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# Assessment of Knowledge Towards Good Documentation Practices Among Pharm D Pharmacology Students

[1]L.J. Kiran, [2]K.G. Shivashankaramurthy, [3]M. Naveen Kumar and [4]N. Lavanya

*[1,2]Department of Pharmacology, SS Institute of Medical Science and Research Center, Davangere, Karnataka, India*

*[3]Department of Pharmacology, Haveri Institute of Medical Sciences, Haveri, Karnataka, India*

*[4]Department of Pharmacology, Basaveshwara Medical College and Research Institute, Chitradurga, Karnataka, India*

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**Corresponding Author**
N. Lavanya,
Department of Pharmacology, Basaveshwara Medical College and Research Institute, Chitradurga, Karnataka, India

**Author Designation**
[1]Professor and HOD
[2]Professor
[3]Associate Professor
[4]Professor and Head

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**ABSTRACT**

Documentation is an integral component of clinical research. This study assessed the knowledge of Pharma D pharmacology students towards good documentation practices (GDP) in clinical trials by comparing the results of pre-and post-workshop. A structured questionnaire comprising 15 questions on GDP was developed by the research team and validated by experts. This questionnaire (pre-and post-workshop surveys) was created using Google Forms and consisted of multiple question types. The link to the survey was then sent via email to all participating students before and after the workshop. The results were compared and presented as percentages. A total of 35 pharmacology students participated in the pre-workshop survey, of which only 20 completed the post-workshop questionnaire survey. Of the students, 77.1% were familiar with the complete ICH-GCP, but this number decreased to 50% following the post-workshop survey. An increase in the students' knowledge of the approval board was observed following the post-workshop survey (20%). The workshop's outcomes enhanced the students' understanding of the pediatric eligibility age for clinical trials, boosting their knowledge from 60-85%. In the post-workshop survey, a larger percentage of students were able to provide correct answers. The majority of the participants were successful in identifying that the consent form would be obtained from legally authorized representatives, as indicated by the pre-workshop survey, which showed 97.1% correct responses and the post-workshop survey, which reported 100% accuracy. In the pre-workshop survey, 80% of the participants answered correctly, whereas after the workshop, this figure increased to 90% in relation to site monitoring visits. This study demonstrated positive outcomes in terms of increasing students' knowledge of good documentation practices in clinical trials. It is essential to devote additional effort to enhancing documentation practices by offering structured training and workshops on documentation standards to all pharmacology students, fostering positive attitudes and inspiring them to create a culture of information.

## INTRODUCTION

Good documentation practice (commonly abbreviated GDP/GDocP) is a term used in the pharmaceutical and medical device industries to describe standards by which documents are created and maintained. In recent years, the number of clinical trials conducted globally has increased considerably, thereby presenting a multitude of prospects for individuals seeking to pursue careers in the research sector. A multi disciplinary team is necessary to conduct the design, coordination and analysis of clinical trials. This team typically comprises principal and sub-investigators, clinical research coordinators (CRC), research pharmacists and clinical research associates (CRA)[1]. The individuals responsible for conducting clinical research must be adequately trained in compliance with the set guidelines. Pharmacists involved in research can significantly affect the conduct of clinical trials and contribute to various aspects of the research process. Pharmacists can apply their specialized knowledge by working directly on pharmaceutical aspects, including drug composition and overseeing indications, dosage, administration, contraindications, adverse effects and interactions with investigational drugs (IDs). Pharmacists play a significant role in ensuring the safety and rights of human subjects in research. In order to carry out these functions, pharmacists must have thorough knowledge of documents such as research protocol, informed consent form, investigator's brochure and standard operating procedures of the Research Centre. These procedures must meet regulatory, ethical and legal requirements as defined by local Institutional Review Boards (IRBs). The effective management of investigational drugs is crucial for the success or failure of clinical trials. In this regard, pharmacists are the most important team members to perform this task. The primary responsibility of the pharmacist is to ensure that the receipt of drugs is accurately recorded in the study documents or in the interactive voice response system, along with the primary responsibility of drug dispensing to study participants[2]. In addition, well as to verify the packaging and labelling, drug substance analysis, pharmaceutical form, lot number, manufacturing and expiration dates, proper usage, handling and storage conditions, administration routes and specific dosage instructions, dispensing, incineration and handling procedures to ensure that the investigational drug is in good condition for use. In addition, pharmacists must ensure that the investigated drugs are stored according to the room conditions (Temperature, light and humidity) determined by the sponsor. Pharmacists should ensure that the transportation of investigational drugs is conducted in accordance with the instructions provided by the sponsor during the receipt and shipment process. If there are any queries about the quality or physical properties of an investigational drug, the pharmacist should not dispense the medication and should promptly contact the sponsor instead. All of these data must be documented in study logs in accordance with GDP requirements for future external audits[3]. Therefore, the quality of data is crucial to ensure that the information obtained from the study is dependable and comprehensive to accurately evaluate the safety and effectiveness of the investigational drug. Therefore, a questionnaire-based study was conducted to assess the knowledge of Pharma D Pharmacology students regarding good documentation practices.

## MATERIALS AND METHODS

**Study Design and Population:** This questionnaire -based study was conducted on 35 Pharm D Pharmacology students who participated in the workshop. GDP knowledge was assessed by administering a structured questionnaire comprising 15 questions developed by the researcher team and validated by experts in the domain.

**Data Collection Method:** A list of students was obtained from the course coordinator and faculty. Before starting the workshop, the lead researcher (First author) asked the students to provide information about the purpose of the study. Informed consent and questionnaires (Pre-and post-workshop surveys) were designed and created in Google Forms with multiple question types and sent via mail to all participating students before commencing the workshop sessions. The students were guided on how to complete the questionnaires. After the workshop, the same post-workshop survey was conducted and the data were collected. The responses obtained were stored, analyzed and presented as percentages.

## RESULTS AND DISCUSSIONS

A total of 35 PharmD pharmacology students were involved in the pre-workshop survey, of which only 20 completed the post-workshop questionnaire survey, as they were absent during the second half session. Responses to the completed survey forms were scrutinized question by question. The first question pertained to the full form of ICH-GCP. A significant number (77.1%) of participants were familiar with the complete form of the ICH-GCP, but this number decreased to half (50%) after the post-workshop survey and the second question pertained to the authorization process for conducting clinical trials. It is mandatory to obtain clearance from the Drug Controller General of India (DGCI) to conduct clinical trials. Following the post-workshop survey, there was a 20% increase in the students' awareness of the approval board. The third question pertained to the stage of a clinical trial, known as post-marketing

**Table 1: Pre-Workshop Survey and Post-Workshop Survey**

| | Pre-workshop survey (n=35) | Post-workshop survey (n=20) |
|---|---|---|
| Agree to take part in the survey? | | |
| Yes | | |
| No | | |
| 1. What is ICH-GCP? | | |
| International council on harmonization-good clinical practice | | |
| International committee on harmonization-good care practice | | |
| Institutional conference on harmonization-good clinical | | |
| International conference on harmonization-good clinical | | |
| 2. From whom to seek approval for conducting clinical trials? | | |
| DCGI | | |
| Institutional Ethics committee/International Ethics review board | | |
| ICMR | | |
| Option 1and 2 | | |
| 3. Which phase of a clinical trial is called as PMS (Post Marketing Surveillance)? | | |
| Phase I | | |
| Phase II | | |
| Phase III | | |
| Phase IV | | |
| 4. Which clinical trial document is mandatory before enrolling a subject in a clinical trial? | | |
| Investigor Brochure | | |
| Study Protocol | | |
| Informed Consent from (ICF) | | |
| Case Record from (CRF/eCRF) | | |
| 5. Participation of a clinical trial subject is | | |
| Voluntary and may withdraw consent at any time | | |
| Voluntary but may withdraw consent once it is signed | | |
| Mandatory | | |
| None of the above | | |
| 6. If clinical trial subject is pediatric, which of the following will apply | | |
| Informed Consent from Child | | |
| Informed Consent from parent or guardian | | |
| Child Assent from for 7 years and above | | |
| Option 1 and 2 | | |
| 7. In case of subject is illiterate | | |
| Informed consent is not required | | |
| Consent will be obtained from legally acceptable Representatives | | |
| Consent will be obtained from principle investigor | | |
| None of the above | | |
| 8. In case of both subject and Legally Acceptable Representative are illiterates | | |
| Informed consent is not required | | |
| Consent will be obtained from Impartial witness | | |
| Consent will be obtained from clinical research coordinator | | |
| None of the above | | |
| 9. Informed consent should be explained to the patient in their local language? | | |
| Yes | | |
| No | | |
| 10. Investigators need to report to whom in case of an Adverse Drug Reactions (ADRs)? | | |
| Institutional ethics committee | | |
| Regulatory Authority | | |
| Sponsor | | |
| All of the above | | |
| 11. Subject data will be captured in | | |
| Investigor Brochure | | |
| Study Protocol | | |
| Informed Consent from (ICF) | | |
| Case Record from (CRF/eCRF) | | |

12. Data integrity guidelines are known as
EDC
ALCOA and ALCOA+
ICH-GCP
None of the above

13. What are the attributes of ALCOA+?
Attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring and available
Accurate, legible, complete, original, Attributable
Attributable, Lenghty, clear, outstanding, approveable-plus
None of the above

14. Why Site Monitoring Visits are conducted?
To meet and take care the clinical trial subjects
To ensure the progress of a clinical trial
To ensuring that it is conducted recorded and reported in accordance with the protocol,
SOPs, GCP and the applicable Regulatory requirements
Option 2 and 3

15. Which among the below mentioned Site Monitoring Visits?
Pre-Study Visits
Site Initiation Visits
Interim Monitoring Visits
Close-Out Visits
All of the above

surveillance. It is noteworthy that in both the pre- and post-workshop questionnaires, every student was able to provide a correct response (100%). The fourth question was linked to a mandatory clinical trial document that had to be completed before enrolling a subject. The overwhelming majority of students (97.1%) in the pre-workshop survey and (95%) in the post-workshop survey were familiar with the informed consent form. The fourth question pertained to the participants' participation in the clinical trial. Before attending the workshop, 77.1% of the students opted to withdraw their consent at any point during the clinical trial. This figure increased to 95% in the post-workshop survey. The sixth question assessed age qualifications for children. After the workshop, students' understanding of the paediatric eligibility age for clinical trials improved significantly, rising from 60% to 85%. The seventh question pertained to a situation in which the subject was illiterate. The vast majority of the respondents (97.1% in the pre-workshop survey and 100% in the post-workshop survey) correctly indicated that the consent form would be obtained from legally acceptable representatives. The consent form was the subject of Question 8, which focused on whether both subjects were illiterate legally acceptable representatives. The workshop proved advantageous for attendees, as the proportion of participants who provided correct answers rose from 71.4% in the pre-workshop survey to 95% in the post-workshop survey. Question 9 centered on the topic of the informed consent form and whether it should be translated into the subjects' local language. Only 7.1% of the participants answered correctly before the workshop and all participants (100%) were able to provide correct responses after the workshop. The tenth question was linked to the investigator's responsibility to present adverse drug reactions. In the pre-workshop survey, 68.6% of the participants provided the correct answer, whereas in the post-workshop survey, 65% of the participants were accurate. The eleventh question was about where the subject's data must be captured. In the pre-workshop period, 88.6% of the subjects answered correctly, while in the post-workshop period, 75% of the subjects responded correctly. Question 12 pertained to guidelines for maintaining data integrity. In the pre-workshop survey, only 37.1% of the participants answered correctly, but this figure increased to 85% after the workshop. Question 13 concerned the full form of ALCOA+. It is evident that the workshop was advantageous for the participants because the proportion of participants who responded correctly rose from 45.7% to 95% following the workshop and the aim of Question 14 was to understand the purpose of site monitoring visits. In the pre-workshop survey, 82.9% of the participants responded correctly and this figure increased to 85% in the post-workshop survey. Question 15 assessed the participants regarding different site monitoring visits. In the pre-workshop period, 80% of the respondents answered correctly, a figure that rose to 90% following the workshop. All pre-workshop and post-workshop survey responses are presented in (Table 1).

In clinical research, documentation is meaningful, clear, consistent, complete, precise, reliable, timely and legible to accurately reflect the patient's disease

burden and scope of research objectives[4]. Successful clinical documentation integrity (CDI) programs facilitate the accurate representation of a patient's clinical status that translates into coded data. Coded data is then translated into quality reporting, physician report cards, reimbursement, public health data, disease tracking and trending and medical research[5]. A survey was carried out to evaluate the knowledge of Pharm D pharmacology students. The aim of the present survey was to assess students' understanding of the documentation of clinical data in clinical trials, and it was found that all students were knowledgeable about this topic to some extent. Moreover, the workshop was considered beneficial for providing good examples of documentation and familiarizing participants with the study documents. A wide range of strategies has been developed to deal with the challenges faced by pharmacists who want to pursue careers and who are pursuing careers in clinical research. One approach is to provide clinical research training/workshop[6]. These training programs offer the skills, knowledge, and training required for pharmacists to perform clinical research more efficiently and in accordance with applicable regulatory guidelines and in relation to newer paradigms. In the present survey, the participants were asked about various crucial elements of clinical research as well as GDP, such as ICH-GCP, approving body for conducting the clinical trial, phases, informed consent and assent forms, data integrity, site monitoring and reporting adverse reactions. Even though for some questions, participants answered correctly, the response increased to a higher percentage after the workshop. With this outcome, this study demonstrated a significant improvement in students' knowledge of documentation practice. Therefore, we opine that a workshop may introduce a new idea, inspire participants to further explore it on their own, or illustrate and promote actual process practices. It is a great way to teach hands-on skills, as it gives learners an opportunity to try out new methods and fail in a safe environment. Attending a workshop is like gifting yourself a new possibility to learn something new from peers who have better experience and knowledge to share with you a new bee in the world of professionals.

## CONCLUSION

An increasing number of clinical trials also highlight that more trained personnel will be required and that pharmaceutical companies and research centers will need to appreciate the importance of this professional to a greater extent. To conclude, emphasis should be laid on conducting workshops because they provide students with the opportunity to have real-life experiences with patients.

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