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Impact of Educational Intervention on Knowledge, Attitude and Awareness of Good Clinical Practice among Health Care Providers

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Abstract:*Introduction: 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. The present study intends to assess health care professionals' knowledge, perception, and attitude towards compliance with the International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines in basic aspects of conduct of clinical trial and associated regulatory as well as ethical issues before and after the educational intervention in form of a workshop on Good Clinical Practice (GCP).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.Methods: After obtaining approval from the IEC and valid informed consent, the participants were recruited into the study. A cross-sectional descriptive questionnaire-based study was conducted amongst health care providers, i.e., clinicians and ethics committee members of total 70 participants were enrolled for this one day workshop. Participants completed the questionnaire before and after undergoing a day training program in GCP guidelines. Comparison between answers in pre and post workshop questionnaire was done. The primary outcome was knowledge, which was evaluated using the paired t test.Results: In Pre workshop, out of 70, total 60 (85.7%) participants had answered all 20 questions; while 7 (10%) participants had skipped to answer one question .3 out of 70(4.3%) participants had not answered 4 to6 questions out of 20. Total 66 out of 70 (94.3%) participants in post workshop answered all questions. All 20 (100%) questions were answered correctly in post workshop as compared to 14 (70%) questions in pre workshop. So, in post-workshop, there were significant (P <0.005) gains in knowledge regarding all good clinical practice questions. 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: Ethics, Questionnaires,Awareness, clinical research, good clinical practice, health-care providers.*

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I. Introduction

Good clinical practice (GCP) guidelines are prepositions for healthcare providers to generate reliable clinical trial data.The ICH-GCP guidelines are used in clinical trials throughout the world with the main aim of protecting and preserving human rights.[1] Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected; consistent with the principles that have their origin in the declaration of Helsinki, and that the clinical trial data are credible.[2]

In India, these guidelines have evolved with consideration of the WHO, [3]USFDA, [4]and European GCP[5]guidelines as well as the Ethical Guidelines for biomedical research on human subjects issued by the Indian Council of Medical Research.[6] 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.[7]

The number of trials in India, as per reports of clinical trials. gov, 1.4% of global clinical trials are done in India, while the country has 16% of the world's population and carries 20% disease burden in the world. However the number of clinical trials in India becoming more stable and predictable.[8]

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.As there is a good number of clinical trials conducted across India, the need of the hour to evaluate the knowledge of the clinicians and ethics committee members conducting clinical trials in our institution. So, 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.

II. Aims And Objectives

The aim of 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.

III. Materials and Methods

***Study design and study population*:**After obtaining approval from the IEC and valid informed consent, the participants were recruited into the study. A cross-sectional descriptive questionnaire-based study was conducted amongst health care providers (clinicians and ethics committee members) of a Tertiary Health Care and Teaching Institute, AMC, KGH, Visakhapatnam in February 2018.

***Sample size*:** 70 individuals.

A total of 70 health care providers were enrolled for this One day workshop on "Good Clinical Practice", which included important ethical and regulatory issues regarding clinical research. Various resource persons from industry and academia were chosen to address the workshop. Pre-workshop questionnaire of 20questions were distributed before the actual topic started. Each participant had to fill the questionnaire form and return it within 15 minutes. Again at the end of workshop, post-workshop questionnaire containing the same questions were distributed and the participants were asked to fill the form. Sequence of questions was changed in post workshop questionnaire. Comparison between answers in pre and post workshop questionnaire was done. The primary outcome was knowledge, which was evaluated using the paired t test.

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 paired t test was used. All statistical calculations were performed using Microsoft Excel and the statistical package for Graph pad Prism version 8.0.The significance was assessed at a 5% level of significance ($P< 0.05$) with 95% confidence interval.

IV. Results

In Pre workshop, out of 70, total 60 (85.7%) participants had answered all 20 questions, while 7 (10%) participants had skipped to answer one question. 3 out of 70 (4.3%) participants had not answered 4 to 6 questions out of 20. Total 66 out of 70 (94.3%) participants in post workshop answered all questions. All 20 (100%) questions were answered correctly in post workshop as compared to 14 (70%) questions in pre workshop. So, in post-workshop, there were significant ($P <0.005$) gains in knowledge regarding all good clinical practice questions.

For the correctness of the knowledge, paired t test was used to evaluate change in objective knowledge. Differences in percentage were calculated. Highest increase in knowledge was seen with questions involving Declaration of Helsinki and ICH. Majority of participants knew about "IRB", "Sponsor", "SAE" etc. 16 out 20 questions were answered correctly by all the participants (100%) in post workshop evaluation.

***Table no 1*: Showsdifference % of correct answers between before and after GCP workshop.**

S.NO	QUESTIONS	% OF CORRECT ANSWERS		DIFFERENCES
		PRE WORKSHOP	POST WORKSHOP	
1.	Maximum number of trials an investigator can conduct at any given time is?	71.4%	100%	28.6
2.	Audio-visual recording of informed consent process is mandatory for cases where vulnerable population is involved?	78.5%	100%	21.5
3.	In cases of clinical trials involving HIV patients or those effected by Sexually Transmitted Disease, is Audio-visual recording mandatory?	70%	100%	30
4.	Registration of Ethics Committee should be renewed after how many years?	68.6%	100%	31.4
5.	Clinical trials which involves patient population needs approval from which of the following EC?	61.4%	100%	38.6
6.	National Regulatory Authority (NRA) under Directorate General of Health Services, Ministry of Health & Family	85.7%	100%	14.3

	Welfare, Government of India, responsible for safeguard and for enhancing public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices is?			
7.	What is the time period within the occurrence of a SAE in which the investigator should report to DCGI, Sponsor and EC?	82.8%	100%	17.2
8.	A new drug is defined as one which is approved for use but has been on the market for less than how many years?	46.3%	72.4%	26.1
9.	In the case of permission for conduct of Investigator Initiated Study (IIS) with 'new drug', not intended to submit to the regulatory authority, is approval from DCGI mandatory?	28.3%	68.3%	40
10	Formulae for Compensation for death in case of a clinical trial are?	81.4%	100%	18.6
11.	Indian diagnostic & research laboratories can import/export biological material without the need of an import/export license?	85.7%	100%	14.3
12.	For addition of a new site in a study, approval from DCGI is mandatory?	8.3%	67.7%	59.4
13.	For addition of a new investigator in a study, approval from DCGI is mandatory?	70%	100%	30
14.	When was the revised version of ICMR guidelines 'Ethical Guidelines for Biomedical Research on Human Participants' released?	71.4%	100%	28.6
15.	Name of the online portal for application, submission, processing and grant of permission for clinical trials, in India?	71.4%	100%	28.6
16.	What is the minimum validity of test license of imported study drugs in India?	57.3%	73.6%	16.3
17.	For approval of a clinical trial application, which is the first body that approves it in the three tier review process?	48.5%	100%	51.5
18.	What is the timeline for IEC during which it should submit its detailed report on the SAE, along with its opinion on the financial compensation to the DCGI?	47.9%	100%	52.1
19.	Within how many days the detail report of SAE report along with complete analysis should be send by an investigator to DCGI, Chairman of IEC and the Head of the institution where the trial has been conducted?	77.7%	100%	22.3
20.	When should a study/clinical befirst registered in CTRI?	77.1%	100%	22.9

V. Discussion

Good Clinical Practice is the process to define and ensure ethical and scientific quality standards for clinical research and it is consistent with the principles enunciated in Declaration of Helsinki and International Conference of Harmonization (ICH). Medical faculties are likely to become principal investigator in different areas of clinical research or member of institutional ethics committee. Due to larger number of patient load as well as other responsibilities of medical education, knowledge regarding these regulatory guidelines always remains in grey area.So one day workshop was conducted to educate medical faculties on the core areas of GCP. Knowledge was assessed by pre workshop and post workshop questionnaire. Similar kind of study was undertaken by Sorensen GB & Kristensen AB involvingDanish physicians.[9]They used questionnaire that consists of 22 questions as compared to our 20 questions. Also, there was involvement of 1000 physicians of different hospitals. In present study, only 70 participants were included. 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.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. 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, medical writers, report writers, trial designers, investigators, monitors, and analyzers, etc. can be acquainted with research methodology and with compliance of regulatory authority of clinical trials.

VI. 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. Hence multiple workshops on GCP will help us to know the efficient methodology of imparting awareness of

GCP among stakeholders. Further studies are needed to know the impact of such programs. However, changes in behaviour and attitude were not studied by this questionnaire based study.

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