

## Knowledge of medical students on clinical trials

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### ABSTRACT

**Background:** Basic research can help medical school students improve critical thinking skills required by medical practice. In this era of evidence-based medicine, the combination of medical education with clinical research is the key to ensure scientific discoveries are translated into clinical practice. This study's objective was to know the awareness about clinical trials among undergraduate medical students.

**Methods:** After obtaining approval from the Institutional Ethics Committee of NRI Academy of Medical Sciences, Guntur, India, this cross sectional study was conducted in second year medical students after taking their consent. A sample of 90 was considered for statistical analysis. A structured questionnaire was used to measure the objective of this study, which had general, regulatory and ethical questions related to clinical trials. Qualitative data variables were expressed by using frequency and Percentage (%).

**Results:** Out of 90 students, it was observed that in the general questions category, 70% of students were aware of the purpose of conducting clinical trials, 50% were aware of the pre-requisites for a participant before participating in a clinical trial and 50% were aware of the parameters evaluated in a clinical trial. 95% of students did not know the response for regulatory questions. The students' awareness regarding ethics related to clinical trials was better than the other two categories.

**Conclusions:** The overall awareness of clinical trials was low among students though they demonstrated good awareness regarding few aspects of clinical trials.

**Keywords:** Clinical trials, Knowledge, Undergraduate medical students

### INTRODUCTION

Basic research can help undergraduate medical students improve critical thinking skills required for medical practice. In this era of evidence-based medicine, the combination of medical education with clinical research is the key to ensure scientific discoveries are translated into clinical practice. Training medical students in clinical research could also lead some to consider career paths that include research, which is the need of the hour. India is one of the Asian countries doing excellent academic progress.<sup>1</sup> Thomson Reuters predicts that the research productivity of India will match most G8 nations.<sup>2</sup> Nonetheless, the situation of clinical research in India is fast improving and more medical, paramedical and science graduates are

enrolling for clinical research training.<sup>3,4</sup> This study's objective was to know the awareness about clinical trials among undergraduate medical students.

### METHODS

#### *Study design and study site*

After obtaining approval from the Institutional Ethics Committee of NRI Medical College, Guntur, India, this cross sectional study was conducted in second year medical students during month of January 2019. The participants of this study were interviewed by a pre-tested questionnaire after taking their consent.

**Sample size**

A sample size of 100 was taken for this study, as the aim of the study was to assess only the knowledge of clinical trials among medical students. Initially 10 randomly picked students were given the questionnaire for the purpose of validation. Three experienced professionals reviewed and validated the questions. After validation, the rest 90 students were given the questionnaire and were considered for statistical analysis.

**Outcome measures**

A structured questionnaire was used to measure the objective of this study, which had three sections of questions related to clinical trials (Annexure I). The first section had six general questions (G1-G6) related to clinical trials. The second section had five regulatory questions (R1-R5) and the third section consisted of three ethical questions (E1-E3). The participants were given enough time to provide their responses. The responses were later marked as correct, incorrect and No response. Only descriptive questions were included in the questionnaire to avoid bias and to assess the basic knowledge of the students in clinical trials.

**Statistical analysis**

The data was collected, compiled and compared by frequency distribution and percentage proportion. Qualitative data variables were expressed by using frequency and Percentage (%). Data analysis was performed by using SPSS Version 25.0 (Chicago, SPSS Inc.).

This was only a questionnaire-based study and did not include any experimentation. None received any benefits for personal or professional use from a commercial party directly or indirectly to the subject of this study.

**RESULTS**

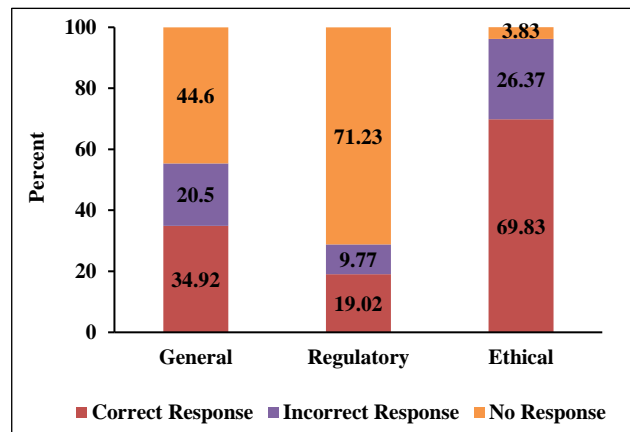
Out of 90 students, it was observed that in the general question’s category, 70% of students were aware of the purpose of conducting clinical trials, 50% were aware of the pre-requisites for a participant before participating in a clinical trial and 50% were aware of the parameters evaluated in a clinical trial. However, majority of students gave incorrect responses or did not know the response to other questions (G3, G4 and G6) in general category. Regarding regulatory questions related to clinical trials, 95% of students did not know the response for R1 and R2. However, 60 % of students knew that AV consent is mandatory for clinical trials. The students’ awareness regarding ethics related to clinical trials was better than the other two categories of questions as seen in Table 1.

Regarding the overall responses for questions regarding the general concept of clinical trials, 35.73% gave correct responses, 20.85% gave incorrect responses and 43.35%

did not give any response. Regarding the regulatory questions of clinical trials, 18.91 % gave correct responses, 10.33% gave incorrect responses and 70.74% did not give any response. Regarding the ethical questions of clinical trials, 70% gave correct responses, 26.3% gave incorrect responses and 3.7% did not give any response as seen in Figure 1.

**Table 1: Percentage of responses to individual questions.**

	Correct Response N (%)	Incorrect Response N (%)	No Response N (%)
G1	63 (70)	21 (23.3)	6 (6.7)
G2	45 (50)	26 (28.9)	19 (21.1)
G3	19 (21.1)	20 (22.2)	51 (56.7)
G4	10 (11.1)	19 (21.1)	61 (67.8)
G5	45 (50)	3 (2.9)	42 (46.7)
G6	11 (12.2)	24 (26.7)	55 (61.1)
R1	1 (1.1)	1 (1.1)	88 (97.8)
R2	1 (1.1)	4 (4.4)	85 (94.4)
R3	54 (60)	10 (11.1)	26 (28.9)
R4	3 (3.3)	6 (6.7)	81 (90)
R5	11 (12.2)	16 (17.8)	63 (70)
E1	83 (92.2)	2 (2.2)	5 (5.6)
E2	69 (76.7)	20 (22.2)	1 (1.1)
E3	37 (41.1)	49 (54.4)	4 (4.4)



**Figure 1: Percentage of overall responses for different categories of questions.**

**DISCUSSION**

The present study aimed to know the level of awareness about the basic concepts of the clinical trials among the medical students. Medical research among the undergraduate students is displeasing compared to developed countries. The overall awareness of clinical trials is low among the medical students in this study. Similar results were found in earlier studies done by Sharma et al, among the medical students in India. It has been observed that similar results were found in other

countries globally.<sup>5</sup> A study conducted in Pakistan showed poor participation of doctors in clinical research.<sup>6</sup> One of the reasons why students are less involved in clinical research may be poor knowledge and interest in research.<sup>7</sup> The other reasons are cumbersome paperwork and time constraints.<sup>8,9</sup>

Research has not become a compulsory part of India's undergraduate medical education curriculum so far. In Germany, where research is an integral part of the undergraduate medical curriculum; 28% of the publications in a particular institution involved undergraduate medical students.<sup>10</sup> A study reported that 23% of undergraduate students in a European country, Croatia, participated in research projects.<sup>11</sup>

Authors recognize this study's multiple limitations. First, our study was based on the convenience sampling method, including only 100 undergraduate students. Second, only one medical college was involved in this study, further limiting the generalization of our findings. Third, questions, which reflected a wide range of topics, could not be included in research on the knowledge aspect of undergraduate students. To bring medical education and quality research at par, the medical teaching curriculum needs to incentivize quality research, which is an indicator of an institute's quality of education and clinical care. Moreover, there is encouragement from many government bodies for the conductance of undergraduate research, for which they grant funds.

In this context, The Indian Council of Medical Research (ICMR) has been rolling the Short Term Studentship (STS) Program from 1979 in order to promote interest and aptitude for research among medical undergraduates.<sup>12</sup> To promote research, the Medical Council of India (MCI) has included Clinical research and Ethics in the undergraduate teaching curriculum for medical students from the year 2019.<sup>13,14</sup>

## CONCLUSION

The overall awareness of clinical trials was low though demonstrated a fairly good awareness regarding few aspects of clinical trials. Good research contributes to evidence - based medicine, thus improving and enhancing patient care with the ultimate goal of health promotion. However, little is being done to improve the clinical research awareness and training in medical undergraduates. Therefore, formal training to prepare the future physicians for careers as investigators and create a research environment to promote good research. This contributes to evidence-based medicine, thus improving and enhancing patient care with the ultimate goal of health promotion.

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## REFERENCES

1. Elsevier BV. Bibliometric study of India's scientific publication outputs during 2001-2010. Study commissioned by Department of Science and Technology- NSTMIS, India; 2012.
2. India ranked 6<sup>th</sup> in global research output in 2013 - The Economic Times. Available at: <https://economictimes.indiatimes.com/news/science/india-ranked-6th-in-global-research-output-in-2013/articleshow/50076643.cms?from=mdr>. (Accessed on 4<sup>th</sup> June 2019).
3. Dhodi DK, Thakkar KB, Billa G, Khobragade AA, Sinha SR, Patel SB. Knowledge, attitude and practices of medical students and teachers towards clinical research in a tertiary care hospital in Mumbai-cross sectional survey. *J Contemp Med Edu.* 2013;1(4):238-44.
4. Kurdi MS, Ramaswamy AH. Current scenario of clinical research exposure and practice in developing countries including India. *Indian J Clin Anaesth.* 2016;3(3):325-8.
5. Sharma KH, Jindal A. Low awareness of clinical research in India amongst final year medical students and physicians: Need for increased emphasis on clinical research in medical curriculum. *Arch Med Health Sci.* 2014 Jul 1;2(2):234.
6. Sabzwari S, Kauser S, Khuwaja AK. Experiences, attitudes and barriers towards research amongst junior faculty of Pakistani medical universities. *BMC Med Educ.* 2009;9:68.
7. Ibrahim Abushouk A, Nazmy Hatata A, Mahmoud Omran I, Mahmoud Youniss M, Faye Elmansy K, Gad Meawad A. Attitudes and perceived barriers among medical students towards clinical research: A cross-sectional study in an Egyptian medical school. *J Biomed Edu.* 2016;2016.
8. Ito-Ihara T, Hong JH, Kim OJ, Sumi E, Kim SY, Tanaka S, et al. An international survey of physicians regarding clinical trials: a comparison between Kyoto University Hospital and Seoul National University Hospital. *BMC Med Res Methodol.* 2013 Dec;13(1):130.
9. Vittalrao AM, Kumari M, Kumari KS, Gill R, Thomson SR. A questionnaire survey on awareness of clinical trials among medical students. *Biomed Pharmacol J.* 2018 Dec 25;11(4):2005-9.
10. Cursiefen C, Altunbas A. Contribution of medical student research to the Medline<sup>TM</sup>-indexed publications of a German medical faculty. *Med Edu.* 1998 Jul;32(4):439-40.
11. Kolèiæ I, Polašek O, Mihalj H, Gombaè E, Kraljeviæ V, Kraljeviæ I, et al. Research involvement, specialty choice, and emigration preferences of final year

- medical students in Croatia. *Croat Med J*. 2005;46(1):88-95.
12. Indian Council of Medical Research | Government of India. Available at: <https://www.icmr.nic.in/>. (Accessed: 13th April 2019)
  13. Competency based undergraduate curriculum for the Indian medical graduate. *Mciindia.org*. 2018. Available at: <https://www.mciindia.org/CMS/wp-content/uploads/2019/01/UG-Curriculum-Vol-I.pdf>
  14. Ananthakrishnan N. Competency based undergraduate curriculum for the Indian Medical

Graduate, the new MCI curricular document: Positives and areas of concern. *SBV J Basic Clin Applied Health Sci*. 2018 Dec 29;2(4):184-92.

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**ANNEXURE I**

<b>General questions related to clinical trials</b>	
G1	What is the main purpose of conducting Clinical Trials?
G2	What are the pre-requisites for a participant before participating in a Clinical Trial?
G3	What are the different types of Clinical Trials?
G4	What do you mean by pre-clinical and clinical studies?
G5	What parameters of a drug are evaluated during a Clinical Trial?
G6	In which phase of a Clinical Trial is post-marketing surveillance done?
<b>Regulatory questions related to clinical trials</b>	
R1	What is ICH-GCP?
R2	What are the Underlying Principles of GCP?
R3	As per guidelines, is AV recording mandatory for Clinical Trials?
R4	What does DCG(I) stand for?
R5	What is the role of USFDA in approving new drugs?
<b>Ethical questions related to clinical trials</b>	
E1	What is Placebo?
E2	Is there any risk involved for the participant in a Clinical Trial?
E3	Will the participant be paid money to participate in a Clinical Trial?