | Percent | Cumulative Percent |
| 1 | 1 | 0.6 | 0.6 |
| 4 | 1 | 0.6 | 1.3 |
| 6 | 2 | 1.3 | 2.6 |
| 7 | 1 | 0.6 | 3.2 |
| 8 | 2 | 1.3 | 4.5 |
| 9 | 6 | 3.9 | 8.4 |
| 10 | 4 | 2.6 | 11 |
| 11 | 4 | 2.6 | 13.6 |
| 12 | 9 | 5.8 | 19.5 |
| 13 | 14 | 9.1 | 28.6 |
| 14 | 30 | 19.5 | 48.1 |
| 15 | 33 | 21.4 | 69.5 |
| 16 | 28 | 18.2 | 87.7 |
| 17 | 15 | 9.7 | 97.4 |
| 18 | 4 | 2.6 | 100 |
| | 154 | 100 | |

TABLE 4 SCORE SUMMARY

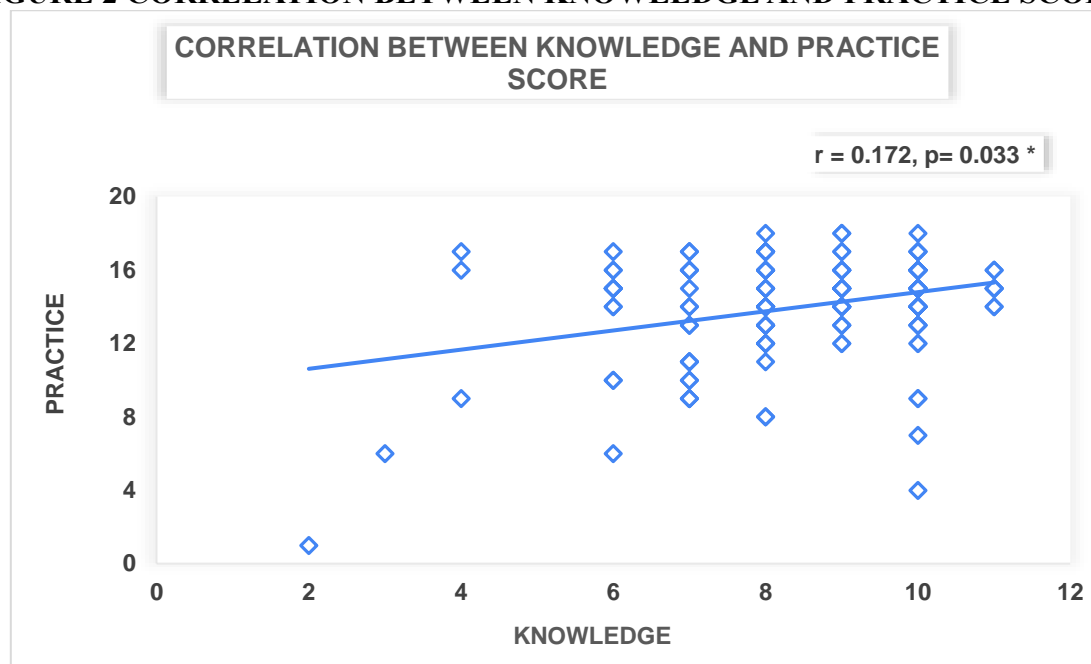
| | Mean \pm SD | Median (IQR) | (Min, Max) |
|-----------|------------------|--------------|------------|
| Knowledge | 8.49 \pm 1.65 | 9 (10 - 8) | (2 ,11) |
| Attitude | 7.35 \pm 1.78 | 8 (9 - 6) | (0 ,10) |
| Practice | 14.01 \pm 2.75 | 15 (16 - 13) | (1,18) |

FIGURE 1 CORRELATION BETWEEN KNOWLEDGE AND ATTITUDE SCORES



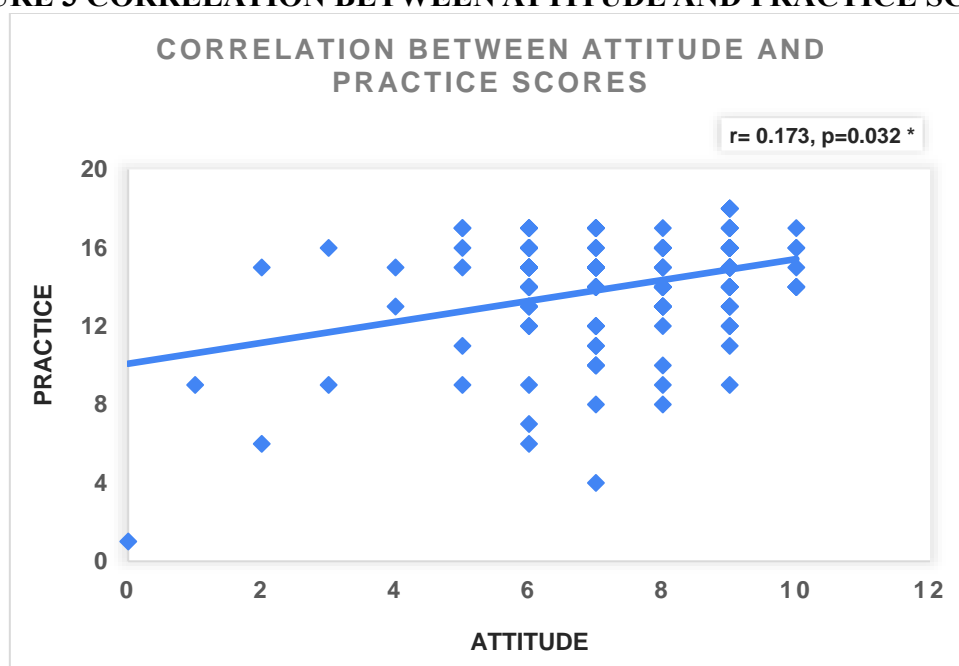
There was moderate positive correlation between Knowledge and Attitude scores with $p < 0.001^{***}$

FIGURE 2 CORRELATION BETWEEN KNOWLEDGE AND PRACTICE SCORES



There was weak positive correlation between Knowledge and Practice scores with $p = 0.033 *$

FIGURE 3 CORRELATION BETWEEN ATTITUDE AND PRACTICE SCORES



There was weak positive correlation between Attitude and Practice scores with $p = 0.032 *$

Discussion:

Knowledge Scores:

The majority of participants scored high on knowledge, with a cumulative percentage of 94.8% achieving a score of 8 or above out of 11. Questions covered a range of topics, including familiarity with ethical principles, awareness of the functions of ethics committees, and the review process for scientific and ethical aspects of research proposals. The knowledge regarding informed consent among PG resident doctors was found to be high, which was similar to the finding in a study done by Hussain et al⁵

Attitude Scores:

The attitude of the researcher is of utmost importance as a person might have enough knowledge but unwillingness to apply it, which may prove detrimental to the research study.

Attitude scores indicated a broad spectrum of responses, with a cumulative percentage of 95.5% scoring 8 or above out of 10. Participants expressed average attitudes toward various ethical considerations, such as the need for ethical review, the role of scientific committees, and the inclusion of research ethics in postgraduate curriculum.⁶

Practice Scores:

Practice scores exhibited a wide range of responses, with a cumulative percentage of 100% having scores ranging from 1 to 18 out of 18. Questions covered practices related to obtaining consent, considerations for vulnerable populations, language preferences for consent, and measures to protect participant confidentiality. The findings of this study reveal that there are gaps in the perceptions and practices of postgraduates regarding clinical ethics.⁷

Correlation Analysis:

Knowledge and Attitude: There was a moderate positive correlation between knowledge and attitude scores ($p < 0.001$ ***). This suggests that individuals with higher knowledge tend to exhibit more positive attitudes toward research ethics.

Knowledge and Practice: A weak positive correlation was observed between knowledge and practice scores ($p = 0.033^*$). While the correlation is weak, it indicates a tendency for those with higher knowledge to also demonstrate better ethical practices.

Attitude and Practice: Another weak positive correlation was found between attitude and practice scores ($p = 0.032^*$). This implies that individuals with positive attitudes may be more likely to engage in ethical research practices.

Although, assessment of knowledge and attitudes about clinical research among post graduate students showed positive results but discrepancies were observed in its practice.

Overall Implications:

The high knowledge and attitude scores suggest a strong foundation in ethical principles among participants. Weak correlations between knowledge/practice and attitude/practice indicate that while knowledge and attitude may influence ethical practices, other factors could play a role. The case studies add context to participants decision-making processes, providing a more comprehensive understanding of their ethical reasoning.

Limitations:

The study's generalizability may be limited to the specific population surveyed.

The self-reported nature of responses may introduce bias.

Further qualitative exploration could provide deeper insights into participants reasoning and decision-making.

Conclusion

Promoting a strong foundation in human research ethics among postgraduate medical students is essential for fostering a culture of responsible research. Integrating comprehensive ethics education into the curriculum, addressing specific concerns through targeted training programs, and providing mentorship opportunities are needed. Apart from these, efforts in development of national regulations and guidelines, establishment of relevant national bodies, capacity building, and accreditation system are required. At the institutional level necessary structured process and independence of ethical committees is required.

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