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ORIGINAL ARTICLE

Awareness Of Clinical Trials Among University Pharmacy Students – A Questionnaire Survey

MEENAKUMARI K*, AMBERKAR MB*, RAJAKANNAN T, RAO E*, MOHAN L***, PRASHANTH****, MAHIMA******

ABSTRACT

Background: There is an increasing trend to undertake clinical trials in India from the past one decade, but its awareness has not reached to the maximum among the health care professionals and pharmacists in particular. The present study was aimed to evaluate the general awareness of the clinical trials among pharmacy undergraduates and postgraduates. To ascertain their interest to be involved in clinical trials and research studies in the present and future scenarios and to evaluate the various barriers in the way of conducting clinical trials from their perspective. **Materials and methods:** This was a questionnaire based study which was conducted among the University Pharmacy students. The respondents were enrolled after explaining to them the aims and objectives of the study and their willingness was checked before their participation in the study. The basic demographic information and qualitative statements were noted. **Results :**A total of 102 students participated in the study. A majority of the students had a very poor concept regarding the designing of the study, the sponsors, the role of DCGI, protocol writing/ IRB /ethics committee (60- 80%), etc. However, they scored on an average scale in knowing the basic concepts of clinical trials, preclinical testing, adverse events (30-40%), etc. **Conclusion:** Increasing boom in clinical research opens a door for more job opportunities and advanced research; hence, it is mandatory to educate the students at the grass root level about this advanced branch in itself. From this study, we conclude that the awareness about clinical trials and research in pharmacy students stands at an average. These major pitfalls could be improved by conducting many workshops, CMEs, panel discussions and symposiums at the college level itself.

Key words: Survey, clinical trials, awareness, pharmacy students,

Key Messages:
There were no studies regarding the awareness of clinical trials and hence, this study was undertaken to know the awareness of the globalization of clinical trials in India among the student population.

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Introduction

Clinical trials are research studies which are conducted with people who volunteer to take part in a study to find better ways to prevent, screen for, diagnose and treat a disease. There are certain steps and protocols which need to be followed while carrying out the actual clinical trials. The standard treatments used now are the base for developing future better treatments [1]. It is estimated that 20-30% of the global clinical trials are conducted in developing countries [2]. With escalating pressure on research and development across the global pharmaceutical industry, there is an increased focus on reducing the cost of clinical development. The additional problem of delayed development is also affecting new drug introductions, thus losing out on incremental revenues. As the multinational drug companies in the United States and Western Europe look eastwards to outsource research and clinical trial activities, countries such as India will gain proficiency and expertise, assisting its move from generic and speciality contract manufacturing to innovative drug discovery and development in its own right, setting the stage for increased global competition [3]. There is increasing difficulty for the testing of drugs in Western countries due to strict regulations, elaborate safety and compensation requirements and small populations. The scenario is different in India because of its rich technical resource pool, huge treatment-naive patient population, English speaking doctors, the relative ease and the attractive economics of recruiting a large number of patients and the sheer diversity in the country's genetic mixture [4].

We did this study after thorough screening of the pharmacy course curriculum. Apart from teaching about research methodology and clinical trials, it is a routine job for all the senior faculties to conduct many workshops, CMEs, panel discussions and symposiums on these sensitive aspects, so that the students will be well aware about these subjects at least before they leave the college. In this respect, we did the study only on the final year B. pharmacy and all M. pharmacy students. Moreover, it was mandatory for all M. pharmacy students to know about clinical trials in the 1st year for the following branches, namely a) pharmacology b) pharmaceutics c) pharmacognosy d) pharmaceutical chemistry, etc. and also, they are expected to complete at least one research project in the 2nd year of their course.

Efforts are needed to create a more widespread awareness of clinical research amongst the general public, patients and medical community, especially doctors and pharmacists to build confidence and move away from the "guinea pig" syndrome, if India is to take the fair share in the clinical outsourcing business [5]. The majority of the clinical trials are conducted and held by pharmacists at different levels along with other healthcare professionals. There were no studies regarding the awareness of clinical trials in the recent past among both under and post graduate pharmacy students and hence, this study was undertaken to screen out their role at different levels in the pharmaceutical industry.

Aim

1) To know the awareness of the globalization of clinical trials in India, especially among the student population.
2) To evaluate the general awareness on clinical trials among the undergraduate and postgraduate students of pharmacy colleges.
3) To ascertain their interest in being involved in clinical trials and research studies in the present and future scenarios and to evaluate the various barriers coming in their way in conducting clinical trials.

Material and methods

This was a questionnaire based study which was conducted in the Manipal College of Pharmaceutical Sciences after obtaining approval from the University ethics committee. It was conducted during the months of October and November 2009 when the students were in the second year of M. Pharmacy. The questions were reviewed and validated by experienced professionals who are currently involved in many clinical trials. The study protocol tool was examined and validated by conducting a well designed pilot study for readability and the ease of understanding.

The students were explained about the aims and objectives of the study and were invited to participate. Student feedback was obtained by using a questionnaire which 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 statistic analysis was done by using SPSS version 16.

Results

A total of 102 students responded to the survey. We enrolled only 40 B. pharmacy and 62 M. pharmacy students in our study. For the statement regarding the concept of clinical trials, around 21.6 % fell in the good category, 59.8% in the average category and 18.6% in the poor category. Regarding the statement for the need of clinical trials, 58.8% were poor responders, 27.5% were average and 13.7% were good. The information as to 'from where people could find about the clinical trials' was known by most of the students (73.5%), whereas 26.5% were ignorant about it. The statements regarding the participation in the clinical research study showed that a majority was in the poor response category (89.2%) as compared to 9.8% in the good category.
The knowledge regarding preclinical and clinical testing was average in around 52.9% students, good in 22.5 % students and poor in 24.5% students. Around 73 students were not aware about the Institutional Review Board or the ethics committee in comparison to 29 students who showed average response. The role of the US-FDA in approving new drugs was not known to a majority of the student population (91 students) as compared to 10 students who had good knowledge about it. There was a similar response about the knowledge trend on the role of the "Drugs and cosmetics act 1940" and the "Drug controller general of India", where 53.9% of the students showed poor response in comparison to 46.1% who showed good response.

Average response by 40 students was seen regarding the prerequisites for a participant before joining the clinical trial and also regarding the potential benefits and the risks involved, 45 students showed poor response and the rest were good. The statements pertaining to the knowledge regarding leaving a research study was responded by 41 students in comparison to 61% students who showed poor response. Ninety five percent of the students were not aware whether the participant should know the results of a clinical research study. A majority (85.3%) were not aware about what type of study design was to be incorporated. The knowledge about the sponsors was seen as average response in around 28.4% and as poor and good response in 66.7% and 6.9% students respectively. Around 15.7% showed good response regarding adverse event categorization and reporting and 35.3% showed average response.

Discussion

The present study was aimed to know the level of understanding and awareness about the most sensitive aspects of the clinical trials in pharmacy students. Also, we can plan to enrich

their current knowledge by giving presentations at pharmacy colleges and by raising awareness on the growing career opportunities for pharmacists in clinical research. Pharmacists are often called clinical research officers or project managers, these scientists typically write protocols, choose investigators and study sites, monitor clinical trials and collect and analyze trial data, report adverse events and write and publish clinical-study reports. Within the clinical research enterprise, pharmacists often move into leadership positions in drug-development studies. But because the work is behind the scenes, only few pharmacists hear about these job opportunities. People who go through the Pharmacy course training have the knowledge of chemicals and the development process and how it interacts with the patient, which adds a tremendous dimension to the clinical trials. Individuals trained in pharmacy are in a perfect position to bridge the gap between the flood of genomic information becoming available and the goal of personalized medicine.

In the present scenario, why should an Indian pharmacist know about clinical trials at the student level?

It is mandatory to have a complete knowledge about clinical trials and research before joining and after completing the pharmacy course. Pharmacists play a variety of roles, some designing phase I, early-stage clinical trials and others occupying executive-level management positions. Still, other pharmacists work as clinical research associates in late-phase clinical trials, traveling to investigator sites to oversee compliance with clinical protocols and investigating adverse drug events and safety concerns. For most pharmacy students however, experience and training in clinical research comes from a postgraduate fellowship. These are typically 1- to 2-year training programs following the completion of a B. Pharmacy course. These can open the door to positions in the pharmaceutical industry or in academic research. Some programs allow the fellows to rotate through several departments, whereas others offer intensive training in one area such as regulatory affairs or drug labeling.

One main challenge which is related to patient compliance is education. As many patients in the trial scenario are from rural and semi-urban areas, care must be taken to ensure that they are well educated and that compliance issues are well understood. The last five years have also witnessed a tremendous interest and activity in the area of clinical research services in India; it is mainly due to a huge medical infrastructure, the availability of large banks of treatment-naive patients with a variety of diseases, increasing GCP awareness among the clinical investigators and the cost effectiveness of Indian operations. So, while India builds up on the potential of being an attractive clinical research destination, it is important that the emerging professional contract research organizations (CROs) maintain high standards of ethics and GCP compliance to support this endeavour. There is great boom in clinical research in India, since it is a home to a wide variety of diseases ranging from tropical infections to degenerative diseases; it offers the opportunity for pharma companies to develop drugs for a wide spectrum of diseases; to name a few multidrug resistant ones, pneumonia, hepatitis B, diabetes and cancers [6].

In this study, we had chosen sensitive, easily understandable and the most prolific areas of clinical trials and research which were at par with the student's knowledge. From the derived results of the questionnaire study, we found that the students had excellent knowledge about, "Where can common people find information about clinical trials" and that they were well aware about the "general concepts of clinical trials and preclinical studies"; however, there was a poor response regarding "the participation in clinical research", "designing the study", "protocol writing /IRB/Ethics committee, the role of DCGI, US-FDA and the sponsors", as shown in the [Table/Fig 1]. Though quite a large number of students were totally ignorant regarding the important aspects of the clinical trials, their interest and zeal to know and be a part of the clinical trials could not be underestimated.

Based on history, what a Pharmacist can do in research is really limitless and what's new is that we have an actual pathway to train the under and postgraduate students to go into research. Although pharmacists who pursue research careers are still a small minority, their ranks are

expanding quickly within the pharmaceutical industry and in the myriad organizations which develop and test pharmaceutical compounds. However, pharmacists are perfectly poised to bridge the knowledge gap between laboratory data and opportunities for them in clinical practice are only going to expand.

Questions	Good	Average	Poor
Concept of clinical trial	21.6	59.8	18.6
Need of clinical trial	13.7	27.5	58.8
Where can people find about it	73.5	-	26.5
Participation in clinical research study	9.8	-	89.2
Preclinical testing	22.5	52.9	24.5
Protocol/IRB/Ethics committee	-	28.4	71.6
Role of US-FDA	9.8	-	89.2
Role of DCGI	46.1		53.9
Prerequisites of participant	16.7	39.2	44.1
Leaving a research study	40.2	-	59.8
Knowing the results of CRS	4.9	-	95.1
Design of study	14.7	-	85.3
Sponsors	6.9	28.4	64.7
Adverse event	15.7	35.3	49

[Table/Fig 1]: Percentage of Response for each category of questions.

The profession of pharmacy has a lot to offer in the field of clinical trials and research. Such projects aim to meet a growing need for the pharmacists within the clinical research system. The recognition of international product patents is now expected to spur pharmaceutical research in India, to supplement the global efforts for searching for new molecules for unmet medical needs and to develop generic products to reduce healthcare costs**.**

Limitations of the study:

1) The study would have been more comprehensive if working industrial pharmacy researchers were also included and if their level of awareness was compared with that of the pharmacy students.

2) We received very good response from the students; however, one of the barriers for not responding correctly to our questionnaire study would have been the exhaustive teaching class hours.

3) This study was done randomly in students; we could have missed good scholar students.

Conclusion

We conclude from this questionnaire survey that the knowledge about clinical trials and research in pharmacy students stands average. These major pitfalls could be improved by conducting many workshops, CMEs, panel discussions and symposiums, so that the students would be well aware of these aspects right from the student level.

We can broaden the spectrum of the qualitative knowledge and the skills of pharmacists at the student level by conducting many questionnaire studies like this. Also, these kind of active programmes stir up the awareness levels regarding the clinical trials and research, which can help pharmacists and more ambitious Indian pharmaceutical companies to fulfill their aspirations of becoming players in the global pharmaceutical industry.

“There is always light at the end of the tunnel” ….. So, in spite of all the present pitfalls, the country is certainly gearing up to attract more and more researchers from around the world to conduct their clinical trial studies in India. The regulatory system is being polished, laws are being amended to facilitate the entry of global clinical trials and massive concerted efforts are on to train research pharmacy professionals and to increase the base of investigators and supporting staff. These initiatives are certain to improve the current situation, especially for the pharmacists and doctors. In brief, Indian pharmacists are already off the starting blocks and are gearing up for an inundation of clinical research trials. India is poised to offer the global pharmaceutical industry high quality and cost-effective contract services to support drug discovery, clinical trial conduct, data management and manufacturing.

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APPENDIX

Name: _____ *Date:*

Qualification:

Student(B. Pharmacy)	Research Scholar	Post Graduate (M. Pharmacy)

Studying course and year:	Institution / Hospital:

Contact mail ID:

Instructions for filling up this questionnaire:

Kindly tick
'Y' for 'Yes'
'N' for 'No' and
'DK' for don't know.

Status of the Student -

1. I have not involved in any of the clinical trials, but interested in attempting the following questions	
2. I have been a part of clinical trials in the past	
3. Currently I have involved in clinical trials	

General questions to know the interest of clinical trials

1	I am aware about clinical trials	Y	N
2	Is there any need for clinical trial research	Y	N
3	I believe clinical trials are the basic need for betterment of mankind and health status	Y	N
4	I would like to participate in clinical trials as a researcher if i get opportunities in future	Y	N
5	I believe clinical trials are unethical, incorrect and purely inhuman	Y	N
6	The incidence of harmful events are more than the benefits to the patient	Y	N
7	Conducting clinical trials is waste of time, man power and money	Y	N

COMMON QUESTIONS FOR ALL IRRESPECTIVE OF THE PARTICIPANT´S STATUS IN THIS STUDY

NOTE: THIS STUDY INCLUDES BOTH POSITIVE AND NEGATIVE QUESTIONS

A. Concept of Clinical Research Study (CRS) or Clinical Trial

1	Clinical trials are used to determine whether new drugs or treatments are both safe and effective	Y	N
2	Carefully conducted clinical trials are the fastest and safest way to find treatments that work	Y	N
3	What are the different types of clinical trials. (Tick the empty box if you know) a. Prevention trials ☐ b. Diagnostic trials ☐ c. Screening trials ☐ d. Quality of Life trials or Supportive Care trials ☐		

B. The need of clinical trials

1. Clinical trials are conducted

1	Always by the companies to earn more money and compete with others for their name and fame	Y	N
2	Because of insufficient research data available from previous study	Y	N
3	To compare new drug or device with the existing treatments to determine which is better	Y	N
4	To study different ways to use the standard treatments so they will be more effective, easier to use, and/or decrease side effects	Y	N
5	By the Universities ☐ Clinics ☐ Doctor's offices ☐ Hospitals ☐ Federally- and industry-funded research sites ☐		

C. Where can people find out about clinical trials

1	www.ClinicalTrials.gov is an interactive online database, managed by the National Library of Medicine. It provides information about both federally and privately supported clinical research in human volunteers.	Y	N

D. Participation in clinical research study(CRS)

1	It is also important to conduct research in a variety of people because different people may respond differently to treatments	Y	N
2	Some people participate in clinical trials because they have exhausted standard (approved) treatment options - which either did not work for them, or they were unable to tolerate certain side effects	Y	N
3	Clinical trials are usually conducted in healthy human volunteers	Y	N

E. Preclinical and clinical testing

1	Pre-clinical studies involve *in vitro* (i.e. test tube or laboratory) studies and trials on animal populations (in vivo)	Y	N
2	Following are the animals used for preclinical testing a. Rats ☐ b. Mice ☐ c. Rabbits ☐ d. Guinea pigs ☐ e. Frog ☐ f. Monkeys ☐		
3	What is the average time period required for the drug development starting from human testing till it gets marketed		

	a. 2.6 - 4.6 yrs ☐ b. 4.6 -6.6yrs ☐ c. 6.6 -8.6 yrs ☐ d. 8.6 -10.6 yrs ☐		
4	Following are the different clinical phases conducted in human volunteers a. Phase I ☐ b. Phase II ☐ c. Phase III ☐ d. Phase IV ☐		
5	Phase IV is also called as post marketing surveillance	Y	N
6	Post marketing surveillance of drug usage is important to detect how fast the drug is sold	Y	N
7	The following parameters of a drug are evaluated during different phase of clinical trials a) Pharmacokinetics ☐ b) Pharmacodynamics ☐ c) Toxicity profile ☐ d) Tolerability ☐ e) Pharmacovigilance ☐		
8	Phase I is first human trial, also called as micro dosing testing studies	Y	N

F. The Protocol / Institutional Review Board or Ethics committee / Safety of the participant

1	Clinical trial procedures are reviewed by Institutional Review Board (IRB)	Y	N
2	None of the IRBs are located at the local investigator's hospital or institutions	Y	N
3	The purpose of an IRB is to protect the rights and welfare of participants as subjects of research	Y	N
4	IRB will approve the research trial , even if the risks to participants are found to be too great	Y	N
5	IRB looks into the informed consent document to ensure that it includes all the elements required by law, and that it is at an appropriate reading level and understandable to study participants	Y	N
6	For Safety reasons, many clinical trials of drugs are designed to exclude women of childbearing age, pregnant women, and/or women who become pregnant during the study	Y	N
7	A required twice weekly "continuing review" report from the investigator updates the IRB on the progress of the study and any new safety information related to the study.	Y	N

G. The role of the US- FDA (Food and Drug Administration) in approving new drugs

1	The US- FDA job is to make sure medical treatments are safe and effective for people to use	Y	N
2	US -FDA helps in the development of new therapies and conducts the clinical trial to demonstrate safety and effectiveness	Y	N
3	FDA staff members meet with researchers, and perform inspections of clinical trial study sites to protect the rights of participants and to verify the quality and integrity of the data.	Y	N

H.The role of “Drugs and Cosmetics Act 1940” and “Drug Controller General of India (DCGI)” in India

1	The import, manufacture, distribution and sale of drugs and cosmetics in India are controlled by the Drugs &Cosmetics Act, 1940	Y	N
2	No new drug shall be manufactured for sale or imported unless it is approved by the DCGI	Y	N
3	DCGI is responsible for approval of licenses of specified categories of Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera	Y	N

I. Prerequisites for a participant before joining clinical trial

I. Informed consent document

1	Is the process of learning the key facts about a clinical research study before deciding whether or not to participate	Y	N
2	If the native language is not English, the participant must be disqualified from the study	Y	N
3	The sponsor and the local site investigators are jointly responsible for writing a site-specific informed consent	Y	N
4	Is highly confidential and no information written about the potential true risks and benefits of participating in the study	Y	N
5	Includes details about the study A. Its purpose ☐ B. How long it lasts ☐ C. Required procedures ☐ D. Key contacts ☐		
6	Participant should <u>not be withdrawn</u> from the trial, after signing an informed consent document	Y	N

II. Potential Benefits

Participating in well-designed and well-executed clinical trials is one approach for eligible patients/ volunteers to

1	Get actively involved in their health care	Y	N
2	Gain access to potentially new research treatments	Y	N
3	Help others by contributing to medical research	Y	N
4	Procure medicine free of cost and very minimal health risk	Y	N

III. Possible risks

There are generally known and unknown risks associated with clinical trials, such as:

1	There may be unpleasant, serious, or even life-threatening side effects resulting from the treatment, which is very common and usually goes unnoticed	Y	N
2	The treatment may not be effective for the participant still he can be a part of CRS	Y	N
3	The protocol may require more of the participant's time and attention than a standard treatment	Y	N

J. Leaving a research study

1	Just as people can refuse to participate in a study, after enrollment they may choose to stop participation at any time	Y	N
2	Leaving a clinical trial before it is over will result in huge penalty to the participant	Y	N

K. Knowing the results of a CRS

1	Will not always be informed of results that might influence the participant decision to	Y	N

	withdraw the research study		
2	If the study is blinded medical information may be shared before the research study is completed	Y	N

L. Design of the study /placebo/ control group

1	Most Phase III drug trials are designed as randomized, double blind, and placebo-controlled	Y	N
2	A placebo is an active substance that is designed to look exactly like real medication or a real medical device	Y	N
3	To see if a new drug works, researchers must compare a group of people who took the drug with a group of people who did not. This group is called a "control group"	Y	N

M. The Sponsors

1	Some times volunteers are required to pay for clinical research studies like for medications, doctor visits, tests and procedures	Y	N
2	The participant can freely discuss what costs are involved with the researchers prior to joining in the study	Y	N
3	Throughout the clinical trial, the sponsor is responsible for accurately informing the local site investigators of the true historical safety record of the drug, device or other medical treatments to be tested	Y	N
4	Funding for clinical research comes from A. Federal government agencies such as the National Institute of Health. ☐ B. Private industry like pharmaceutical and biotech companies. ☐ C. Private institutions ☐		

N. Side Effects /Adverse Reactions / Adverse Event- (AE)

1	AE is any adverse change in health or "side-effect" that occurs in a person who participates in a clinical trial.	Y	N
2	AE can be classified as a) Serious or minor ☐ b) Expected or unexpected ☐ c) Study-related ☐ d) Possibly study-related ☐ e) Not study-related ☐		
3	AE occurring in patients participating in clinical trials must be reported to the local Institutional Review Board (IRB) and the study sponsor	Y	N
4	Death, illness requiring hospitalization, life-threatening events, involving Permanent Impairment or Damage or Congenital Anomaly categorized as "serious" AE.	Y	N
5	both minor and serious AE must be reported to the regulatory authorities immediately	Y	N
6	The sponsor collects AE reports from the local researchers, and notifies all participating sites of the AEs at the other sites	Y	N