

## A Questionnaire Survey on awareness of Clinical Trials Among Medical Students

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There is an immense need to inculcate research in the medical curriculum of undergraduate medical students, which will help them to interpret the evidence based literature like journal articles, analyze, interpret & to help their decision making ability. Involvement in innovative research will help them develop a holistic attitude towards the patients especially in terms of informed consent and ethical decisions. This study a questionnaire survey was conducted on undergraduate medical students. It consists of statements spread over various aspects of clinical trials. The percentage of questions answered correctly in each group was graded as good, average and poor depending on scores. A total of 257 students participated in the study. Students had average knowledge about statements describing concept, need of clinical trial, participation, about Food and Drug Administration, informed consent had average knowledge. The response was poor for statements on Institutional Review Board (IRB) and Drug Controller General of India (DCGI). The medical undergraduates are future innovators, clinicians and scientific explorers. It would be better if they are trained at earlier days of learning about clinical trials/research and medical ethics these can be made a part of medical curriculum so that they can build their concrete future.

**Keywords:** Clinical trial, Undergraduate, Awareness, Research.

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Clinical trials render an important role in timely improvement of quality of healthcare practice<sup>1</sup>. It helps us to find a safe and effective treatment<sup>2</sup>. Good clinical practice guidelines are the backbone for the conductance of these trials. These guidelines help in ensuring the wellbeing & safety of the participants<sup>3</sup>

Most of the teaching medical institutions are involved in clinical trials. The clinicians serve as principle investigator to many trials. Some highly

interested medical students at least observe how these trials are conducted. Undergraduate medical students are also taught in the pharmacology curriculum about the different phases of clinical trials in brief, the process of conducting a trial and administration of informed consent to the patient. As there is encouragement from many government bodies for the conductance of undergraduate research, for which they are funded. There are only a small number of GCP trained physicians who

are involved as investigators<sup>4</sup>. In the present era undergraduate research is off importance, hence a greater number of medical students are taking up research<sup>5</sup>. There is a need for these future investigators to be trained in the basic research methodology and the ethics involving medical research, as some of the students may pursue a career in clinical trials and some of them may be a part of clinical trials also.

This study was planned to know the awareness about clinical trials among undergraduate medical students.

#### **Aim**

1. To know the awareness of clinical trials amongst the undergraduate medical students in India.
2. To ascertain their interest in being involved in clinical trials and research studies.

#### **MATERIAL AND METHODS**

This was a questionnaire based study<sup>6</sup> After obtaining University ethics committee approval, it was conducted at Kasturba Medical College, Manipal. The questionnaire was administered to medical students from second year to final year including interns. Experienced professionals involved in clinical trials reviewed and validated the questions. A pilot study was done to examine and validate the study protocol tool for readability and the ease of understanding.

There was voluntary participation by the students. The questionnaire was administered in English which was the medium of instruction. The questionnaire was divided into three parts; part one contained demographic profiles, the second part was a general statement regarding the status of the participant as a student, research scholar or postgraduate and the third part contained 14 main statements with many sub statements. To understand the knowledge in depth and to avoid bias, certain statements were deliberately reframed as negative questions. The students who were enrolled in the study, were the ones who had a pharmacology background.

The answered questions were rewarded as follows: A. Positive or Negative questions answered correctly - +02 points. B. Positive or Negative questions answered incorrectly - +00 point. C. If the question had multiple positive or

negative answers; each option ticked correctly was rewarded +01 point

The percentage of questions which were answered correctly in each group was calculated and this was categorized to pre-fixed grades as follows; 80-100% as good, 50-80% as average and <50% as poor. The sample size was calculated by using the WHO epi info software. Statistical analysis-Descriptive statistical analysis was done by using SPSS version 16.

#### **RESULTS**

A total of 257 students had participated in the study. Around 93.8 % of them had not involved in any of the clinical trials. Only 3.1% had been a part of a clinical trial. Majority of them were aware about what clinical trials are? Around 93.8% responded that there is a need for clinical trial research. The question whether clinical trials are the basic need for betterment of mankind and health status was responded yes by 85.6 %. A good number of students (79.8 %) wanted to participate in clinical trials, if any opportunities were given. Only 7% of students felt clinical trials are unethical, incorrect & purely inhuman. Around 47.9 % of students felt the incidence of benefits to the patient is more. Majority felt that conducting clinical trials is not a waste of time, manpower and money. (TABLE-1)

The response for the statement on concept of clinical trial 56.4 % were in average category & 27.2 % in good category. Around 54.9% were average responders, 23.3 % good & 21.8 were poor responders for the statement on need of clinical trials. Majority (65.8%) did not know where can people find about clinical trials. The statement on participation in clinical research study had 44% responders in average category & 38.5 % in poor category. The awareness about preclinical & clinical testing had 52.1 % average responders in comparison to 29.2 % poor responders. Majority around 51.4 % did not know about Institutional Review Board & its purpose. The role of USFDA in approving new drugs had an average response of 50.6% in comparison to 38.1 % poor responders. Around 41.6 % were poor responders for the statement on the role of DCGI in India in comparison to 28.8% good responders. Regarding the knowledge of the informed consent form 41.6

% were average responders, 31.9 % were good responders & 26.5 % poor responders.

The statement on potential benefits of participating in clinical trials had an average response of 44.7%, good response of 39.7 % and poor response of 15.6%. There was an average response of 53.7%, poor response of 33.9% and good response of 12.5 % for the statement on possible risks associated with clinical trials. The statement on leaving a research study had a good response of 46.7 %, average 31.9 % and poor 21.4 %. Regarding the statement on knowing the results of a clinical research study, majority were poor responders (50.2 %), 33.1 % average and 16.7% were good responders.

The statement on design of a study & the knowledge about sponsors showed average response of 47.9 %, poor response of 32.3 % & 47.5% in both groups & good responses of 19.8 % in Design of a study & 20.2 % about the knowledge of sponsors. There was an average response of 47.9 %, poor response of 27.6% and a good response of 24.5 % for the statement on adverse reactions. (TABLE 2)

## DISCUSSION

In the present study we wanted to know the awareness about clinical trials. Most of the questions have shown an average response. As many of the students take at least one research project of short term duration funded by our medical college and few funded by ICMR. Students have presented their research work at National and International level, which boosts them to conduct more research. They are governed by the student

**Table 1.**

Questions	Not involved	Been part	Involved
Status	93.8	3.1	3.1
Questions	Yes	No	Don't know
Aware	85.6	10.5	3.9
Any Need	93.8	1.2	5.1
Betterment	85.6	3.5	10.9
Participate	79.8	8.9	11.3
Unethical	7.0	79.8	13.2
Harmful	16	47.9	36.2
Conducting	5.1	86.4	8.6

research forum of our college. There is also a student wing of medical ethics, where seminars on ethics are presented by the students. This could be the reason for their better awareness about clinical trials.

There is no organized structure in medical education regarding student's participation in clinical research. The early involvement of undergraduate students in research will help them to make evidence based decisions for their future practice. One of the reasons for less involvement of students in clinical research could be poor research knowledge and interest<sup>5</sup>

Due to time constraints of the physician, the undergraduate medical students prove to be a good population to assist the clinician investigators for conductance of trials and for documentation. We should develop a mandatory course on GCP and research ethics for every medical student. As recent reports have stated lack of knowledge of ethics & GCP guidelines for management of clinical trials among investigators<sup>7</sup>. Abundant information and educational material related to clinical trials should be provided through seminars, classes, pamphlets as well as educational websites<sup>8</sup>. The low rates of participation of clinicians in clinical trials suggests that more attention should be given to enhance research experience of medical students, interns to increase their involvement in clinical trials<sup>9</sup>

**Table 2.**

Questions	Good	Average	Poor
Concept of clinical trial	27.2	56.4	16.3
Need of trial	23.3	54.9	21.8
Where to Find	33.9	4	65.8
Participation in research	17.5	44	38.5
Pre clinical testing	18.7	52.1	29.2
IRB	10.9	37.7	51.4
US_FDA role	11.3	50.6	38.1
DCGI role	28.8	29.6	41.6
Informed consent	31.9	41.6	26.5
Potential benefits	39.7	44.7	15.6
Potential risks	12.5	53.7	33.9
Leaving a research study	46.7	31.9	21.4
CRS results	16.7	33.1	50.2
Design of study	19.8	47.9	32.3
Sponsors	20.2	47.5	32.3
Side effects	24.5	47.9	27.6

Percentage (%) of response for each category of questions

Clinical trial training conducted in an efficient manner will help to tide over issues regarding the credibility of clinical research being done in India, which has cropped up in recent times<sup>10</sup>. As per Chatterjee<sup>11</sup> only 10.9% students were aware of the existence of an Institutional ethics committee and 42.8% did not know its exact role. The Institutional ethics committee should publish reports related to its involvement in different health –related activities within the institution & these should be circulated among students as well<sup>11</sup>. Divya Goel has suggested clinical research education should be part of undergraduate pharmacology curriculum. Students should be given small projects.

Regarding concept of clinical trial and knowledge about clinical trial is similar to a study done by Kamal H Sharma<sup>12</sup> *et al.* This could be due to various terms and types of clinical trials are partly covered in undergraduate pharmacology. If students are involved in research, it will help them to develop skills like literature search, collecting and analyzing data. To boost undergraduate research involvement, strategies like elective assignments can be given, to include student sections in journals, holding workshops and organizing student conferences<sup>13</sup> Many undergraduate students participate in research so that it will help them to join residency programs<sup>14</sup>

One of the barriers for initiating clinical studies is cumbersome paperwork and time constraints<sup>8</sup> According to Supriyo Choudhury *et al* observed 90% of doctors wanted clinical trial training to be incorporated in the undergraduate curriculum. If there is a structured training for doctors in clinical trials, there would be a level of uniformity throughout country. In our study around 47.9% had an average response towards the knowledge about side effects and adverse reactions. This could be due to the sensitization about pharmacovigilance in the undergraduate curriculum<sup>15</sup>

In comparison to a similar study done on pharmacy students on awareness of clinical trials the medical students knowledge was better .This could be due to larger sample size in the present study<sup>6</sup>

As some percent of medical undergraduates may be future investigators. Hence they need to be trained in their study period about clinical research

and medical ethics. As UM Thatte<sup>16</sup> has suggested to conduct clinical trials one need to have sound knowledge about basic principles of clinical research, ethical and regulatory requirements and good clinical practices<sup>17</sup>.

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