JURNAL ILMU KEFARMASIAN INDONESIA
Indonesian Journal of Pharmaceutical Sciences
ISSN p-ISSN 1693-1831 (Print) e-ISSN 2614-6495 (Online) PUBLISHER : Faculty of Pharmacy Universitas Pancasila

The association between knowledge and implementation of good compounding practice among pharmacy practitioners at community pharmacies in Central Jakarta

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Received: 19 February 2024 / Accepted: 10 October 2024

ABSTRACT: Drug compounding in community pharmacy is an important process in providing drugs according to patient needs. Poor compounding practices can pose serious health and safety risks. To improve the quality of compounds used in medicinal preparations, Pharmacists need to increase their knowledge and Good Compounding Practice (GCP). This study aimed to analyze the application knowledge of pharmacists regarding GCP of non-sterile preparations in Central Jakarta Regional Pharmacies. This type of research is observational research using cross-sectional descriptive methods. Data collection was carried out using a questionnaire distributed to 82 pharmacy practitioners working in the pharmacy community and using a structured questionnaire to evaluate the level of knowledge and implementation of GCP. The data analysis technique used is chi-square. Most of the Pharmacy Practitioners had good knowledge scores (71.95%). Meanwhile, the level of implementation of GCP has a good implementation value (82.92%). Good knowledge and implementation of Good Compounding Practice is very important to maintain the integrity and safety of drugs produced in compounding practices. This must be implemented in the training and education of pharmaceutical practitioners to help maintain the quality of safe and effective drug compounding practices.

KEYWORDS Good compounding practice; implementation; knowledge.

INTRODUCTION

Extemporaneous compounding is a process in which medicines are made directly by a pharmaceutical practitioner or health professional on-site (such as a pharmacy or other health facility) according to the patient's needs or in certain situations where a medicine that suits the patient's needs is not commercially available. Extemporaneous compounding can involve mixing, measuring, and preparing medications in dosage forms according to a doctor's or health worker's prescription. These medicines are made according to a doctor's prescription or patient's request, which requires formulations or dosages that are not available in commercial forms that are already on the market[1]. However, extemporaneous compounding remains a pertinent pharmaceutical service numerous pharmacies offer[1]. In the contemporary pharmaceutical landscape, which encompasses both industrial and clinical aspects driven by patient care, there is a continued emphasis on compounding to address the personalized therapeutic requirements of individuals with rare diseases, pediatric patients, and those necessitating specific dosage forms[2].

In the United States, guidelines for good compounding practice are contained in USP chapter 795. Many other countries have adopted these guidelines. In Good Compounding Practice (GCP), there are more in-depth instructions on good compounding in preparing compound drug formulations for humans or animals[3]. Drug compounding is one of the pharmaceutical jobs that can be carried out by pharmaceutical staff consisting of pharmacists and pharmacy technicians. Drug compounding is the provision of drugs needed by individual patients, made in pharmacies or health facilities, due to the limited availability of available drugs[4]. Supporting buildings, facilities, and equipment can determine the quality of concoction drug preparations. Compounding preparations in Indonesia are generally powder, dry syrup, and concoction ointment preparations[5].

In Indonesia, drug compounding is done based on the experience of the compound. This happens because, in Indonesia, there are no specific regulations governing the compounding of drugs. Meanwhile, in developed countries, there are already guidelines for making good compounding of medicine[6]. GCP

How to cite this article: Kurniawan AH, Safrina U, Yusmaniar Y. The Association between Knowledge and Implementation of Good Compounding Practice among Pharmacy Practitioners at Community Pharmacies in Central Jakarta. JIFI. 2024; 22(2): 214-223.

ISSN: 2614-6495

competency is one of ten competencies that need to be mastered by pharmacists[7]. The quality of medicines produced from compounding practices must comply with the standards set by health institutions (BPOM and the Ministry of Health). Knowledge and application of GCP by pharmaceutical personnel are essential to maintain the quality of the medicines produced. Pharmacy practitioners' knowledge and attitudes regarding GCP can be influenced by their education, training, and work experience[8]. The knowledge gained through formal education and training can affect how pharmacists conduct compounding practices. Studies on the educational background and training of pharmaceutical practitioners can provide insight into the availability of qualified human resources in the region[9].

The research results in United States America (USA) show that there is quite good knowledge about simple compounding involving the pharmacist profession, with the main competency in the field of community service in the pharmacy sector[10]. There was an increase in the knowledge of pharmacy students, and their understanding of the role of pharmacists regarding drug compounding in Australia was quite good[11]. The research results in Indonesia indicate that pharmacists' knowledge of applying aspects of compounding still needs to improve. There are still many uses of multifunctional compounding tables to be discovered, and the data on drug compounding still needs to be well documented[6].

Compounding non-sterile preparations are carried out in many pharmacies in the Central Jakarta area, but this practice has never been assessed and characterized by previous research. This research was designed to analyze the application knowledge of pharmacists and pharmacy technicians regarding GCP of non-sterile preparations in Central Jakarta Regional Pharmacies. By understanding the knowledge and implementation of compounding practices (GCP) in pharmacies in Central Jakarta, this research will provide valuable insight for improving education, training, and work practices in the pharmaceutical sector. This will contribute to improving patient safety and overall health service quality. This research can identify the extent to which socio-demographic characteristics and knowledge have influenced the implementation of GCP.

▪ MATERIALS AND METHODS

Materials

This descriptive cross-sectional research was conducted at Community Pharmacies in Central Jakarta, Indonesia, from February to August 2022. This research employed non-probability sampling, explicitly utilizing the purposive sampling method. Ethical approval for the study was obtained from the Research Ethics Committee of Poltekkes Kemenkes Jakarta II (KEPK-PKJ II), indicated by license number LB.02.01/I/KE/39/494/2022. Out of the 98 individuals initially approached, 82 participant successfully completed all questionnaire items, resulting in a response rate of 83.67%. This calculation was based on Cochran's sample size formula, aiming for a precision within ±5% and a confidence level of 95%. Inclusion criteria included Pharmacists and pharmacy technicians who worked on compounding non-sterile preparations at Pharmacies in Central Jakarta. Pharmacy professionals expressing a willingness to engage in this study were provided with written informed consent, accompanied by verbal explanations outlining the study's objectives. Additionally, participants were explicitly informed of the voluntary nature of their involvement, and assurances of the confidentiality of their responses were given. Individuals who declined participation or provided incomplete responses to the questionnaire were excluded from the study. Equipment. The instrument used in this study was a questionnaire obtained from other researchers' questionnaire data sources, including Implementation data by Heru Mahmudi (2016) and Timothy McPherson and Patrick Fontane (2010). In the knowledge data, the researcher made 20 questions in the form of multiple-choice questions (A, B, C, D, and E). Respondents' implementation data used a questionnaire in the form of "Yes and No" answer statements. Research data instrumentation came from research conducted by Heru Mahmudi (2019). Following this, the ultimate questionnaire design underwent content validity testing by a panel of academic experts and community pharmacists. Additionally, a pilot phase of the study, involving approximately 5% of the total sample size (n = 20), was conducted to assess question uncertainties and gather reliable data, which was subsequently excluded from the final statistical analysis. Regarding the validation of this study, the R table value utilized was 0.4336. It signifies that the calculated R-value surpassed the R table value, leading to the classification of the questionnaire instrument data as falling within the reliable category. Chronbach's alpha value on the knowledge questionnaire was 0.92 and GCP implementation was 0.89, meaning that the knowledge and GCP implementation questions were declared valid (very strong).

Methods

Questionnaire design and implementation

The conclusive version of the survey comprised 30 questions distributed across three sections. The initial segment, comprising four items, focused on gathering participants' demographic details, encompassing age, gender, academic discipline, experience with Good Clinical Practice (GCP) training, and work history.

The second part (20 items) gathered data to assess the implementation of good compounding practice with six topics, such as the definition/principle of GCP, facility, material, drug's stability, personal thing, and compounding process, each of which answered multiple choice questions for knowledge. The results of the answers to the questions consist of right/true and wrong false. Knowledge level measurement consists of good = 71-100% and poor = ≤70%. To measure the implementation of GCPs, Guttman scale was used. On this scale, only two choices are given: high (Yes, implemented) or low (Not implemented). For positive choices, a value of 1 is given, while for answers that have a negative value, a value of 0 is given.

Data analysis. Univariate data analysis for this study utilized Microsoft Office Excel 2016 and SPSS Statistical Analysis System version 23. Descriptive statistics, including numbers, percentages, and means (with standard deviations), were employed to portray the characteristics of the study population. Responses to the GCP Knowledge questionnaire, categorized as "true" and "false," were also expressed as percentages. The application of good compounding practices (GCP) assessed through the Guttman scale was likewise presented in percentage terms. The chi-square test was applied to examine the associations between sociodemographic factors of pharmacy practitioners and the questionnaire items gauging GCP knowledge and implementation levels. The threshold for statistical significance was set at $p > 0.05$.

The OR (Odds Ratio) value was used to find out how big the relationship between the two variables tested was, and the odds ratio can be applied if the two variables have a significant relationship or the P-value is less than 0.05. In the research, the results of the chi-square test can be said to be valid if the expected frequency is more than 5. However, if the expected frequency value is less than 5, the Fisher test can be used.

▪ RESULTS

Patient's Characteristics. In this study, the data were taken to describe the sociodemographic characteristics of the respondents, namely gender, age, place of work, length of work, and academic discipline. Demographic data were used to view the statistical distribution and frequency of a population in the region, shown in Table 1.

Table 1. Distribution of sociodemographic characteristics of the study participants.

Characteristics	Category	Frequency (n=82)	Percentage (%)
Age (mean±SD)		**28.50±2,6**	
Gender	Female	49	59.76
	Male	33	40.24
Academic dicipline	Pharmacist	49	59.76
	Pharmacy Technician	33	40.24
Length of work	≤ 3 years	34	41.46
	> 3 years	48	58.54
GCP training experience	Yes	46	56.09
	No	36	43.91
GCP Knowledge	Good	59	71.95
	Poor	23	28.05
GCP Implementation	High	68	82.92
	Low	14	17.08

The total number of respondents was 82 people taken from several pharmacies in Central Jakarta. There were criteria for respondents refusing in the study, so only 83.67% were in accordance with the inclusion and exclusion criteria.

Table 1. shows that the number of female respondents was more significant, namely 49 people (59.76%), while the number of male respondents was 33 people (40.24%). In this study, the characteristics of pharmaceutical education studied were divided into two professions, namely pharmacist and pharmaceutical technician. Most respondents, or as many as 48 people (58.54%), had worked for over three years. Most respondents' workplaces were hospital pharmacies, with 59 people (71.95%). Most respondents, or 63 people (76.83%), had received GCP training. The respondent's knowledge of Good Compounding Practice had a very good value in 59 people (71.95%). Respondents' implementation of GCP was in the positive category at 56.09%.

GCP (Good Compounding Practice) knowledge. Knowledge is a comprehensive understanding of the principles, standards, guidelines, and practices related to providing medicines through compounding practices that are safe, high quality, and in accordance with applicable regulations. This knowledge covers various aspects, including basic principles, facilities, materials, drug stability, personal, compounding processes, equipment, and compounding calculations. GCP knowledge is shown in Table 2**.**

Table 2. Proportion of pharmacist knowledge level questionnaire answers on Good Compounding Practice (GCP).

Topics	Knowledge	Frequency answered the questions correctly of respondents			
		Pharmacist (N=49)	Percentage (%)	Pharmacy technision (N=33)	Percentage (%)
Princip	Cause dispensing drugs in pharmacies is very necessary	42	85.71	29	87.88
	Dry syrup is a compounding category and needs medication labeling	43	87.75	28	84.85
Facility	Requirements for Water used in the compounding of drugs	41	83.67	29	87.88
	Lighting and sanitation facilities in Pharmacy	45	91.83	30	90.91
Drug's stability	BUD: dossage form is containing water (salep, cream, solution)	35	71.42	24	72.73
	BUD dossage form do not contain water, for example, powder, dry syrup and capsules	32	65.31	22	60.61
Personal	The pharmacist's role as a supervisor in dispensing drugs	49	100	30	90.91
	Personal protective equipment (PPE) is used when compounding drugs	41	83.67	30	90.91
	Requirements that pharmacists are not allowed to use accessories when compounding drugs	44	89.79	27	81.82
Compounding process	Factors that are included in the critical process when compounding drugs	35	71.42	25	75.76
	Pharmaceutical preparations that should not be crushed due to physical and chemical changes to the drug	41	83.67	20	60.61
Compounding equipment	How many times should the tool calibration be done if there are no calibration instructions from the factory	37	75.51	22	66.67
Calculation	Calculation of drug dispensing	38	77.55	24	72.72
	How many tablets to take for compounding a recipe	40	81.63	27	81.82
	What needs to be included when labeling the drug	45	91.84	29	87.88

Table 2. shows that most respondents had good knowledge of the GCP categories, namely GCP principles (87.88%) and meaning, as well as facilities (91.83%) and personnel (90.91%). However, some pharmaceutical practitioners (pharmacists and pharmaceutical technicians) still had poor knowledge, including BUD for pharmaceutical preparations that do not contain water (powder, dry syrup, and capsules), with percentages of correct answers of 32 pharmacist respondents (65.31%) and 22 pharmacy technician respondents (60.61%). Proportion of Pharmacist Implementation Level Questionnaire Answers on Good Compounding Practice (GCP) is shown in **Table 3.**

Table 3. Proportion of pharmacist implementation level questionnaire answers on Good Compounding Practice (GCP).

Topics	Implementation	Frequency answered the questions correctly of respondents			
		Pharmacist (N=49)	Percentage (%)	Pharmacy technision (N=33)	Percentage (%)
Facility	The pharmacy where you work has adequate lighting and space when dispensing	48.0	97.96	29.0	87.88
	MSDS (material safety data sheet) that is used is easy to acces	40.0	81.63	27.0	81.82
	The water used to mix water-containing medicines is purified water	45.0	91.84	28.0	84.85
	The compounding room is separate from the medication storage area	46.0	93.88	32.0	96.97
Personal	I may bring food in the drug compounding room	47.0	95.92	31.0	93.94
	I always use the equipment that has been cleaned to medicine compound	46.0	93.88	32.0	96.97
	After every time I have compounded medicine, I always wash the equipment that has been used	47.0	75.51	23.0	69.69
	I always pay attention to the MSDS so that I can handle the drug substance safely.	40.0	81.63	24.0	72.73
	I always dispensing prescription drugs one by one	44.0	89.79	31.0	93.94
	I use a wristwatch, bracelet or other accessories when dispensing medicine	46.0	93.88	29.0	87.88
	PPE (personal protective equipment) is complete when dispensing drugs	35.0	71.42	22.0	66.67
drug's stability	Drug ingredients used in pharmacies are always checked for legality	40.0	81.63	29.0	87.88
	The reconstitution results are given taking into account the beyond use date of each dosage form	21.00	63.43	18	54.55
	How to store active ingredients and excipients according to the manufacturer's recommendations or pharmacopeia	47.0	95.92	28.0	84.85
Compounding equipment	The scales used to mix have been calibrated	34.0	69.39	22.00	66.67
	Measuring tools used for compounding are calibrated periodically	34.0	69.39	21.0	63.64
SOP	There is an SOP that applies to pharmacies for compounding(	37.0	75.51	24.0	72.73
	There is an SOP for cleaning compounding equipment	40.0	81.63	25.0	75.76

Topics	Implementation	Frequency answered the questions correctly of respondents			
		Pharmacist (N=49)	Percentage (%)	Pharmacy technision (N=33)	Percentage (%)
Material	The legality of the medicinal ingredients used in pharmacies is always checked	44.0	89.79	24.0	72.73
	How to store the active drug ingredients and excipients according to the manufacturer's recommendations or pharmacopeia	46.0	93.88	28.0	84.85

Table 3 shows that the overall implementation of compounding practice shows a good category (82.92%). However, the application of GCP indicators still needs to be improved, including dispensing equipment that is not continuously calibrated (69.39%) and does not record the deadline for using dosage forms after reconstitution / BUD (54.55%). This activity is still minimally carried out by pharmacists, especially pharmacy technicians (63.64%).

The association between Knowledge and Implementation of Good Compounding Practice among Pharmacy Practitioners at Community Pharmacy in Central Jakarta, shown in **Table 4**.

Table 4. The association between knowledge and implementation of Good Compounding Practice among pharmacy practitioners at community pharmacy in Central Jakarta.

Variable	Category	Implementation GCP				p-value	OR
		High	%	Low	%		
Knowledge	Good	33	40.24	13	15.85		
	Poorl	26	31.72	10	12.19	0.344	0.804
	Total	**69**	**71.96**	**23**	**28.04**		

The results of the analysis between knowledge of good compounding practices and their implementation obtained a P-value of 0.344, meaning that there was no significant relationship between knowledge and implementation of good compounding practices in community pharmacies.

▪ DISCUSSION

Pharmacists with more than three years of work experience have better knowledge than pharmacists with less than three years of work, other research data shows that women have better knowledge (56.70%) with work experience that varies significantly between 4 and 47 years (71.40%). Long work experience can strengthen a person's practical knowledge. Long work experience can strengthen the practical knowledge a person has. The longer a person works in medication compounding, the more situations and cases they experience, which can increase their understanding of how to compound medication correctly[12]. However, it is important for pharmacy practitioners that good theoretical knowledge in drug compounding. This includes understanding the latest regulations, guidelines, and trends in the pharmaceutical industry. The combination of extensive practical experience and good theoretical knowledge will make a person a competent and safe medication-compounding professional[13].

Pharmacy professionals possessing proficient knowledge exhibited confidence in compounding oral liquid dosage forms, such as suspensions and solutions, considering them to be particularly relevant in practical application[14]. Most of the respondents had good knowledge of GCP, including the principles and meaning of GCP, as well as facilities and personnel. Patients, physicians, and pharmaceutical practitioners may focus on the understanding of compounded medications through a systematic procedure involving the proper calibration and cleaning of equipment, sourcing ingredients from FDA-approved suppliers, ensuring production personnel possess the requisite knowledge and training, and conducting appropriate laboratory tests to confirm the potency, purity, and quality of the compounded drugs[3].

The frequency of Drug stability knowledge on Good Compounding Practice (GCP) with true answers (60.61%). There were some pharmaceutical practitioners (pharmacists and pharmaceutical technicians) who still needed more knowledge, including BUD, for pharmaceutical preparations that did not contain water (powder, dry syrup, and capsules). However, there are still some pharmaceutical practitioners (pharmacists and pharmaceutical technicians) who need more knowledge, including BUD, for pharmaceutical preparations that do not contain water (powder, dry syrup, and capsules). This data is supported by the fact that some pharmacists and pharmaceutical technical personnel in Indonesia have low BUD knowledge regarding the compounding of various non-sterile dosage forms[15]. Beyond Use Date (BUD) after it is made is the main problem in compounding practice. BUD is the date that determines how long the product produced through compounding can be considered safe and effective for use. The stability of the compounded drug is closely related to choosing the BUD (Beyond Use Date). This determination must be made conservatively and professionally based on knowledge and experience[15].

It aligns with research conducted by Choo et al. which showed that pharmaceutical practitioners' knowledge about compounding was in a high category (70.40 %). Non-sterile preparations concoction Non-sterile preparations are compounding drugs packaged in tight containers that are light-resistant and stored at the right temperature. Medicines that are packaged in tight containers that are light-resistant and stored at the right temperature. Recommendations for determining the BUD include: For dry syrup preparations, the BUD is for 6 months or not more than the expiration dates of the other materials used (use the closer one). For oral preparations that contain water, the BUD is 14 days at maximum, and they must be stored at cold temperatures. As for topical, mucosal, and semisolid preparations, the BUD is at most 30 days. Pharmacies need to provide clear information to patients about the BUD of the products they receive so that patients can use these products safely and effectively[16]. In compounding practice, understanding and compliance with BUD is key to ensuring safety, effectiveness, and regulation compliance[6]. Continuous monitoring, research, and training are required so that BUD can be calculated accurately and adhered to in accordance with applicable pharmaceutical standards[17].

Several pharmacies accept minimal compounding prescriptions, partly due to a lack of compounding equipment and limited drug supplies (64.50%)[18]. These guidelines require each licensed pharmacy to have appropriate compounding equipment. This equipment includes various instruments and devices used in the drug compounding process, including containers, measuring instruments, and sterilization equipment. The goal is to ensure drug compounding is done safely and effectively[19]. There are some pharmaceutical practitioners who minimalize GCP indicators, including compounding equipment that needs to be continuously calibrated and a lack of equipment supplies. Only complete calibration tools and scales can produce products that meet the desired specifications. This can affect the product quality produced through compounding in terms of stability, strength, and other physical properties[8]. Therefore, it is important to ensure that the tools used in compounding practice are regularly calibrated and comply with applicable pharmaceutical standards. This will help maintain product quality, patient safety, and compliance with applicable regulations[20].

Pharmacy technicians still lack the implementation of washing equipment that has been used and the use of complete Personal Protective Equipment (PPE) when compounding drugs. The use of washing equipment, pure water (not mineral water), the correct mixing table base (made of stainless steel), and the use of complete Personal Protective Equipment (PPE), such as gloves, masks, and suits, are important factors in compounding practices to maintain the safety of patients and pharmacy staff [20]. Pharmacy technicians' lack of awareness or compliance in this regard can have a negative impact on compounding practices. Pharmacies must implement various strategies to ensure PPE is available for continuously compounding sterile and non-sterile products [20]. To meet these competency standards in preparing pharmaceutical preparations according to operational standards, pharmacists and pharmacy technicians must apply general principles of compounding so that the resulting compounded medicine has acceptable dosage strength, quality, and purity and is in accordance with the prescription or medicine order[5].

Analysis between knowledge and implementation of GCP in pharmacies showed low significance ($P > 0.05$), in which the cross-tabulation results show that respondents with a high level of knowledge do not necessarily have a great opportunity to implement GCP better[21]. In general, the relationship between knowledge and implementation in the context of Good Compounding Practice (GCP) is closely relevant. A strong knowledge of GCPs is usually an important prerequisite for implementing good medication-compounding practices. However, in some cases, knowledge may only sometimes have a direct impact on

GCP implementation, and other factors can also influence the outcome[5]. Several considerations related to this, such as awareness, resources, management, motivation, and work context, also play a role in successful implementation. Therefore, there is only sometimes a simple relationship between knowledge and GCP implementation, and these factors must be considered in efforts to promote good compounding practices[2]. This can be caused by various limitations encountered when implementing GCP. Even though the pharmaceutical practitioners who were respondents had fairly good knowledge, in reality, the compounding equipment needed to be calibrated regularly, and information beyond the use date (BUD) was rarely provided to patients[22].. The limitation of this research is that the samples obtained by researchers were still small and needed to be evenly distributed throughout Indonesia. Then, due to limited time, the questionnaire created covered only some aspects of compounding contained in USP 34 chapter 795[22].

▪ CONCLUSION

Good knowledge and implementation of Good Compounding Practice is very important to maintain the integrity and safety of medicines produced in compounding practices. This must be implemented in the training and education of pharmaceutical practitioners to help maintain the quality of safe and effective drug compounding practices.

Acknowledgements: The authors express gratitude to all study participants. Special thanks to the Jakarta II Health Polytechnic Institution under the Ministry of Health, South Jakarta, particularly the Directorate, for supporting and assisting in securing research permits through an independent research scheme. This study was funded by The Diploma of Pharmacy Studies Program, Jakarta II Health polytechnic of the Ministry of Health, Jakarta, Indonesia, (No: HK.02.03/I/0706/2023.).

Author contributions: Concept – A.K., U.S., Y.S.; Design – A.K.; Supervision – Y.S.; Resources – A.K., U.S; Materials – A.K.; Data Collection and/or Processing – A.K., U.S.; Analysis and/or Interpretation – A.K., U.S., Y.S.; Literature Search – A.K., U.S; Writing – A.K.; Critical Reviews – A.K., U.S., Y.S.

Conflict of interest statement: The authors declared no conflict of interest

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