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Original Research

Knowledge, attitude & practices of medical students and teachers towards clinical research in a tertiary care hospital in Mumbai – cross sectional survey

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ABSTRACT

Healthcare workers should be adequately trained and equipped with up-to-date knowledge and skills to ensure quality and reliability of clinical research. Lack of trained manpower is one of the challenges faced in clinical research. We conducted this study to elucidate the knowledge, opinions and practices of medical students and teachers, the cohort most likely to undertake clinical research. A questionnaire based cross sectional – Knowledge, Attitudes and Practices (KAP) - survey was conducted among 450 participants from a tertiary care teaching hospital in Mumbai, after clearance from the Institutional Ethics Committee (IEC). Overall, 230/395 (58.3%) had worked on clinical research projects. The meaning of clinical research was known to 60.8% (240/395) of the respondents, while 50.6% (200/395) knew its types and scope and had basic knowledge about clinical trials. Yet, 61% (241/395) could not correctly answer the questions about methodology of clinical trials and the regulatory requirements. On comparing the number of completed questionnaires returned and the number of questions correctly answered, participants from the pre/para clinical field fared better than those from clinical fields ($p<0.05$). Only 36.3% had taken formal training in clinical research but 73% were in favour of including clinical research training in medical curriculum. Sixty three percent wanted to make a carrier in clinical research. The knowledge gaps and misconceptions regarding clinical research should be annulled by training the trainers and including clinical research training in the medical curriculum. The government should take initiative in promoting clinical research training in medical schools.

INTRODUCTION

The main challenges facing clinical research are lack of trained manpower and inadequate funding [1-3]. From amongst these, the lack of trained manpower is the most worrisome, but at the same time more manageable, especially in the developing countries like India where human resources far exceed the financial capabilities. The only question remains is their effective training.

Evidence-based medicine (EBM) has become indispensible in today's health care paradigms [4,5]. Good quality clinical research should not only be statically significant but also scientifically sound and ethical. Knowledge about the standard guidelines is a pre requisite before conducting any form of clinical research [6].

In the state of Maharashtra, with the exception of MD Pharmacology and DM Clinical Pharmacology degree courses, training in clinical research has not been made a part of the medical curriculum [7,8]. There are separate training courses in clinical research but there is a lack of formal university structure, University Grants Commission (UGC) / All India Council for Technical

Education (AICTE) recognition, or recognition under any state act [9]. This has led to knowledge gaps and irregularities in the clinical research methodology. A study conducted in 2008-09 in Mumbai, had highlighted many such irregularities that were discovered during site monitoring visits [10].

As per the Medical Council of India (MCI) requirements, resident doctors have to carry out a dissertation project as a part of their MD/MS curriculum [11].

Another study conducted in Mumbai, which evaluated the project application forms submitted to institutional ethics committee, found that majority of the academic project proposals were lacking basic details like appropriate titles, budget details, method of recruitment and details regarding vital issues like vulnerability and compensation for participation/injury [12].

Thus, we conducted this study to elucidate the current knowledge, attitudes and practices of medical students and teachers, to delineate the lacunae present if any and the factors responsible for them. This will help us design an effective and targeted training program to develop a ethically and scientifically skilled workforce for conducting clinical research.

METHODS

Study Design

The study was a cross –sectional questionnaire based survey to find out the knowledge, attitude and practices of medical students and teachers conducted between June – December 2011, after obtaining permission from the Institutional Ethics Committee.

Sample size and profile of participants

For 95% confidence interval and 50% expected prevalence of knowledge and awareness, the sample size calculated was 385. Considering a drop-out rate of 15%, 450 participants were selected by stratified random sampling as shown below.

- First, the study population was divided into 3 strata: medical teachers, 3rd year postgraduate students and interns such that they were mutually exclusive and collectively exhaustive. The first two strata were further divided into 2 subgroups: clinical and pre/para clinical streams. Then, depending on their relative proportion, participants were selected from each stratum. After that, at the stream level, an equal level of participants were selected from clinical and pre/ para clinical to ensure homogeneity.
- One fifty medical teachers selected randomly, comprised of 75 teachers from clinical departments (medical, surgical and allied) and 75 from the pre and para-clinical departments (anatomy, physiology, biochemistry, microbiology, pathology, pharmacology and forensic medicine).
- Hundred second and third year post graduate students pursuing MD (Doctor of Medicine) or MS (Master of Surgery) degree courses comprising of 50 students from the clinical departments (medical, surgical and allied) and the remaining 50 from the pre and para-clinical departments (anatomy, physiology, biochemistry, microbiology, pathology, pharmacology and forensic medicine).
- Two hundred medical students pursuing internship.

Data collection tool

The questionnaire was prepared containing an equal number of positive and negative statements, with mixed response open and closed questions taking guidance from previous similar studies [13-15]

Draft of the questionnaire was thoroughly reviewed by 4 senior teachers of the Department of Pharmacology, Grant Medical College and Sir J J Group of Hospitals. Their suggestions were incorporated in the final version.

The questionnaire was peer reviewed and pilot tested among 10 participants similar to the study cohort and validity and reproducibility were assured. Out of these 10, 6 were medical teachers (3 each from clinical and pre/para clinical streams). Out of the remaining 4, 2 were 3rd year postgraduate students and 2 were interns. After giving them the questionnaire, their feedback was taken regarding the comprehensibility of the questionnaire and also their responses were assessed to see if the participants understood the questions. No discrepancies were observed in the pilot study.

The questionnaire contained three sections. The first section had questions regarding knowledge of basics of clinical research, clinical trials, clinical research methodology, pre requisites etc. The second section dealt with the attitudes of the participants about the importance of clinical research, need for training, future prospects of a career in clinical research and status of India on the global clinical research map. The final section asked the participants about their participation in various forms of clinical research, conducting training in clinical research and scientific writing.

Procedure

Four hundred and fifty self administered paper questionnaires were distributed. The participants were requested to fill the questionnaire without referring any aids like books/journals or the internet.

Statistical analysis

Statistical analysis was done using descriptive statistics. The results on the continuous measurements scale were presented as Mean ± 2SD and the results on the categorical measurements were presented as Numbers (%). The significance was assessed at a 5% level of significance (P<0.05) with 95% confidence interval using the appropriate statistical tests. All statistical calculations were carried out with OpenEpi: A Web-based Epidemiologic and Statistical Calculator [16].

RESULTS

The response rate was 395/450 (87.8%). The age range of our study participants was 23 – 60 years with mean age 30.6 years with a SD of 2.4 years. The characteristics of our study participants are shown in Table 1.

The proportion of completed questionnaires returned as per the stream is given in Table 2.

Knowledge regarding clinical research

The meaning of clinical research was known to 240/395 (60.8%) of the respondents, while 200/395 (50.6%) knew its types and scope and had basic knowledge about clinical trials. Yet, 241/395 (61%) could not correctly answer the questions about methodology of clinical trials and the regulatory requirements.

The average number of questions (Mean ± 2SD) answered correctly (out of 14) by medical teachers, post graduate students and interns were, 7.2 ± 5.2; 7 ± 4.2 and 6.8 ± 5.4 (p=0.4), respectively.

Number of questions answered correctly out of 14, based on the stream of medical teachers and post graduate students is as shown in Table 3.

Table 1. Characteristics of participants (n=395), Mumbai, 2011.

Characteristic		% (n)
Gender	Male	50.6 (200)
	Female	49.4 (195)
Age groups	20-30yrs	64.3 (250)
	31-50 yrs	25.3 (100)
	>50yrs	11.4 (45)
Designation	Medical teachers	32.9 (130)
	Post graduate students	22.8 (90)
	Interns	44.3 (175)

Table 2. The proportion of completed questionnaires returned by participants (n=220) as per their stream: Clinical Vs Pre/para clinical and designation: medical teachers and post graduate students, Mumbai, 2011.

Designation	Stream		*CMLE Odds ratio	
	Clinical	Pre and para-clinical	Value	Confidence limits Lower, Upper
Medical teachers	80% (60/75)	93.3% (70/75)	0.29	0.09, 0.82
Post graduate students	84% (42/50)	96% (48/50)	0.22	0.03, 1.02
Total	81.6% (102/125)	94.4% (118/125)	0.26	0.10, 0.63

* Conditional maximum likelihood estimate of Odds Ratio, P-values < 0.05 for all, by using Mid-P exact test

Table 3. Number of questions answered correctly out of 14, based on the stream of participants (n=220): Clinical Vs Pre/para clinical, Mumbai, 2011.

Stream (n)	Number of questions answered correctly: Mean ± 2SD	p value *
Pre and para clinical (118)	9.4 ± 3.6	0.0004
Clinical (102)	7.9 ± 2.4	

*p value calculated using the Two-Sample Independent *t* Test.

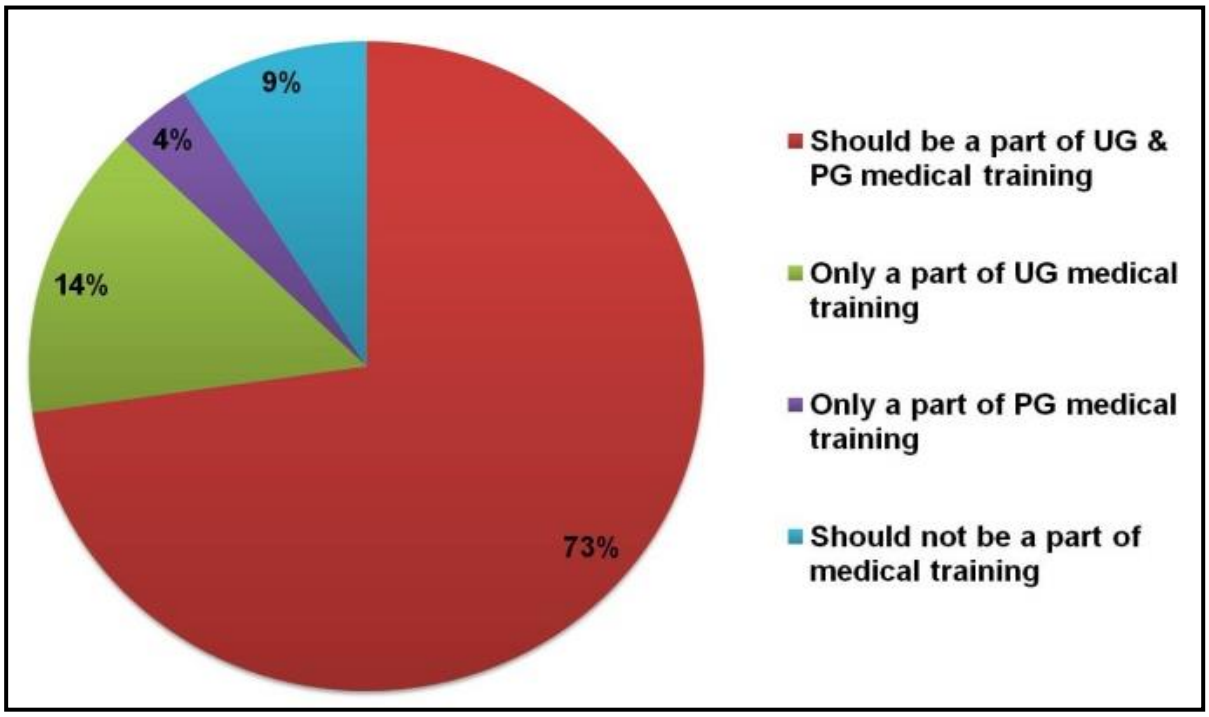

Figure 1. Opinion of the participants (n=395) regarding inclusion of clinical research training in the medical curriculum for undergraduate (UG) and postgraduate (PG) students, Mumbai, 2011.

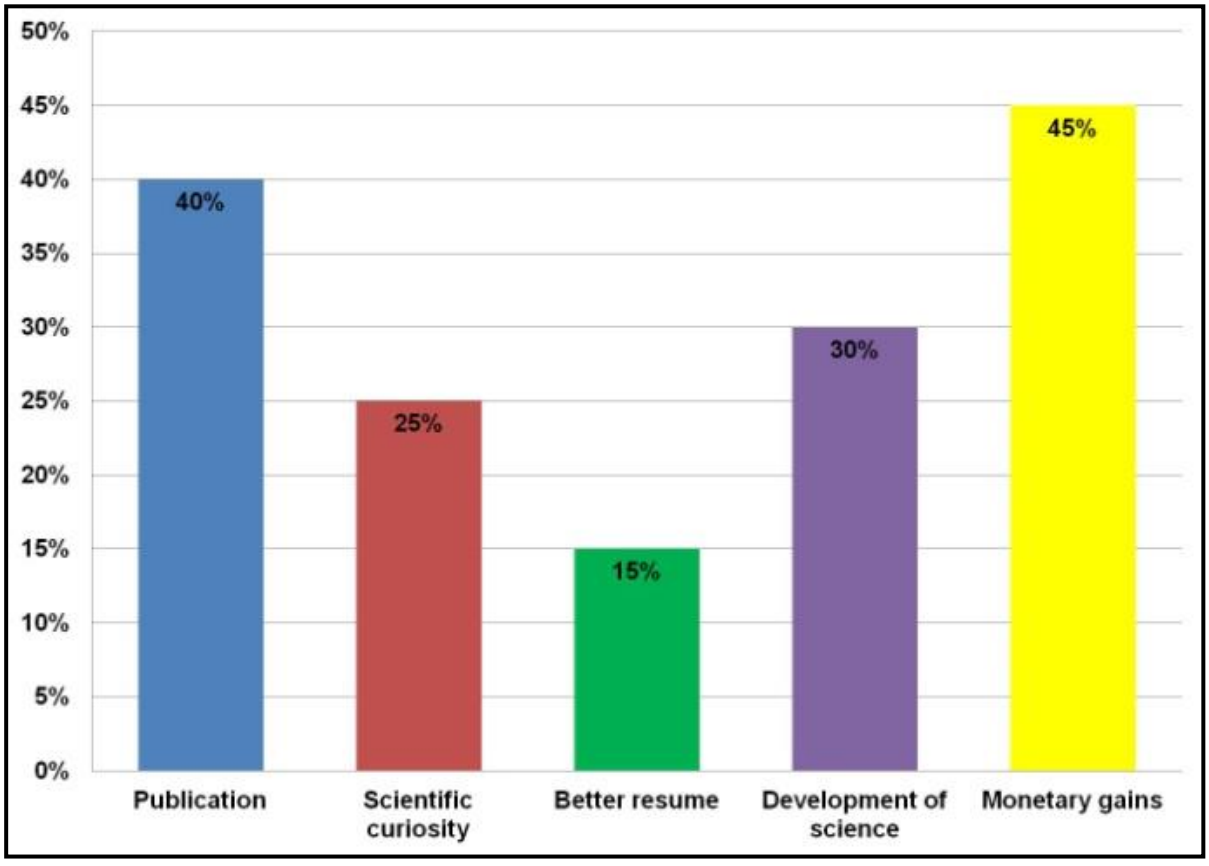

Figure 2. Reasons given by participants (n=395) for wanting to conduct clinical trials, Mumbai, 2011.

Attitudes and practices regarding clinical research

1. Three sixty out of 395 (91%) participants thought that clinical research was important for progress in medical science

Figure 1 shows the opinion of participants regarding importance of clinical research training in medical curriculum

2. Three forty five participants (87.3%) wanted to be a part of clinical trials and the reasons given were: (Refer Figure 2)

Out of the 50 who would ***not*** like to undertake clinical trials, 35 said that it was very time consuming and 15 gave the additional reason that it involves a lot of unnecessary paper work.

3. Career in clinical research:

Two hundred and fifty one participants (63.5%) would like to make a career in clinical research and the reasons given by majority were: financial benefits – 48.6%, no emergency duties – 39.8%, and fixed working pattern – 35.5%.

4. Training in clinical research:

One hundred participants (36.4 %) had taken some formal training in clinical research.

Thirty five (12.7 %) had been trainers/faculty members who had conducted training sessions in clinical research.

5. Active participation in clinical research:

Overall, 230/395 (58.3%) had worked on clinical research projects; All post-graduate students had conducted a research project as a part of their coursework (dissertation) but only 30/90 (33.3%) had undertaken any other research study.

Sixteen percent interns had worked on projects such as "Short Term Studentship" research projects sponsored by the Indian Council of Medical Research (ICMR).

Further analysis showed that 106/230 (46.1%) had conducted clinical trials, 30/230(13.4%) in Drug Utilization studies and 15/230 (6.5%) in Bioequivalence studies.

One thirty five participants (34.2%) had at least one publication in an indexed journal; 80/395 (20.3%) planed to publish in the near future.

6. Status of India in clinical research:

Three forty four participants (87.1%) said that India is an upcoming nation but at the same time 170/395 (43%) said that clinical trials conducted in the Indian scenario might not be up to scratch.

DISCUSSION

Our study has shown that absence of a formal standardized clinical research training program in the medical curriculum has lead to knowledge gaps and misconceptions amongst the medical professionals who play a major role in conducting clinical research. This notwithstanding, there could be other plausible reasons for the observed results like lack of time, perceived complexity of clinical research, lack of stringent regulations and monitoring and a casual attitude that leads to undermining the importance of good clinical practices in clinical research.

Most of our participants were in favor of including clinical research training in the medical curriculum both at undergraduate and postgraduate level. The most common reason given to undertake clinical research was to be able to publish articles followed by scientific curiosity and monetary gains. A large majority would also like to make a career in clinical research as it it might be more rewarding financially and promise a stable life style and fixed hours of work. This is particularly encouraging, given the current mismatch in the demand and supply of trained clinical research specialists in India [17].

Many participants knew what clinical research was, its types and scope. Knowledge gaps exist as far as clinical trials are concerned: types, phases and regulatory requirements of clinical trials. There is lack of correlation in responses observed in sections 1, 2 and 3. This highlights, how lack of knowledge leads to varied and erroneous interpretations and opinions because when on one hand 63% wanted to make a carrier in clinical research, the meaning of clinical research was known to only 60.8% of participants. It is possible that in clinical research studies, one or two individuals, who are appropriately trained, guide and direct rest of the team who, albeit may not know/understand the key concepts, just follow orders.

We quote from a recent report emphasizing the need for training in clinical research in India, *"A large majority of potential investigators lack knowledge of regulations, ethics and GCP, and skills for clinical trial management."* [18]. Only one third of our participants said that they had a publication in an indexed journal reflecting the lack of training in medical writing also. According to one study, research articles by health researchers in South Asia comprised a mere 1.2% of all annual research on health topics within the Institute for Scientific Information's database from 1992 to 2001 [19]. This was also reflected in a study conducted in Pakistan in 2004, according to which only 20% of residents read medical journals monthly, only 12% had ever written for medical journal publication, and 12% had never read a medical journal [20]. By

understanding where the knowledge gaps exist we can plan a more targeted approach in clinical research training.

Only a small percentage of our participants had taken any formal training in clinical research. Despite this, many had participated in some or the other form of clinical research. This is in contrast to a study conducted in Pakistan which showed poor participation of doctors in clinical research [21]. If we consider post graduate students, besides their dissertation projects, they have hardly conducted any other research and the same was also seen in another study conducted in Mumbai in 2010 [13]. According to our study, the current practice of conducting clinical research is dependent more on experience rather than knowledge. The main reason given by the participants who would not like to undertake clinical research is the paucity of time. A study conducted in Mumbai, had a similar finding along with other reasons like lack of clinical research training in medical curriculum, lack of financial resources and little support from faculty [13].

The participants from the pre /para-clinical field returned more completed questionnaires and also answered more questions correctly from the *Knowledge* section compared to those from the clinical field. The difference albeit small was significant. There was no statically significant difference between the knowledge of medical teachers, post graduate medical students and interns, reflecting the need for training at all levels [22]. *Training the trainer* is where one should start to ensure effective percolation of knowledge among the medical students. Training and encouraging medical students to undertake clinical research also has a number of benefits like contributing to the overall publications from the institute, improving critical appraisal of medical literature and medical writing skills [23-25].

Majority of our participants echo the popular sentiment that India has a great future in clinical research yet they also say that credibility of research conducted here could be doubtful. The reason is a lack of trained clinical research specialists undermining the quality of clinical research. Having said this, the situation is fast improving and more and more medical, paramedical and science graduates are enrolling for clinical research training [17].

Though special care was taken to select questions representing various facets of clinical research, the questionnaire was not designed to test exhaustive knowledge about clinical research. Various types of responder bias may affect the results, for example, the social desirability bias, central tendency bias and acquiescence bias [26]. The latter was dealt with by having an equal number of positive and negative answer options. Also, the individuals who chose to complete the questionnaires may be different from those who did not, thus biasing the results. The study sample was selected from only one state run teaching tertiary care hospital from the city of Mumbai, so we may not be able to generalize the results.

Conclusion and recommendations:

Health care providers should be effectively educated in clinical research to enhance their knowledge, remove misconceptions and motivate them to undertake clinical research. Including clinical research training in the medical curriculum will go a long way in achieving the above goal. Rules and regulations should be stringent and regular monitoring should ensure that the clinical research personnel are adequately trained and apt for the job. The government should take initiative in promoting clinical research training in medical schools by organizing workshops, conferences and making policy decisions that will make India a global name in the field of clinical research.

Conflict of Interest

There was no conflict of interest

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