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Knowledge, Attitude & Practices of Clinical Research with Special Reference to GCP (Good Clinical Practice) among Post-graduate Medical Students & Medical Teachers in a Tertiary Care Hospital, Pune – A Cross-sectional Survey

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Anil Pardeshi[1*], Pallavi Pardeshi [2]

[1] University Department of Interpathy Research & Technology (UDIRT), MUHS Nasik (INDIA)

[2] CSMSS Ayurved College, Aurangabad (INDIA)

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ABSTRACT

Good **C**linical **P**ractice (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(DoH), and that the clinical trial data are credible.[1] The GCP not only serves the interest of clinicians and those involved in the research process but also protects the rights, safety, and well-being of subjects[11] Participants were screened according to inclusion & exclusion criteria. Informed consent of the participant was obtained. A validated questionnaire was given to participant & was collected after completion of answering questions by the participant. Assessment of Knowledge, attitude, and practice (KAP) characteristics for GCP was done with the help of collected questionnaire & by using statistical tests. It was found that the participants were aware of the Informed Consent Process(76%)& about Sponsor, Investigator & IEC responsibilities (75%); but having less knowledge about Essential Documents & Pharmacovigilance (58.33%). The KAP of Medical Teachers (77.1%) was found to be more than the KAP of Post-graduate Medical Students (67%). Pearson's Correlation statistical test was applied. The value of R is 0.4916 at 0.01 level (2-tailed) which is significant. There is significant positive correlation was found between knowledge, attitude & practice among Medical Teachers & post-graduate Medical students about GCP. This study helped to find the knowledge of participants about GCP. It has assessed the attitude and practice about GCP. This study will definitely help to increase the awareness about the GCP and its use in medical research.

INTRODUCTION:

It is known that the triad of knowledge, attitudes, and practices (KAP) in combination governs all aspects of life in human societies, and all the three pillars together make up the dynamic system of life itself. [(1)] These three components can be defined thus: Knowledge is the capacity to acquire, retain and use information; a mixture of comprehension, experience, discernment, and skill. [(1)] Attitudes refer to inclinations to react in a certain way to certain situations, to see and interpret events according to certain predispositions; or to organize opinions into coherent and interrelated structures, and practices mean the application of rules and knowledge that leads to action. 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)]

Clinical research imparts skills that are a literature review, data collection, statistical analysis & critical appraisal of evidence. Training for research skills & clinical research experience may help career decisions.[(3)]

It is seen that research programs in medical colleges get the lowest priority because of lack of funding, manpower resources hence responsible for poor quality in research-oriented medical education. [(4)] In the state of Maharashtra, with the exception of MD pharmacology, MSc Pharmaceutical Medicine & DM Clinical Pharmacology degree courses, training in clinical research has not been made a part of the medical curriculum.[(5)]

The study conducted by Shetty YC *& et.al,* explains that the project application forms submitted to IEC, found that majority of the academic project proposals were lacking basic details, method of recruitment and details like appropriate titles, budget details, method of recruitment details regarding vital issues like vulnerability, and compensation for participation/ injury.[(6)]The objective of this ICHGCP Guideline is to provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in this jurisdiction.[2] The guideline was developed with consideration of the

current good clinical practices of the European Union (EU), Japan and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization (WHO).[2]

The practice of medicine today is driven by evidence: data derived from published, peer-reviewed reports, many of which come from randomized controlled clinical trials.[7] In the past 30 years, the number of clinical trials has increased, consistently with the increase in the number of new drugs, devices and the treatment strategies.[8]

Published research usually alters clinical practice and a few landmark clinical trials have resulted in major changes in medical practice.[9] The increasing number of trials generated a need to ensure that participants in clinical trials are protected and that the data reported are valid.[10] As a result, a standard international guideline named Good Clinical Practice was developed by the World Health Organization in the mid-1990s for this purpose.[(11,12)] 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.[(11,12)]

The GCP guideline is intended for all research, including : all types of sponsors, including private, government, university or industry ; all study designs, including randomized clinical trials (RCTs), double blinded, open-label or comparator ; all study phases, including Phase I to Phase IV trials and all investigational products, including new drugs, new indications, biomedical devices, new methodology or new surgical techniques. The World Health Organization Good Clinical Practice consists of 14 principles.[(11, 12)]

The vigorous ethical requirements of Good Clinical Practice (GCP) for the protection of the study subject will improve their rights, safety, and well-being.GCP demands more of the clinical researcher in time, resource and money. In return, the data obtained from clinical trials conducted in accordance with the GCP should be more reliable, having undergone an extensive quality control process. The conduct of clinical research in accordance with the principles of GCP helps to ensure that clinical research participants are not exposed to undue risk and that data generated from the research are valid and accurate. Thus the GCP not only serves the interest of clinicians and those involved in the research process but also protects the rights, safety, and well-being of the subjects and ensuring that investigations are scientifically sound and advance public

health goals. Beneficence and autonomy are of utmost importance although at times it may be difficult to draw a clear boundary between right and wrong and what is ethical and not.

When assessing the KAP of a community, it is useful to divide that community into smaller sub-categories. In this case, these categories can be defined as the Medical Community and the General Community. The Medical Community consists of those who are responsible for the provision of Medical Care to the population. It includes the doctors, paramedics, pharmaceutical providers, and others. This category could be further split into Medical Practitioners and Paramedical Personnel in areas with a large enough population of these two groups. (1)

REVIEW OF LITERATURE:

2013:The study done by **Dhodi DK & *et.al*,** lack of trained manpower is one of the challenges faced in clinical research. The knowledge gaps & misconceptions regarding clinical research should be annulled by training the trainers & including the clinical research training in the medical curriculum.(20)

2009: The GCP was established as a basis both for the scientific and ethical integrity of research involving human subjects and for generating valid observations and sound documentation of research findings. It provides a framework for clinical investigators and pharmaceutical companies to conduct clinical trials according to similar rules and regulations, to ensure clinical research is consistently performed to high ethical and scientific standards and an assurance that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial subjects are protected.[13]

2004: The conducting of clinical research in accordance with the principles of GCP helps to ensure that the participants in clinical research are not exposed to undue risk and that data generated in the research are valid and accurate. Thus the GCP not only serves the interest of clinicians and those involved in the research process but also protects the rights, safety, and well-being of subjects and ensures that investigations are scientifically sound and advance public health goals.[14]

RATIONALE:

The conducting of clinical research in accordance with the principles of GCP helps to ensure that the participants in clinical research are not exposed to undue risk and that data generated in the research are valid and accurate. Thus the GCP not only serves the interest of clinicians and those involved in the research process but also protects the rights, safety, and well-being of the subjects and ensures that investigations are scientifically sound & advance public health goals.

Our study helps to find the knowledge participants about GCP. It has assessed the attitude and practice about GCP. This study helps to increase the awareness about the GCP and its use in medical research.

STUDY DESIGN:

Study Type:	Prospective, Observational & Cross-sectional
Study Duration:	1 Year.
Study Site:	Tertiary Care Hospital, Pune
Sample-size:	150

Inclusion Criteria-

1. Participants of Tertiary Care Hospital, Pune such as Professors and medical students of various departments of Hospital.
2. Participants of either sex.
3. Participants willing to give voluntarily free written informed consent.

Exclusion Criteria-

1. Participants unable to continue the study during study duration.

MATERIALS & METHODS:

1. **Validation of Questionnaire-**

The pre-defined questionnaire was used for the study. Validation of Questionnaire was done prior the study initiation from UDIRT, MUHS Nasik. Content validation was used for validation of a questionnaire. For the process of validation, a questionnaire was introduced to 10 study participants providing them space for suggestions. Changes were reintroduced to participants & reliability of the questionnaire was also be checked by giving the option for rating the each question. After that, a questionnaire was given to expert of their opinion & again reliability was checked for the questionnaire. The process of validation was completed & then it was used for the study.

2. **Written Informed Consent**-

This was performed prior to enrollment of participant in the study. After screening the participant according to inclusion-exclusion criteria, the interviewer ensured that the participant has been given enough information, both written & oral about the possible risks, benefits that the study will evolved. They were informed that participation is purely voluntary. ICF was signed & dated by the participant & a copy of PIS (Participant Information Sheet) document was given to the participant & a copy was retained in the study records.

Sample Size Estimation-

This is an observational study & no such previous study has been done. So, no formal sample-size calculation was done. Total 150 participants were taken for study.

Outcomes of study-

1. Knowledge, attitude and practice of participants towards GCP.
2. Association of Knowledge, attitude and practice characteristics among participants for GCP.
3. Factors influencing the Knowledge, attitude, and practice for GCP among the participants.

Statistical Analysis-

Pearson's Correlation Statistical Test was applied for collected data and analysis was done with the help of SPSS.

ACKNOWLEDGEMENT

We are especially grateful towards our study participants who encourage us by giving information of Questionnaire, also the Institutional Ethics Committee (IEC) MUHS Nasik for granting us to do the study.

Conflict of Interest- No

RESULT:

During the study, we randomly circulated KAP study questionnaire among 175 participants from different departments. Out of that 150 Participants were responded & filled the questionnaire. Participants included in the study were from various departments of Tertiary Care Hospital, Pune. Out of which 105 participants were male & 45 were female participants.

Department wise No. of Participants-

Sr No	Department	No of Participants
1	Medicine	39
2	Pediatrics	27
3	PSM	13
4	Skin	12
5	Nephrology& Neurology	7
6	Clinical Pharmacology	8
7	Chest TB, ART	4
8	Anaesthesiology	14
9	Anatomy	6
10	Physiology	5
11	Biochemistry	3
12	Microbiology	3
13	Forensic Medicine & Toxicology	4
14	Pathology	2
15	Others	3

Designation wise No of participants-

Sr No	Designation	No of Participants
1	HOD	4
2	Professor	6
3	Asso. Professor/ Addl Professor/ Asst Professor	9
4	Senior Resident	49
5	Junior Resident	82

Assessment for Knowledge of Clinical Research as per GCP -

Sr.No	Questions	Correct Answer (%)	Wrong Answer (%)
1	What isICHGCP?	85%	15%
2	GCP Deals with Clinical Research & not Clinical Practice?	78%	22%
3	As per new guidelines, AV recording is mandatory for new Clinical Trials?	60%	40%
4	The Head of Regulatory Authority in India is ? (DCGI)	84%	16%
5	Does GCP states responsibilities of Sponsor or Investigator?	78%	22%
6	The protocol should be approved by IEC before study Initiation?	72%	28%
7	Does GCP give ED required for Medical research?	77%	23%
8	ICF is mandatory in Clinical trials?	76%	24%
9	Is any procedure given in GCP to report any ADR occurred during clinical research?	66%	34%
10	Safety &Well-beingof the Subjects have been given priority in GCP?	73%	27%

Assessment for Attitude towards Clinical Research as per GCP-

Sr. No	Questions	Correct Answer (%)	Wrong Answer (%)
1	What do you think; Academic clinical trials are more ethical than industry-sponsored CT?	70%	30%
2	Risk-benefit ratio should be assessed in any Clinical trial?	65%	35%
3	Do you think, it is necessary to take consent of every Participant during research?	82%	18%
4	IRB/IEC has rights to stop the clinical trial, What do you think?	58%	42%
5	What do you think, 'If it is not documented it is not done' This is followed by GCP?	72%	28%

Assessment for Practice of Clinical Research as per GCP-

Sr No	Questions	Correct Answer	Wrong answer
1	Do you prepare the research protocol according to GCP?	89%	11%
2	Do you give information about 'Placebo' if it is involved in the trial?	90%	10%
3	Have you conducted Phase I studies in childbearing age female volunteers?	70%	30%
4	Informed Consent Process is not 'informed 'at all, Did it happen with you?	54%	46%
5	Do you disclose Participant's Identity & Address to Sponsor for Reimbursement purpose?	60%	40%
6	Do you give money to the patient for participation in the study?	68%	32%
7	Do you take Assent for pediatric age group?	73%	27%
8	Registration of Clinical Trials is not necessary for Academic Clinical trials?	77%	23%
9	Do you take consent of LAR if the patient is illiterate?	75%	25%
10	Do you give priority to safety, rights, and well-being of participant during research?	74%	26%

DISCUSSION

All members of IECs should be aware of the different safety terminologies and pharmacovigilance activities conducted during clinical trials to safeguard the subjects. However, the study conducted by ***Bhowmick S & et.al,***(in 2014) had shown the low level of awareness among both medical and nonmedical members of IEC about safety terminologies mentioned in GCP.[15] Our study which was done in Post-graduate Medical Students & Medical Teachers of Tertiary Care Hospital (Pune) have shown about 75% knowledge& 69.40% of attitude &73% practice about the GCP.

The study was done by ***Kuyare SS & et.al***,(2014) had shown the inability of investigators to defend studies due to lack of good clinical practice (GCP) and research methodology training or unwillingness of sponsors to comply with local IEC requirements could be potential reasons for studies remaining uninitiated. Continued GCP training of investigators and IEC members and development of uniform ethical review standards across IECs are strongly recommended by them.[16] But our study shows that the knowledge(75%) , attitude(69.40%), & practice(73%) about GCP was even if good, proper training time to time is necessary about GCP(especially more about Medical students).

In another recent study from India (2013), a survey questionnaire was developed and mailed to clinical research professionals. Among the items covered were EC functioning and training and whether GCP training should be mandatory for all EC members and requirement of other training. All the 34 responders agreed that GCP training must be mandatory for EC members, along with training on other topics such as (a) applicable regulations; (b) compulsory continuing medical education; (c) protocol review process; d) ethics and ethical thinking; (e) EC standard operating procedures; and (f) roles and responsibilities of each quorum member.[17] Our study states that not only EC members but also Medical Teachers & Students should also be aware of GCP guidelines& they should follow it while conducting clinical research.

The study was done by ***Shaw D& et.al,*** (2013) shown that the best ethical guidelines for clinical research would be neither over-prescriptive in regard to particular ethical issues (as the Declaration of Helsinki is) nor neglectful of them (as GCP is); correctly framed ethical principles will provide sufficient protection to participants while also ensuring a culture of ethicovigilance

in clinical trials. [18] In our study, it was found that 73% of the study participants think that subject's safety is having priority in the GCP.

The study was done by ***Iijima Y*** (in 2011) mentioned the importance of GCP (as like our study) that when researchers plan clinical research, they must determine the type of clinical research and appropriate ethical guideline for the type of clinical research. In Japan, clinical research of medical products, the principally trial of new pharmaceutical products is regulated by GCP (Good Clinical Practice). [19]

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FIGURES:

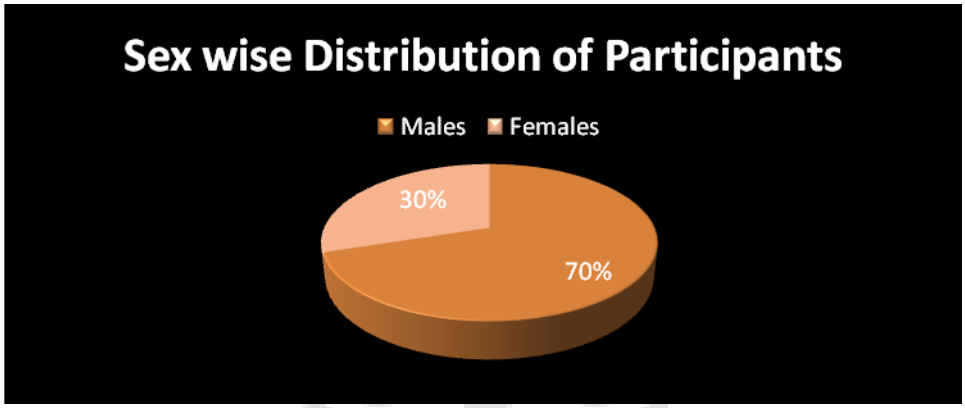

Fig.1. Sex wise Distribution of Study Participants:

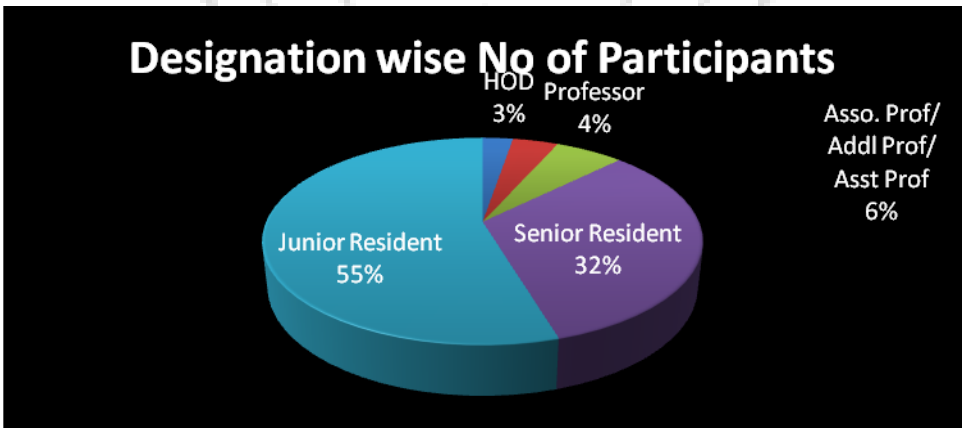

Fig.2. Designation wise No of Study-participants:

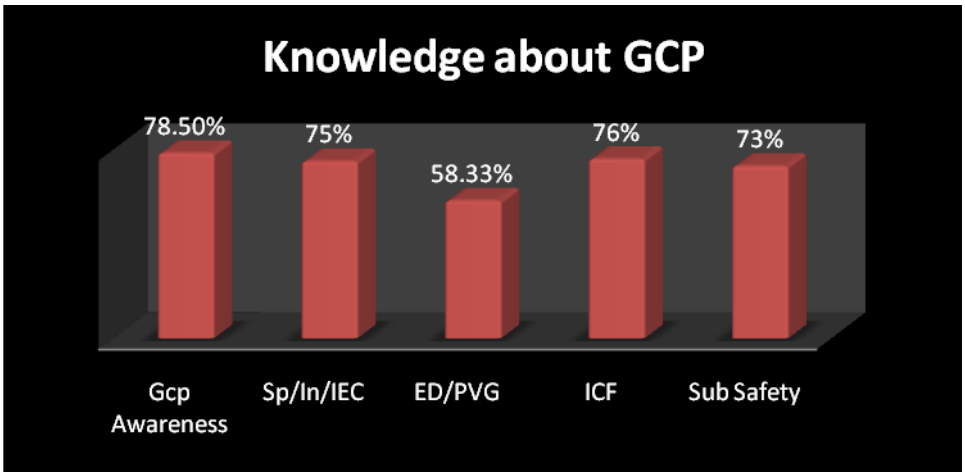

Fig.3. Knowledge about GCP: