

Impact of educational intervention on knowledge, attitude and awareness of good clinical practice among health care providers

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Abstract

Background: Clinical trials play an important role in the generation of evidence-based data in health care practices. To ensure the credibility of data and the safety and well-being of the patients Good clinical practice (GCP) guidelines play an important role. At present, we have little knowledge about awareness of GCP guidelines among health care providers in India.

Aim: To assess the level of awareness, and perception of the health care providers toward GCP and subsequent change in these after a day training session on GCP guidelines.

Settings and Design: A cross-sectional descriptive questionnaire-based study was conducted amongst health care providers, that is, doctors, dentists, nurses of a Tertiary Health Care and Teaching Institute.

Materials and Methods: Participants were given descriptive questionnaire; they completed the questionnaire before and after undergoing a day training program in GCP guidelines.

Statistical Analysis Used: The impact of the effectiveness of educational intervention among healthcare professionals was evaluated by two-tailed Z-test.

Results: Out of 120 participants, 80 were medical doctors, 20 dental doctors, and 20 nurses. A day training program on GCP guidelines was found to increase positive attitudes toward various aspects of clinical trials.

Conclusion: A day's training program on GCP guidelines may help to increase the knowledge as well as awareness about principles and techniques of clinical research, which will increase the credibility of clinical research in the country.

Keywords: Awareness, clinical research, good clinical practice, health-care providers

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INTRODUCTION

Good clinical practice (GCP) guidelines are prepositions for healthcare providers to generate reliable clinical trial data. GCP guidelines are used for designing, conducting, recording, and

reporting clinical trials that involve participations of human beings.^[1] Apart from generating the reliable data, aim of GCP is also to ensure the well-being and safety of participants. In

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India, these guidelines have evolved with consideration of the WHO,^[2] USFDA,^[3] and European GCP^[4] guidelines as well as the Ethical Guidelines for biomedical research on human subjects issued by the Indian Council of Medical Research.^[5] Worldwide, most of the research sites conduct clinical trials in compliance with GCP standards and in India, Drug Controller General of India has also made mandatory that GCP guidelines should be followed for conducting all clinical trials.^[6]

Clinical trials play an important role in improving the quality of health care practice and are an essential component for the approval of new drugs and medical devices. India is emerging as global hub of clinical trials because of so-called Indian advantages such as availability of large number of patients, highly motivated medical expertise with English dialect, large pool of paramedical workers, strong information technology supplies, and low cost.^[7] In spite of these factors, India is still lagging behind other Asian countries in number of registered clinical trials. For the flawless conduct of trials, one needs competent and well-trained personnel, well-versed with GCP guidelines. However, knowledge about various principles, ethics, the methodology of clinical trials in accordance with GCP guidelines is first imparted to health care professionals during the process of clinical trials. Recently, Supreme Court of India has criticized the laxity on the part of government as well on health care professionals on the way clinical trials are being conducted in India.^[8] Because clinical trials are necessary to translate scientifically advanced knowledge into better public health, so answer cannot be an abandonment of clinical trials.

To improve the credibility of data and to ensure the safety and well-being of the patients GCP guidelines play an important role. However, the irony is that little is known about the awareness about GCP guidelines among health care providers who are primarily responsible for conducting these clinical trials. This study was planned to know the awareness and perception of health care workers about GCP guidelines and change in that after an educational training program.

Aims and objectives

The aim behind conducting this study was to explore awareness and perception of the health care providers towards GCP and subsequent change in these after a day's training session on GCP guidelines.

Study design and study site

A cross-sectional descriptive questionnaire-based study was conducted amongst health care providers of a Tertiary Health Care and Teaching Institute of North India in February 2015. A total of 120 voluntary health care providers were enrolled in the study.

Study instrument

A self-administrated questionnaire was framed in English language. The questionnaire consists of three parts. The first part contained the basic demographic data of the participants. Part two was a general statement regarding the role of participant as health care provider, that is, physician, or dental doctors or nursing staff. The third part contained the main descriptive set of questions seeking the knowledge in depth of health care providers about GCP guidelines. A day's interactive educational training program was given by experts in GCP guidelines, and again a self-administrated questionnaire was given. Verbal consent was obtained before giving the questionnaire; participants were ensured that their participation is voluntary, and their identity will not be disclosed, and confidentiality will be maintained.

Statistical analysis

Statistical analysis was done using descriptive statistics. To measure changes in the perception and awareness of GCP guidelines among healthcare professionals between pre- and post-intervention and to evaluate the impact of effectiveness of educational intervention among healthcare professionals, the two-tailed Z-test was used. All statistical calculations were performed using EPI INFO, a web-based epidemiological and statistical calculator. The significance was assessed at a 5% level of significance ($P < 0.05$) with 95% confidence interval.

RESULTS

Out of 120 participants, 80 were medical doctors (48 specialists, 22 residents), 20 dental doctors, and 20 nurses. The ratio of male to female participants was 5:3 in doctors, 3:1 dentists and 1:8 nurses. It was found that 60% of medical doctors, 45% of dental doctors, and 20% of nurses claimed their awareness about good clinical principles. Details of participants' characteristics are shown in Table 1.

Among respondents, 70 (87.5%) medical doctors, 15 (75%) dental doctors showed interest for conducting clinical trials, and 17 (85%) nurses also wanted to be part of clinical trials, of that 30 (37.5%) doctors, 5 (25%) dentists

Table 1: Participants and their awareness about GCP guidelines

	Doctors	Dentists	Nurses
Age group years			
≤29	20	5	12
30-39	30	8	5
40-50	20	2	3
>51	10	5	0
Male: female ratio	5:3	3:1	1:8
Awareness about GCP guidelines (%)	48 (60)	9 (45)	4 (20)
Past experience of conducting clinical trials (%)	30 (37.5)	5 (25)	0

GCP=Good clinical practice

reported their past participation in clinical trials. After the training session on GCP, there was increase in a number of the participants who were interested in participating in clinical trials (75 of medical doctors, 17 dentists, and 18 nurses). Most of the respondents 75 (93.4%) doctors, 15 (75%) dentists, and 12 (60%) nurses were aware of “informed consent” and other issues related to “informed consent.” None of the participants had taken any formal training in GCP guidelines in the past. However, 55 (68.8%) doctors, 16 (80%) dentist acquired some knowledge through journals, whereas 60% of nurses responded that they never had any opportunity to gain such information.

To know the attitudes of participants about clinical trials, participants were asked regarding the benefits of conducting the clinical trials, 85 (70.8%) of participants, before attending the training program, 92 (76.7%) of participants after attending the training program were of opinion that clinical trials will

help the patients with new treatments. 25 (20.8%) participants felt that conducting clinical trial is just a waste of time and energy but after training session only 10 (8.33%) of these stick to that ($P = 0.002$) [Table 2].

The participants were also questioned about their awareness about principles of the World Medical Association Declaration of Helsinki. Among all respondents, 65 (81.2%) doctors stated that they had knowledge of the declaration but to some extent, only two doctors were fully aware about this declaration [Figure 1]. This was reflected by their response to next question on ethics related to this declaration as only two doctors were able to answer all questions related to the declaration correctly.

After the training session on GCP, 20 (25%) doctors were of the opinion that they fully understood the declaration of Helsinki, 50 (71.4%) felt that they now know most of it and 10 (1.3%) to some extent [Figure 2]. When asked about the

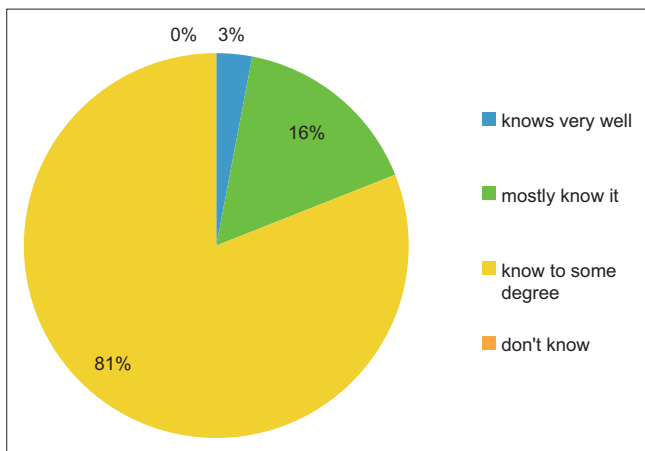


Figure 1: Pre-training awareness of principles of declaration of Helsinki

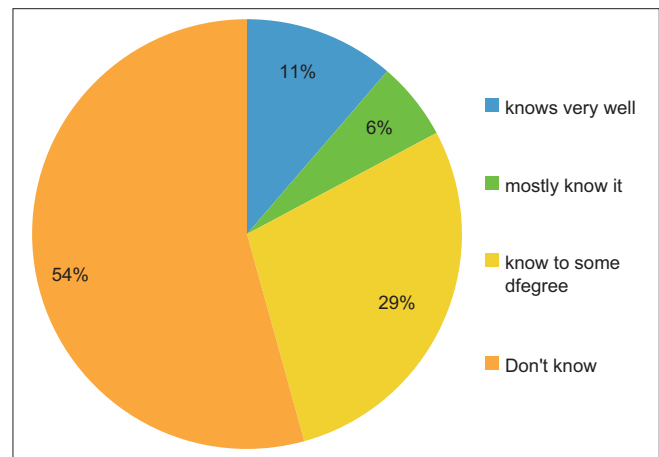


Figure 2: Post-training awareness of principles of declaration of Helsinki

Table 2: Pre-training and post-training response and perception of the participants

	Pre-training response n (%)	Post-training response n (%)	P
Interest in conducting/part of clinical trials	Doctors-70 (87.5) Dentists-15 (75) Nurses-17 (85) Total-102 (85)	Doctors-74 (92.5) Dentists-17 (85) Nurses-18 (90) Total-109 (91)	0.281 0.114 0.632 0.153
What do you think are the merits of conducting clinical trials?			
1. May help patients with new treatments	85	92	0.089
2. Can contribute to medical progress	70	78	0.158
3. Can obtain a wider and deeper understanding of the disease	65	90	0.0001
4. Can obtain research grants or other rewards	65	80	0.009
5. Can write papers about the clinical trials	75	85	0.053
6. Conducting clinical trial is just a waste of time and energy	25	10	0.002
7. Others	6	4	0.477
What are the major problems in conducting clinical trials?			
1. Lack of time	65	65	0.744
2. Shortage of clinical research coordinators	74	85	0.035
3. Insufficiency of infrastructure	60	50	0.119
4. Difficulties in communication with the ethical committee	25	20	0.354
5. Enrollment of trial participants	10	30	0.0001
6. Funding	67	68	0.869
7. Others			

major problems they are likely to face in conducting clinical trial, majority 60 (75%) of doctors and 14 (70%) dentists felt shortage of clinical research coordinators/research associates, whereas 17 (85%) nurses stated lack of knowledge about various issues related to clinical research. After training session, number of participants who thought that it is difficult to enroll the trial participants increased from 10 (8.33%) to 30 (25%) ($P = 0.0001$) [Table 2].

In addition, participants were asked that how we can overcome the obstacles for the development of clinical trials majority of participants want trained specialized people in clinical trials and the establishment of clinical trial centers [Figure 3].

DISCUSSION

We desired to study the level of understanding, awareness, and perception of the health care professionals toward GCP Guidelines and impact of educational training program on this as there is paucity of data regarding this in English literature.

It was found that most of the participants wanted to be part of clinical trials even though only few of them had previous experience of conducting clinical trials. Furthermore, the inclination of the health professional toward clinical research increased after a day of the educational training program. This is in contrast to a study conducted in Pakistan which showed the poor response of doctors toward clinical research.^[9]

The number of participants who actually had formal training in the GCP guidelines was found to be very low, which is in synchronous with recent report which stated that there is lack of knowledge of ethics, GCP guidelines and other skills for management of clinical trials among investigators.^[10] However, it was observed that majority wanted to acquire these skills, but could not because of one reason or the other. The major hindrance participants felt was a shortage of trained clinical

research associates. This is in contrast to study done in Mumbai where the major reason stated was paucity of time.^[10,11] The difference in views might be because of more opportunity for health professionals in Mumbai to acquire training in GCP guidelines. A financial constraint was also considered as an important factor responsible for less number of research trials. However, after training program, need for more clinical trial training centers was felt rather than just financial support. Clinical trial training will increase the number of skilled personnel to conduct the clinical trials in an efficient manner. This will further help to tide over the recent controversy of conducting clinical trials in India and issues regarding the credibility of clinical research being done here.

Our current curriculum lacks a formal training for clinical research and health care professionals have to learn by their own means. By creating more awareness in physicians, dental doctors, and nurses about clinical research, we can build confidence in them to conduct the clinical trials more diligently, and move away from “guinea pig syndrome.” Our current guidelines recommend that clinical trials can only be done at those centers which are certified for purpose, and members of ethics committee of that site should be trained in GCP guidelines. Based upon these we recommend that:

1. Clinical research education should be part of undergraduate pharmacology curriculum. Apart from having theoretical approach the students can be given small research project so that they can have a little experience in conducting, data collection and result analysis in research studies
2. To ensure that the clinical research personnel are adequately trained, Government should help in setting up of more clinical trial training centers so that those who are involved in clinical trials that is, trial designers, investigators, monitors, and analyzers, etc. can be acquainted with research methodology of clinical trials.

CONCLUSION

The results of the present study demonstrate that an educational intervention can increase the knowledge and awareness about principles and techniques of clinical research among health care providers and this knowledge would help them remove misconceptions and motivate them to undertake clinical research. Further studies are needed to know the impact of such programs.

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Nil.

Conflicts of interest

There are no conflicts of interest.

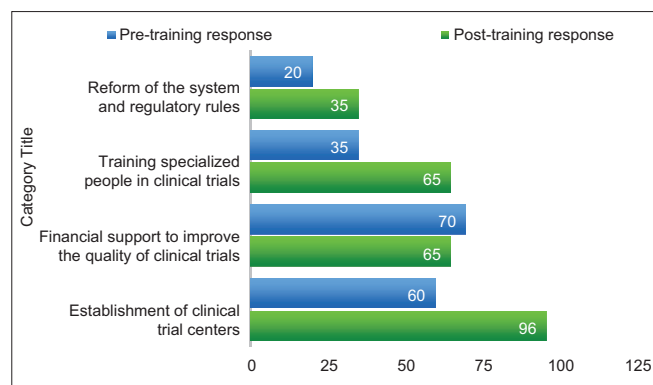


Figure 3: Pretraining and posttraining response on improvement of clinical trials quality

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