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Original Article

Biochemistry Section

Effect of Good Clinical Laboratory Practices Quality Training on Knowledge, Attitude and Practice among Laboratory Professionals-Quasi Experimental Study

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ABSTRACT

Introduction: Good Clinical Laboratory Practices (GCLP) play a vital role in early and accurate diagnosis, providing high-quality data, and timely sample processing. Adhering to a robust Quality Management System (QMS) that complies with GCLP standards is crucial for laboratory personnel in a clinical laboratory to deliver outstanding healthcare services and reliable, reproducible reports.

Aim: To assess the Knowledge, Attitude, and Practice (KAP) of laboratory professionals towards quality in the laboratory through GCLP training.

Materials and Methods: This pre-test, post-test quasi-experimental study was conducted in the Department of Biochemistry at ESIC Medical College and Hospital, Faridabad, Haryana, India, from February 2022 to June 2022. The study included 58 participants, consisting of 22 doctors and the remaining laboratory assistants. GCLP online training program was conducted every Friday in March 2022 for four weeks. An online questionnaire containing 34 questions was administered to all the participants before and after the training. Data were collected and analysed using a paired t-test.

Results: A total of 58 responses were received from the participants via Google form before and after the training. The results indicate no significant difference in participants' responses to 12 closed-ended questions regarding QMS before and after training. A similar trend was observed for 22 questions on a Likert scale, where participants rated their agreement, neutrality, or disagreement.

Conclusion: The study demonstrates that all technical staff fully complied with GCLP guidelines and accreditation requirements. Furthermore, the laboratory staff acknowledges the importance of Standard Operating Procedures (SOPs), document maintenance, record-keeping, and identifying non-conformities, all of which contribute to effective traceability of the testing process in the clinical laboratory.

Keywords: Clinical laboratory assistants, Good clinical laboratory practices, Quality assurance, Quality control, Standard operating procedures

INTRODUCTION

Clinical laboratories are an indispensable part of healthcare services as they provide test results crucial for decision-making by physicians and clinicians in screening, diagnosis, treatment, and disease monitoring [1-3]. The quality of reports generated by laboratory personnel significantly impacts patient outcomes and treatment. Errors in any of the three phases (pre-analytical, analytical, and post-analytical) of analysis can have disastrous consequences for patient care [4]. Therefore, it is essential for laboratorians to have a comprehensive understanding of quality systems, as they are the first point of contact in sample handling and test procedures.

To provide reliable and reproducible results for outstanding healthcare services, laboratory personnel must adhere to a robust QMS that complies with GCLP standards [5]. Currently, there are multiple standards available to guide laboratorians on Quality Control (QC), Quality Assurance (QA), and QMS. Well-known organisations such as the International Organisation for Standardisation (ISO) [6] and the Clinical and Laboratory Standards Institute (CLSI) [7] establish standards and guidelines for laboratory quality. Additionally, organisations like World Health Organisation (WHO), Indian Council of Medical Research (ICMR), and Division of AIDS (DAIDS) provide guidelines to upgrade laboratory quality from time to time.

Good Laboratory Practices (GLP) are a set of principles that define a quality system concerning the organisational process and conditions under which laboratory studies are planned, performed, monitored, recorded, archived, and reported [8]. GCLP is based on the implementation of GLP principles for the analysis of clinical samples. GCLP focuses on key aspects of a quality system, including QC, assay validation, laboratory safety, sample management, records, proficiency testing programmes, Laboratory Information Systems (LIS), overall quality management plans, and training of laboratory personnel. Implementing GCLP ensures the generation of high-quality data along with timely sample processing, enabling early and accurate diagnosis leading to desired clinical outcomes. To protect patient safety and ensure data reliability, it is vital to avoid GCLP breaches by executing integrated, harmonised operations and establishing an effective laboratory quality system [9].

Clinical laboratories and laboratory personnel have an ethical obligation to provide accurate and precise results that are cost and time-effective, necessitating strict adherence to quality planning. Quality planning includes standardising laboratory processes, QC, QA, and Continual Quality Improvement (CQI) [5,10]. Training plays a key role in ensuring correct implementation of guidelines and achieving quality output at all levels of laboratory personnel [11]. Furthermore, laboratorians need to have good knowledge and a positive attitude towards QA, which can be achieved through training on GCLP for QA implementation.

Therefore, this study aimed to assess the KAP towards quality in the laboratory through GCLP training, as the quality system depends on the skills, knowledge, commitment, and continuous practice of laboratory personnel.

MATERIALS AND METHODS

A pre-test, post-test quasi-experimental study was conducted in the Department of Biochemistry at ESIC Medical College and Hospital, Faridabad, Haryana, India, from February 2022 to June 2022. The study was conducted after obtaining ethical clearance from the institutional ethics committee (Ref No: 134 X/11/13/2022-IEC/12), and all participants provided verbal consent for the study.

Inclusion criteria: A total of 58 College and Hospital staff who enrolled for GCLP training were included in the study.

Exclusion criteria: Participants unwilling to participate or who did not attend the GCLP training were excluded.

Sample size: In this study, 58 participants were enrolled, including 22 doctors and the remaining laboratory assistants from four departments (Department of Biochemistry, Pathology and Microbiology, Immunohaematology, and Blood Transfusion) of ESIC Medical College and Hospital. Samples were chosen using a non-probability convenience sampling method since the study was based on an online questionnaire.

Procedure

Data collection: The GCLP online training program was organised by the Clinical Development Services Agency (CDSA) and the Translational Health Science and Technology Institute (THSTI) in collaboration with the Employees' State Insurance Corporation (ESIC) Medical College and Hospital, Faridabad. The training took place every Friday in March 2022 for a period of four weeks. Eminent experts and experienced trainers from CDSA and THSTI conducted the online training from 1:30 PM to 5:00 PM. The training programme consisted of four modules covering GCLP guidelines, infrastructure, organisation, personnel, equipment, reagents, examination process, pre and post-examination process, ethical considerations, internal QC, external assessment/proficiency testing, quality management, risk management, quality indicators, test method validation, verification, safety in laboratories, data management, laboratory information system, internal audit, and GCLP dos and don'ts. Participants who successfully completed the programme and met the administrative requirements, including attendance, feedback, and a minimum score on the exit assessment, were awarded a certificate. The training module was prepared by THSTI in collaboration with ESIC MCH, referring to GCLP guidelines [12]. Each session started with a recap of the previous session presented by randomly chosen participants. An exit assessment, conducted as a proctored online exam by THSTI, Faridabad, was administered after the completion of the four modules.

The questionnaire was explained to all participants, including the types of questions (Yes/No, Likert Scale: agree 1/neutral 2/disagree 3), the mode of answering, and the deadline for submission. Anonymity of responses was maintained throughout the study. The questionnaire consisted of 34 questions, including 12 closed-ended questions with predefined options and 22 questions regarding participants' opinions on accreditation, IQC, EQAS, QMS, etc. A pilot study was conducted with a group of 10 senior faculty members from the departments of Biochemistry, Pathology, and Microbiology to test the online questionnaire, and it was modified accordingly. The reliability score, calculated using Cronbach's alpha test, was found to be 0.99. Participants included in the pilot study were excluded from the main study. The revised questionnaire was used for data collection. The questionnaire was distributed electronically to all participants using Google Forms. The same questionnaire was distributed to participants before and after GCLP training, and data were collected.

Questionnaire: A pre-designed questionnaire in the English language was used in the study, based on previous studies [11,13]. The questionnaire was distributed electronically using Google Forms, with a link sent to all participants. The participants were given 60 minutes to fill out the questionnaire. The questionnaire consisted of 34 questions, of which 22 were analysed using a Likert scale of 1-3 to indicate the participants' level of agreement (1: agreement, 2: neutral, 3: disagreement). The remaining 12 questions were closed-ended with predefined options. Mean scores were calculated from the responses, where a mean score <2 indicated agreement and a mean score >2 indicated disagreement.

STATISTICAL ANALYSIS

Completed responses were exported to Microsoft Excel 2016. Continuous measurements were presented as Mean±SD, including the 22 responses on the Likert scale. Categorical measurements were presented as percentages. A multiple comparison test was conducted to compare the questionnaire responses before and after GCLP training. The paired t-test was used to determine the significance of study parameters on both continuous and categorical scales. Statistical analysis was performed using GraphPad version 07 software. A p-value <0.05 was considered statistically significant.

RESULTS

In the present study, the mean age of the study population was 33±5.3 years. Of the respondents, 59.3% were male and 40.7% were female.

[Table/Fig-1] represents the participants' responses to closed-ended questions regarding their knowledge and attitude towards GCLP (Good Clinical Laboratory Practice) quality. The questions consisted of 12 statements, with 11 related to knowledge and 1 related to attitude. Ten statements had multiple options, requiring participants to choose the correct option, while 2 questions (Q3: Are you aware of the Scope of your laboratory? and Q12: Are you competent to achieve quality in your laboratory setting?) were of Yes/No type. The data showed no statistically significant difference in the responses of participants regarding knowledge and attitude before and after GCLP training.

[Table/Fig-2] summarises the responses from study participants using a three-point Likert scale. This section included 22 questions that assessed participants' opinions on accreditation, IQC (Internal Quality Control), EQAS (External Quality Assessment Scheme), QMS, and other related topics. Among the 22 statements, 2 questions assessed knowledge, 11 questions assessed attitude, and 9 questions

S. No.	Questionnaire	Before GCLP training correct answers N (%)	After GCLP training correct answers N (%)	p-value
	Knowledge			
1	What is quality	22 (38.60%)	24 (45.28%)	0.537
2.	What is the size of your laboratory	41 (71.9%)	39 (72.22%)	1.000
3.	Are you aware of the Scope of your laboratory	57 (100%)	54 (100.00%)	0.322
4.	Identify the INCORRECT statement	32 (56.1%)	14 (26.92%)	0.164
5.	Pre-examination phase starts from the time	45 (78.9%)	48 (88.89%)	0.200
6.	Which among the following is NOT a non-conformity	22 (38.6%)	22 (41.51%)	1.000
7.	Which among the following is a wrong practice in the laboratory	37 (66.1%)	37 (69.81%)	0.674
8.	Full form of POCT is	50 (87.72%)	48 (88.89%)	0.532
9.	IQC results of bilirubin (level 1 >3s), identify the correct laboratory practice	46 (80.70%)	36 (67.92%)	0.322
10.	Ethical conduct includes	52 (91.23%)	52 (96.30%)	0.261
11.	Quality indicators are	54 (94.74%)	49 (90.7.%)	0.070
	Attitude			
12.	Are you competent to achieve quality in your laboratory setting	53 (92.98%)	51 (94.44%)	0.709

[Table/Fig-1]: Responses of laboratory professionals to closed-end questions about their knowledge and attitude towards Quality Assurance (QA) in a clinical laboratory.

assessed practice. Participants were asked to rate their level of agreement related to laboratory quality. The data were presented as Mean±SD (Standard Deviation). The findings indicated no statistically significant difference in the responses of participants regarding the KAP before and after GCLP training.

Regarding attitude, three out of the 11 statements had responses of agree, disagree, and neutral, while the remaining eight statements were related to easiness, difficulty, or neutrality.

[Table/Fig-3] summarises the distribution of responses from study participants using a three-point Likert scale. In terms of attitude, when participants were asked about the necessity of accreditation in their laboratory, no difference was found in the responses before and after GCLP training. Similarly, in terms of practice, when respondents were asked if laboratory services were able to meet the needs of users, an equal number of respondents agreed, and no difference was found in the responses before and after GCLP training.

Overall, the study results suggest that there were no significant differences in participants' knowledge, attitude, and practice regarding GCLP quality before and after GCLP training.

DISCUSSION

The present study aimed to evaluate the knowledge, practice, and attitude of laboratory professionals towards laboratory quality training using an online questionnaire. The study was conducted amongst laboratory professionals in the Clinical Laboratory at ESIC Medical College and Hospital, Faridabad. Participants were asked questions related to QA to assess their KAP. The same questionnaire was administered before and after GCLP training, and the responses were compared.

Knowledge, defined as the understanding of laboratory professionals regarding QA principles, was analysed based on participants' agreement with statements about laboratory QA [13]. Interestingly, the

S. No.	Questionnaire	Before GCLP training Mean±Std. Dev	After GCLP training Mean±Std. Dev	p-value
	Knowledge			
1.	Quality manual is a part of SOP	1.41±0.80	1.46±0.84	0.156
2.	Certification and Accreditation are interchangeable	2.68±0.68	2.37±0.89	0.187
	Attitude			
3.	There is Necessity of Accreditation in your laboratory	1.14±0.40	1.11±0.37	0.193
4.	Accredition will increase workload and undue stress	2.46±0.77	2.22±0.88	0.174
5.	On the Job-Training is necessary for upgradation of knowledge of laboratory personnels	1.05±0.29	1.20±0.56	0.191
6.	Maintenance of equipments and its troubleshooting is	1.70±0.73	1.61±0.76	0.134
7.	Reagents and consumbles stock inventory maintainence is	1.65±0.74	1.48±0.66	0.168
8.	Maintaining IQC and EQAS for precision and accuracy of results is	1.33±0.64	1.56±0.74	0.163
9.	Implementing CAPA (Corrective action preventive action) is	1.51±0.71	1.74±0.82	0.185
10.	The process of sample collection, handling, transportation, storage is	1.42±0.63	1.44±0.74	0.13
11.	Following sample acceptance and rejection criteria along with documentation is	1.53±0.80	1.39±0.65	0.125
12.	Critical alerts maintenance and documentation is	1.32±0.60	1.57±0.81	0.152
13.	Release of final report after reviewing the interim report is	1.19±0.52	1.46±0.69	0.146
	Practice			
14.	Job description should be defined	1.07±0.26	1.09±0.29	0.167
15.	laboratory services are able to meet need of users	1.05±0.23	1.02±0.14	0.156
16.	Responsibility, authority and interesponsibility should be defined and communicated	1.04±0.19	1.11±0.42	0.155
17.	The Advisory services are approachable	1.11±0.31	1.13±0.39	0.128
18.	Encouraging atttitude of Quality Management System (QMS) toward resolution of complaints	1.09±0.29	1.30±0.64	0.191
19.	Monitoring nonconformities and its resolution will ease workflow	1.30±0.63	1.13±0.39	0.163
20.	Infrastructure at workplace is adequate	1.23±0.53	1.19±0.52	0.129
21.	Staff facilities are adequate	1.39±0.70	1.46±0.82	0.175
22.	Co-ordination of LIS with release of results is easy	2.44±0.8	2.19±0.87	0.189

[Table/Fig-2]: Responses of laboratory professionals on a Likert scale about their Knowledge, Attitude, and Practice (KAP) towards Quality Assurance (QA) in a clinical laboratory.

S. No.	Questionnaire		Agree N (%)	Neutral N (%)	Disagree N (%)
	Knowledge				
1.	Quality manual is a part of SOP	Before GCLP training	44 (78.6)	1 (1.8)	11 (19.6)1
		After GCLP training	41 (75.9)	1 (1.8)	12 (22.2)1
2	Certification and accreditation are interchangeable	Before GCLP training	7 (12.3)	4 (7)	46 (80.7)1
		After GCLP training	15 (27.8)	4 (7.4)	35 (64.8)
	Attitude				
3	There is necessity of accreditation in your laboratory	Before GCLP training	49 (87.5)	6 (10.7)	1 (1.8)
		After GCLP training	49 (90.7)	4 (7.4)	1 (1.9)
4	Accredition will increase workload and undue stress	Before GCLP training	9 (16.4)	9 (16.4)	37 (67.3)
		After GCLP training	16 (29.6)	10 (18.5)	28 (51.9)
5	On the job-training is necessary for upgradation of knowledge of laboratory personnels	Before GCLP training	55 (96.5)	1 (1.8)	1 (1.8)
		After GCLP training	47 (87)	3 (5.6)	4 (7.4)

6	Maintenance of equipments and its troubleshooting is	Before GCLP training	Difficult 9 (15.8)	Neutral 22 (38.6)	Easy 26 (45.6)
		After GCLP training	9 (16.7)	15 (27.8)	30 (55.6)
7	Reagents and consumbles stock inventory maintenance is	Before GCLP training	Difficult 9 (15.8)	Neutral 19 (33.3)	Easy 29 (50.9)
		After GCLP training	5 (9.3)	16 (29.6)	33 (61.1)
8	Maintaining IQC and EQAS for precision and accuracy of results is	Before GCLP training	Difficult 5 (8.8)	Neutral 9 (15.8)	Easy 43 (75.4)
		After GCLP training	8 (14.8)	14 (25.9)	32 (59.3)
9	Implementing CAPA (Corrective action preventive action) is	Before GCLP training	Difficult 7 (12.3)	Neutral 15 (26.3)	Easy 35 (61.4)
		After GCLP training	13 (24.1)	14 (25.9)	27 (50)
10	The process of sample collection, handling, transportation, storage is	Before GCLP training	Difficult 4 (7)	Neutral 16 (28.1)	Easy 37 (64.9)
		After GCLP training	8 (14.8)	8 (14.8)	38 (70.4)
11	Following sample acceptance and rejection criteria along with documentation is	Before GCLP training	Difficult 11 (19.3)	Neutral 8 (14)	Easy 38 (66.7)
		After GCLP training	5 (9.3)	11 (20.4)	38 (70.4)
12	Critical alerts maintenance and documentation is	Before GCLP training	Difficult 4 (7)	Neutral 10 (17.5)	Easy 43 (75.4)
		After GCLP training	11 (20.4)	9 (16.7)	34 (60.3)
13	Release of final report after reviewing the interim report is	Before GCLP training	Difficult 3 (5.3)	Neutral 5 (8.8)	Easy 49 (86)
		After GCLP training	6 (11.1)	13 (24.1)	35 (64.8)
	Practice		**Agree**	**Neutral**	**Disagree**
14	Job description should be defined	Before GCLP training	52 (92.9)	4 (7.1)	0 (0)
		After GCLP training	49 (90.7)	5 (9.3)	0 (0)
15	Laboratory services are able to meet need of users	Before GCLP training	53 (94.6)	3 (5.4)	0 (0)
		After GCLP training	53 (98.1)	1 (1.9)	0 (0)
16	Responsibility, authority and interesponsibility should be defined and communicated	Before GCLP training	54 (96.4)	2 (3.6)	0 (0)
		After GCLP training	50 (92.6)	2 (3.7)	2 (3.7)
17	The advisory services are approachable	Before GCLP training	20 (89.3)	6 (10.7)	0 (0)
		After GCLP training	48 (88.9)	5 (9.3)	1 (1.9)
18	Encouraging attitude of Quality Management System (QMS) toward resolution of complaints	Before GCLP training	51 (91.1)	5 (8.9)	0 (0)
		After GCLP training	42 (79.2)	6 (11.3)	5 (9.4)
19	Monitoring non-conformities and its resolution will ease workflow	Before GCLP training	44 (78.6)	7 (12.5)	5 (8.9)
		After GCLP training	46 (86.8)	6 (11.3)	1 (1.9)
20	Infrastructure at workplace is adequate	Before GCLP training	46 (82.1)	7 (12.5)	3 (5.4)
		After GCLP training	47 (87)	4 (7.4)	3 (5.6)
21	Staff facilities are adequate	Before GCLP training	42 (73.7)	8 (14)	7 (12.3)
		After GCLP training	40 (74.1)	3 (5.6)	11 (20.4)
22	Co-ordination of LIS with release of results is easy	Before GCLP training	11 (19.3)	10 (17.5)	36 (63.2)
		After GCLP training	16 (29.6)	12 (22.2)	26 (48.1)

[Table/Fig-3]: Distribution of participants' responses of the KAP survey questionnaire on a Likert scale.

data showed no statistically significant difference in the responses of participants regarding KAP before and after GCLP training. A similar study conducted in Vermont, US, also reported high knowledge levels among laboratory staff, with 85% of the staff being oriented in QA guidelines [4].

Attitude refers to the perception of laboratory professionals regarding the significance of QA, while practice refers to their inclination to follow and comply with laboratory QA procedures [13]. The results indicated no statistically significant difference in participants' responses regarding attitude and practice before and after GCLP training. The study revealed that the working staff was well aware of the importance of GCLP and recognised the impact of quality on results, despite the additional workload associated with maintaining NABL/ISO standards. The consistent adherence to SOPs and maintenance of QC records demonstrated the competence of laboratory professionals, which played a significant role in the timely processing and reporting of samples in the clinical laboratory.

A recent study conducted in Croatia amongst employees of accredited medical laboratories reported a positive attitude towards accreditation and an existing awareness of its benefits. However, the study also highlighted concern such as lack of familiarity with accreditation requirements and insufficient information on new operating procedures and working instructions. These findings emphasise the need for establishing systems to ensure timely and accurate downstream information flow for full compliance with accreditation requirements and working protocols.

Correspondingly, a study conducted in Lahore, Pakistan regarding the knowledge level of their Medical Lab Technologists (MLTs) on QC stated that 76% of their MLTs had average knowledge and 10% had good knowledge [14]. An Ethiopian study of 175 participants has reported that 81.7% of respondents had a better knowledge on internal QC [15]. On the contrary, a Chennai based Indian study of 10 laboratory staff reported a lapse in basic knowledge of laboratory staff on external QA, however their knowledge levels

were improved after the training [16]. Previous studies reported that increased workload for maintaining records like CAPA, QC, LJ charts etc., require long-term time commitment and perceived as a disadvantage of accreditation [17].

The current study clearly indicates that all laboratory professionals acknowledge the importance of well-organised workflows, SOPs, document maintenance, records, and identifying non-conformities, which collectively contribute to the effective traceability of the testing process in the clinical laboratory.

Limitation(s)

The online nature of the GCLP training due to the ongoing Coronavirus Disease-2019 (COVID-19) pandemic, which may have differed from on-site training. Additionally, the assessment relied on subjective responses, potentially introducing response bias. Future plans should include on-site training to enhance knowledge and technical expertise among laboratory professionals.

CONCLUSION(S)

In conclusion, the results of this study indicate no statistically significant differences in perceptions and attitudes of laboratory staff towards quality after GCLP training. The study emphasises that all technical staff fully comply with GCLP guidelines and accreditation requirements. Furthermore, the findings suggest a positive attitude towards GCLP guidelines and accreditation, with laboratory staff being well aware of the benefits they offer. However, frequent training and competence assessments of laboratory professionals are necessary to enhance their technical expertise in accordance with regulatory bodies' requirements. Such training and assessments would also aid in evaluating the performance of laboratory staff, contributing to improved learning, execution of GLPs, and consistent patient care services.

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