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Physician's participation in clinical research – a questionnaire study

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Abstract

Introduction. For a physician, participation in research is very important. It is estimated that 20–30% of global clinical trials are being conducted in developing countries and expanding rapidly due to better accessibility of abundant, diverse group of population, rich manpower, periodical amendments and implementation of rules by regulatory authorities.

Objective. The aim of the study was to elucidate the current knowledge of undergraduate and postgraduate medical students in clinical research.

Materials and method. This descriptive cross-sectional study was conducted at two medical institutes of Punjab in India. The study population comprised of 1st, 2nd, 3rd and 4th year students, interns and postgraduate medical students. The study questionnaire was divided into questions based on the concept of preclinical studies, clinical trials, drug development process and case report forms (CRF). The Cronbach's alpha values (measure of internal consistency) of the level of knowledge for preclinical studies, clinical trials, drug development process and CRF were 0.78, 0.79, 0.91 and 0.98, respectively. Data was presented using frequencies, i.e. mean, standard deviation and knowledge was analyzed by analysis of variance (ANOVA), followed by *post hoc* Tukey's test. P value ≤ 0.05 was considered significant and p-value ≤ 0.005 was considered highly significant.

Results. Knowledge of various parameters (preclinical studies, clinical trials and drug development process) among both colleges was found to be statistically significant ($p<0.005$), and medical students of the private Institute possessed higher mean knowledge than that of the government Institute.

Conclusions. Institutes must take the necessary steps to develop widespread awareness among students about clinical research. Motivation should be carried out for students to participate in clinical research. This would make India a pioneer in global research and development. Research methodology should be incorporated in the teaching curriculum in order to allocate specific time for research

Key words

clinical research, knowledge, medical students, clinical trials, physician

INTRODUCTION

It has been estimated that 20–30% of global clinical trials are being conducted in developing countries and expanding due to better accessibility of diverse population groups, rich manpower, periodical amendments and implementation of rules by regulatory authorities [1, 2]. The rapidly growing field of modern medicine is highly supported by clinical trials, which serve as a scientific proof for safely treating people with a novel drug [3, 4]. For a physician, participation in research is very important. Research training or exposure of medical students to research in the early phases of education will add to an increased opportunity for pursuing a career in research [5]. India has great potential for being an attractive clinical research destination due to its huge medical infrastructure, availability of large banks of treatment, increasing Good Clinical Practices (GCP) awareness among the clinical researchers, and the cost effectiveness of Indian operations. As it is the site of a wide variety of diseases, ranging from tropical infections to degenerative diseases, it offers the opportunity for pharmaceutical companies to develop drugs for a wide spectrum of diseases. Emerging physicians will act within contract research organizations (CROs) in future clinical research and maintain high principles of ethics and GCP compliance in support of this effort [5, 6]. Therefore, this study was conducted to elucidate the current knowledge of undergraduate and postgraduate medical students about clinical research in Punjab, India.

OBJECTIVES

The aim of the study was to assess the current knowledge of undergraduate and postgraduate medical students about various parameters of clinical research, i.e. preclinical studies, clinical trials, drug development process and case report forms (CRF), as well as to evaluate the role played by the education system in the improvement of knowledge during succeeding years of education.

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MATERIALS AND METHOD

Study site. This descriptive cross-sectional study was conducted at two medical institutes (private and government) in the Punjab during the period 15 May 2015 – 30 November 2015. The study population comprised of 1st, 2nd, 3rd and 4th year students, interns and postgraduate medical students, a total of 441 participants. The sampling technique was non-probability convenience sampling. A researcher explained the purpose of the study to all the participants, from whom written consent was obtained prior to the beginning of the study. The participants were also informed that their participation was voluntary and information obtained would be kept confidential.

Questionnaire. The study was conducted using a self-structured questionnaire in the English language. The questionnaire was divided into two parts: part one contained the demographic profile of the participant and information regarding the year of education; part two contained four main descriptive sets of questions pertaining to awareness about clinical research. Inclusion criteria were that all undergraduate medical students from 1st – 4th year MBBS (Bachelor of Medicine / Bachelor of Surgery), interns and all postgraduate students. Exclusion criteria were those who did not consent to participate. The questionnaire was distributed to 441 participants, of whom 404 completed the questionnaires correctly and formed the basis for statistical analysis.

Statistical analysis. Cronbach's alpha values (measure of internal consistency) of the level of knowledge of preclinical studies, clinical trials, drug development process and CRF were 0.78, 0.79, 0.91 and 0.98, respectively, according to the available data collected from two medical institutes. Data was analyzed by Statistical Package of Social Sciences (SPSS) version 20 (IBM, Armonk, NY, USA). Data was presented using frequencies, i.e. mean, standard deviation, and knowledge analyzed by analysis of variance (ANOVA) followed by *post hoc* Tukey's test. P value ≤ 0.05 was considered significant and p -value ≤ 0.005 considered highly significant.

RESULTS

The response rate was good, i.e. 92% (404 out of 441). The number of participants enrolled in the study were: 46 (11%), 77 (19%), 58 (14%) and 66 (16%) from the 1st, 2nd, 3rd and 4th years, whereas interns and postgraduates (PGs) were 77 (19%) and 80 (20%) in number. Distribution of male and female participants is shown in Table 1.

Table 1. Distribution of male and female participants

Year of study	Private Institute		Government Institute		Total n (%)
	Female (n)	Male (n)	Female (n)	Male (n)	
1st year	21	1	19	05	46 (11%)
2nd year	21	6	29	21	77(19%)
3rd year	27	9	15	07	58(14%)
4th year	42	3	14	07	66(16%)
Interns	39	6	20	12	77(19%)
PGs	13	8	36	23	80 (20%)

Knowledge of preclinical studies. Less than half of the study population was aware of the definition of *in vitro* and *ex vivo* study. The majority of participants (69%) were familiar with the term 'preclinical studies' (Tab. 2).

Table 2. Knowledge of preclinical studies

Knowledge of preclinical studies	Correct response
definition of *in–vitro* study	42%
definition of *ex-vivo* study	47%
definition of pre-clinical studies	69%
new drug / investigational product should be tested on animals before trying on human beings	74%

Knowledge of clinical trials. The majority of the participants were aware of the definition (70%) and purpose of clinical trials (72%), whereas 64% of students were familiar with the technical name for testing drugs on human beings, i.e. clinical trials, and 60% were familiar with four phases of clinical trials. However, only 56% of participants correctly stated that a new drug should be tested on a small group of humans before being introduced on the market (Tab. 3).

Table 3. Knowledge of clinical trials

Knowledge of clinical trials	Correct response
clinical trials are experiments conducted on humans	70%
purpose of clinical trial	72%
a clinical trial is the technical name for testing drug on human beings	64%
there are four phases in clinical trials	60%
IRB/IEC* give permission for testing drugs on humans	51%
a new drug should be tested on a small group of humans before being introduced on the market	56%

* IRB – Institutional Review Board; IEC – Institutional Ethics Committee

Knowledge of drug development process. Regarding the knowledge of drug development process, half of the study population correctly responded that IND (Investigational New Drug) is given as a number. Very few participants correctly responded about the time for filing IND and NDA (New Drug Application). A good percentage of knowledge (90%) was found regarding the filing procedure for IND. Only 60% and 47% of participants were aware of the duration of drug development and the expenditure involved in developing a new drug (Tab. 4).

Knowledge of CRF. According to the International Conference on Harmonization Guidelines for Good Clinical Practice (ICH-GCP), the case report form (CRF) is defined as a printed, optical or electronic document which is designed to record all the protocol – required information reported to the sponsor on each trial subject. In a clinical trial, the CRF is designed to gather patient data. Development of CRF represents an important part of the clinical trial, and the design of the CRF can influence the success of a study [7].

Only 43% participants possessed knowledge about types and data contained in CRF. In the current study, 68% and 56% of participants were aware of the meaning of electronic and paper CRF (Tab. 5).

Table 4. Knowledge of drug development process

Knowledge of drug development process	Correct response
IND is given as a number	53%
sponsor of pharmaceutical company obtains permission for IND	53%
IND number is applied before phase 1	38%
NDA number is applied before initiating phase 3	37%
permission for testing a new drug is obtained from drug regulatory body as IND	79%
filing IND is mandatory for a pharmaceutical company	90%
filing an IND is a complex procedure and requires establishing a procedure, protocol, method of data recording, and submission of IRB/IEC to a regulatory body	85%
by virtue of IND, the regulatory authority ensures that testing on humans is safe, scientific, ethical and rational	81%
time span for developing a new drug	60%
cost incurred in developing a new drug	47%

Table 5. Knowledge of CRF

Knowledge of CRF	Correct response
two types of CRF	43%
case report form consists of data from a patient	43%
meaning of electronic CRF	68%
meaning of paper CRF	56%
a well -designed CRF should be clear, concise & easy to complete	79%

Comparison of knowledge about preclinical studies, clinical trials, drug development and CRF among medical students of two institutes (private and government). A highly statistically significant difference ($p \leq 0.005$) was observed in the knowledge of students from both institutes for preclinical studies, clinical trials, drug development process and CRF. Mean knowledge of preclinical studies, clinical trials and drug development was found to be higher in participants from the private institute than from the government institute, compared to mean knowledge of CRF (Tab. 6).

Table 6. Comparison of knowledge about preclinical studies, clinical trials, drug development and CRF between private and government institutes

Parameter	Institute	No. (n)	Mean knowledge score	Mean± S.D	p-value
Preclinical studies	Private	196	58.0%	3.09 ±1.26	0.002*
	Government	208	54.5%	2.73 ±1.10	0.002*
Clinical trial	Private	196	68.5%	4.22 ±1.47	0.000*
	Government	208	53.8%	3.28 ±1.48	0.000*
Drug development	Private	196	64.0%	6.48±1.51	0.001*
	Government	208	58.9%	5.98 ±1.90	0.001*
CRF	Private	196	55.0%	3.33 ±1.40	0.004*
	Government	208	63.4%	3.83 ±1.73	0.003*

*p value ≤ 0.005

A statistically significant difference was found in knowledge among students, interns and PGs depending on their year of medical education (Tab. 7). Multiple comparison of knowledge of various parameters (preclinical studies, clinical trials, drug development process and CRF) showed a statistically significant difference (p value ≤ 0.005) among different years of medical education (students, interns and PGs), which itself acted as a confounding factor (Tab. 8).

Table 7. Analysis of variance (ANOVA) of knowledge among students, interns and PGs depending on year of medical education

Variable	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	810.807	5	162.161	9.363	0.000
Within Groups	6893.203	398	17.320		
Total	7704.010	403			

Table 8. Multiple comparison of knowledge among students, interns and PGs depending on year of medical education, using analysis of variance (ANOVA)

Year of education (I)	Year of education (J)	Mean Difference (I-J)	Std. Error	Significance
1st year	2nd year	-1.204	.776	0.630
	3rd year	-2.545*	.822	**0.025***
	4th year	-3.823*	.799	**0.000***
	Intern	-4.321*	.776	**0.000***
	PG	-3.155*	.770	**0.001***
2nd year	1st year	1.204	.776	0.630
	3rd year	-1.341	.724	0.433
	4th year	-2.619*	.698	**0.003***
	Intern	-3.117*	.671	**0.000***
	PG	-1.950*	.664	**0.041***
3rd year	1st year	2.545*	.822	**0.025***
	2nd year	1.341	.724	0.433
	4th year	-1.278	.749	0.528
	Intern	-1.776	.724	0.140
	PG	-.610	.718	0.958
4th year	1st year	3.823*	.799	**0.000***
	2nd year	2.619*	.698	**0.003***
	3rd year	1.278	.749	0.528
	Intern	-.498	.698	0.980
	PG	.669	.692	0.928
Interns	1st year	4.321*	.776	**0.000***
	2nd year	3.117*	.671	**0.000***
	3rd year	1.776	.724	0.140
	4th year	.498	.698	0.980
	PG	1.166	.664	0.496
PGs	1st year	3.155*	.770	**0.001***
	2nd year	1.950*	.664	**0.041***
	3rd year	.610	.718	0.958
	4th year	-.669	.692	0.928
	Intern	-1.166	.664	0.496

*p value ≤ 0.005

Comparison of knowledge of various parameters (preclinical studies, clinical trials, drug development process and CRF) showed a statistically significant difference (p value ≤ 0.005) among females and males for preclinical studies and clinical trials (Tab. 9).

Table 9. Comparison of knowledge of preclinical studies, clinical trials, drug development and CRF between female and male participants using t-test

Parameter	Gender	No. (n)	Mean knowledge score	Mean± S.D	p-value
Preclinical studies	female	296	3.88	1.542	**0.002***
	male	108	3.35	1.524	
Clinical trial	female	296	3.01	1.211	**0.002***
	male	108	2.60	1.102	
Drug development	female	296	3.57	1.612	0.693
	male	108	3.64	1.579	
CRF	female	296	6.32	1.718	0.068
	male	108	5.96	1.798	

*p value ≤ 0.005

DISCUSSION

In medical practice, the physician can respond well to the requests by patients for enrollment in clinical trials, and may act as a patient referral source for those who are interested in volunteering for clinical research. Investigators prefer consultation with personal physicians about the appropriateness of particular patients to be enrolled as study participants. Physicians therefore act as advisors and participate in improving the relationship with a patient for contributing to the success of evidence-based medicine [8].

A radical increase has been observed in the number of clinical research projects, due to the swift development of new drugs, therapies, and devices. This requires recruitment of a target sample size within a stipulated timescale for conducting a research project. To meet these challenges, there is a need for greater participation in research by the physicians, as well as clinicians and patients [9]. Research updates medical students about recent advances in medicine and science, and provides new interpretations of already existing facts. Research is activity of human origin, based on the use of intellect to investigate, interpret and it modify human knowledge concerning different aspects of the world. Participation in research creates medical innovation and promotes satisfaction of intellectual curiosity and assists in career advancement [9]. Physicians are the key players in the research community and can treat patients in remarkably effective ways. Increased participation of medical students in research activities can have an impact on their career selection. Good research skills can increase employment options in the future career of a physician [10]. It is important to study the factors on the basis of which a medical student selects research as career. In order to increase the number of clinical and research studies it is essential for a physician to participate in research [11], and opportunities for research should be incorporated into clinical duties to provide adequate research training during a trainee's education phase. Thus, exposure to a period of research training within a clinical programme can act as a facilitator for exploring more substantial career options [12]. Participation in clinical research may add esteem to a physicians' practice. Clinical research contributes towards escalating the knowledge base of medicine and provides physicians with an opportunity to provide patients with recent cutting-edge treatments [9]. In the era of evidence based practice research, this is an important component of medical practice. Without research, no new development would exist in health care. The involvement of undergraduate medical students in research activities can act as determinants of their future contribution in clinical research [10]. The barriers to conducting research among medical students are found to be lack of time and training courses, lack of professional supervisors, lack of funding, poor availability of research facilities, lack of access to scientific databases [13, 14, 15], lack of interest and examination phobia. The lack of time results from an extensive medical curriculum which is physically as well as mentally demanding, and additional frequent clinical examinations force students to prioritize the major demands of the curriculum to the detriment of research activities. These circumstances result in a lack of interest among medical students to conduct research. Allocating a fixed-time in the academic calendar for student research may minimize the time obstacle, and enable more interaction between students and their supervisors [10].

The presented study was conducted to assess the knowledge about the preliminary aspects of clinical research among the medical students at two institutes in Punjab, India. A large majority (74%) of participants were aware of the statement that medicines are first tested on laboratory animals before being tested on humans, which is in contrast to findings (5.3%) of a study carried in Nigeria. In the current study, 56% of participants knew that medicines which are found to be safe in animals are required to be tested in humans before being introduced on the market, in contrast to findings (6.7%) of a study carried in Nigeria [16]. In the current study, 60% participants correctly responded about the types of clinical trials, compared to 50.6% correct responses of a study carried by Dhodi et al. [17].

In the presented study, it was found that the students had good knowledge about the basic concepts of clinical trials; however, they were less aware about pre-clinical studies, which is similar to the findings of a study conducted in Madhurai, Tamil Nadu State, India [4]. Existence of this knowledge gap among students about clinical research has also been observed in similar studies performed in other parts of India [17, 18, 19]. This shows that the study participants possess a basic level of knowledge regarding clinical trials, indicating the probability of improvement in knowledge [9]. In the current study, 60% of participants were aware of the time span involved in developing a new drug, which is similar to the findings of a study carried in Kalaburagi, Karnataka State, India [6].

The unfortunate lack of medical students in research is associated with their negative attitudes arising from not attending student conferences and research workshops, which act as an impediment to learning research. Clinical research is an attractive career option, as well as the mainstay of evidence-based medicine. Thus, it is essential to educate our future physicians to pursue well-structured, successful and ethically sound scientific research. They should be encouraged to nurture the habit of reading medical journals, attend symposiums, CME and workshops in addition to arranging visits to contract research organizations (CRO) to motivate the students to improve their ideas and views on clinical research [20, 4]. Students in India are rarely exposed to research during the initial stage of their academic development, which is the time when they could really benefit, and overcome the obstacles they face. Steps should

be taken to inspire them to participate in research, although encouragement to participate is insufficient to remove the existing barriers, such as lack of mentoring, funding, and poor availability of research facilities and access to scientific databases [15]. This needs to be addressed in order to improve the participation of student's in clinical research.

An acceptable Cronbach's alpha (≥0.6) suggests that the questionnaire developed for the present study is reliable and the items are internally consistent. The clinical research and pharmaceutical industries should also proactively provide technical and logistic support to train physicians in academic settings in CT science. Lack of knowledge of the relevant science could also be a possible reason of the low rate of CTs being conducted by doctors in government medical institues, desspite the potentially high patient turnover in such settings [11]. Physicians must take a proactive stand in dealing with the factors by which clinical research affects routine medicine practice [8].

CONCLUSIONS

It can be conclude from the study that the knowledge ofr certain aspects of clinical research was insufficient among the medical students investigated. It is necessary to take steps to spread awareness among students about clinical research. There should be good motivation for students to undertake clinical research which would make India a pioneer in global research and development. Medical institutes should incorporate research methodology in their teaching curriculum in order to allocate specific time for research. Medical institutes should allocate supervisors, and faculties should encourage and motivate students to participate in research.

Limitations of the study. As the present study was carried out in only two medical institutes, this limits the generalization of the obtained results.

Competing Interests

All authors declare they have no competing interests.

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