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Assessment of impact of education intervention on knowledge, attitude and awareness of good clinical practice among health care professionals

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Abstract

Background: Good clinical practice guidelines are prepositions for healthcare providers to generate reliable clinical trial data. The present study was conducted to assess impact of education intervention on knowledge, attitude and awareness of good clinical practice among health care.

Materials and Methods: 140 health care providers (Doctors, dentists, nurses) of both genders were given a self-administrated questionnaire was constructed regarding the role of participant as health care provider and knowledge about GCP guidelines. Response was recorded before and after the training.

Results: Awareness regarding principles of declaration of Helsinki at pre- training session and post training session found to be knows very well in 7 and 12 respectively, mostly know it in 11 and 5 respectively, know to some degree in 20 and 58 respectively and don't know in 62 and 25 respectively. There was significant difference in response and perception of the subjects at pre- training and post training sessions ($P < 0.05$).

Conclusion: Training found to improve knowledge as well as awareness about principles and techniques of clinical research.

Keywords: Dentists, good clinical practice, training

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]. 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 [2].

As per the GCP guidelines, everyone involved in the conduct of clinical research must be competent to perform their tasks, qualified, trained, and experienced to ensure that they are prepared to undertake their responsibilities [3]. It is mandatory for the investigators to undergo GCP training before undertaking any project which involves human participants. At the Tata Memorial Centre (TMC), clinicians, and basic scientists; principal investigators submit their proposals to the Institutional Ethics Committee (IEC) for scientific and ethical approval [4]. IEC members of Advanced Centre for Training, Research, and Education in Cancer (ACTREC), TMC identified the need to conduct a GCP training session for researchers. It was also a requirement for certification by the Association for Accreditation of Human Research Protection Programme [5]. The present study was conducted to assess impact of education intervention on knowledge, attitude and awareness of good clinical practice among health care.

Materials and Methods

The present study was conducted among 140 health care providers (Doctors, dentists, nurses) of both genders. All were informed regarding the study and their consent was obtained. Particulars such as name, age, gender etc. was recorded. A self-administrated questionnaire was constructed regarding the role of participant as health care provider and knowledge about GCP guidelines.

A day’s interactive educational training program was given by experts in GCP guidelines. Response was recorded before and after the training. Results were tabulated and statistically analyzed. *P* value less than 0.05 was considered significant.

Results

Table 1: Distribution of subjects

Total-140		
Gender	Males	Females
Number	80	60

Table 2 shows that out of 140 subjects, males were 80 and females were 60.

Table 2: Awareness of principles of declaration of Helsinki

Awareness	Pre-training (%)	Post training (%)	<i>P</i> value
Knows very well	7	12	0.01
Mostly know it	11	5	
Know to some degree	20	58	
Don’t know	62	25	

Table 2, Fig 1 shows that awareness regarding principles of declaration of Helsinki at pre-training session and post training session found to be knows very well in 7 and 12 respectively, mostly know it in 11 and 5 respectively, know to some degree in 20 and 58 respectively and don’t know in 62 and 25 respectively. The difference was significant (*P*< 0.05).

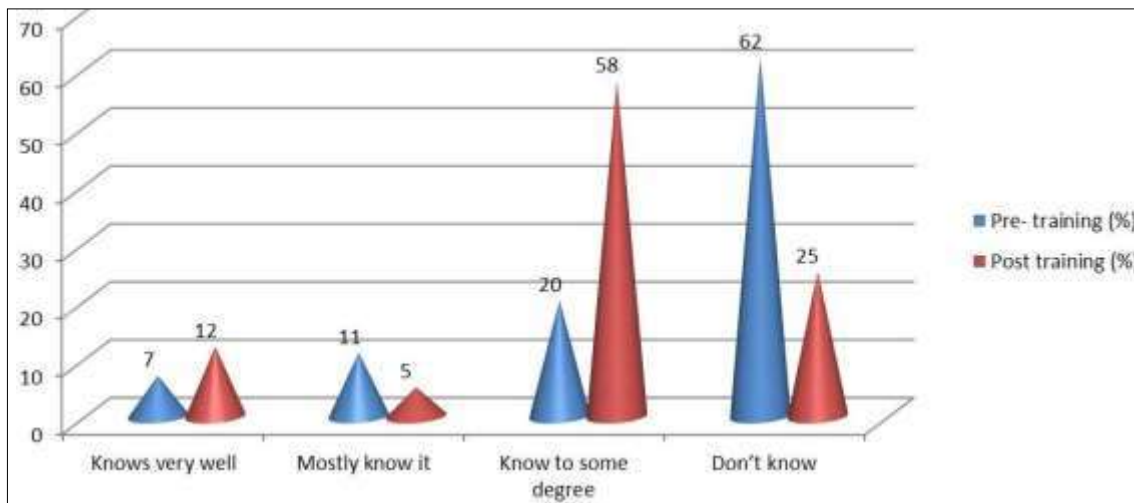


Fig 1: Awareness of principles of declaration of Helsinki

Table 3: Response and perception of the subjects

Awareness	Pre-training (%)	Post training (%)	<i>P</i> value
What are the merits of conducting clinical trials?			
help patients with new treatments	78	89	0.02
contribute to medical progress	85	97	
write papers about the clinical trials	72	86	
obtain research grants or other rewards	84	95	
What are the major problems in conducting clinical trials?			
Lack of time	80	92	0.04
Shortage of clinical research coordinators	77	85	
Insufficiency of infrastructure	90	97	
Funding	82	94	
Others	5	4	

Table 3 shows that there was significant difference in response and perception of the subjects at pre-training and post training sessions (*P*<0.05).

Discussion

Good Clinical Practice (GCP) is a set of guidelines that must be followed when conducting clinical trials to ensure that the rights and wellbeing of the trial participants are protected and that the data generated in the trial is valid [6]. It is an international ethical and scientific quality standard for designing, conducting, performance monitoring, auditing, recording, analysing and reporting on clinical trials that involve human participants [7]. The guidelines were developed in the mid-1990s in order to provide clinical trials with a unified standard across the European Union, Japan

and the United States, and to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions [8]. In-service professional education has proved to be a challenge as it requires efficient training strategies at a clinical research site in which research professionals are actively or indirectly involved in the trial related activities [9]. The present study was conducted to assess impact of education intervention on knowledge, attitude and awareness of good clinical practice among health care.

In present study, out of 140 subjects, males were 80 and females were 60. Goel *et al.* [10]. assessed 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. The impact of the

effectiveness of educational intervention among healthcare professionals was evaluated by two-tailed Z-test. 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.

We found that awareness regarding principles of declaration of Helsinki at pre- training session and post training session found to be knows very well in 7 and 12 respectively, mostly know it in 11 and 5 respectively, know to some degree in 20 and 58 respectively and don't know in 62 and 25 respectively. Awatagiri *et al.* ^[11] conducted a study to strengthen the knowledge and awareness regarding GCP. A semi-structured questionnaire was used to collect the data in pre and post-test. A total of 138 participants were participated in the study. The training session was pre-planned which included a lecture followed by the question-answer session. This study has resulted in overall improvement of knowledge with a median difference of 5 with P -value<0.001. There was a statistically significant improvement of knowledge between pre and post-test of those having GCP training in the past, working group and education.

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 ^[12].

Conclusion

Authors found that training found to improve knowledge as well as awareness about principles and techniques of clinical research.

References

- Poongothai S, Unnikrishnan R, Balasubramanian J, Nair MD, Mohan V. Why are clinical trials necessary in India? *Perspect Clin Res* 2014;5:55-9.
- Chakraborty BS. Clinical research in India: The current scenario and prospects. *J Adv Pharm Technol Res* 2013;4:126-7.
- Sabzwari S, Kauser S, Khuwaja AK. Experiences, attitudes and barriers towards research amongst junior faculty of Pakistani medical universities. *BMC Med Educ* 2009;9:68.
- Dhodi DK, Thakkar KB, Billa G, Khobragade AA, Sinha SR, Patel SB. Knowledge, attitude and practices of medical students and teachers towards clinical research in a Tertiary Care Hospital in Mumbai Cross sectional survey. *J Contemp Med Educ* 2013;1:238-44.
- Pawar DB, Gawde SR, Marathe PA. Awareness about medical research among resident doctors in a tertiary care hospital: A cross-sectional survey. *Perspect Clin Res* 2012;3:57-61.
- Lader E, Cannon CP, Ohman MO *et al.* The clinician as investigator. Participating in clinical trials in the practice setting. *Circulation* 2004;109:2672-9.
- Robertson K, Gan TJ. Clinical research and good clinical practice. *Best Practice and Research Clinical*

- Anaesthesiology 2001;15(4):655-67.
- Hukkanen J, Jacob P III, Benowitz NL. Metabolism and disposition kinetics of nicotine 2005;57(1):79-115.
- Acosta C, Galindo CM, Ochiai RL *et al.* Implementation of good clinical practice guidelines in vaccine trials in developing countries. *Vaccine* 2007;25:2852-7.
- WHO. Handbook for Good Clinical Practice (GCP). Guidance for implementation, World Health Organization. Geneva. Switzerland 2002.
- Goel D, Walia R, Sharma P, Kaur H, Agnihotri P. Impact of educational intervention on knowledge, attitude and awareness of good clinical practice among health care providers. *Perspect Clin Res* 2017;8:90-4.
- Awatagiri K, Gadgil D, Kannan S, Rane P, Bandekar B, Sawant N, Parikh P, Murthy V. Effect of a planned training session on good clinical practice knowledge in research professionals: A pilot study. *Perspectives in clinical research* 2019;10(1):20.