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Original Article

Analysis of Pharmacists' Knowledge of Non-Sterile Good Compounding Practice (GCP) and Implementation in Samarinda City Pharmacies

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ABSTRACT

Background: Drug compounding is a significant concern due to the emergence of various unwanted events, including pharmaceutical problems and drug interactions. Good Compounding Practice (GCP) provides detailed guidance on the proper compounding practices necessary for preparing drug formulations for human use. This study aims to assess the level of knowledge of pharmacists about GCP, the implementation of GCP in pharmacies in Samarinda City, and the relationship between pharmacists' knowledge of GCP and its implementation. **Methods:** This descriptive observational study was conducted using a cross-sectional design. The sampling technique employed was total sampling, resulting in a sample size of 120 respondents. Data analysis was performed using chi-square analysis to determine the correlation between the level of knowledge and the implementation of GCP among pharmacists. **Results:** The study revealed that pharmacists' knowledge of GCP was relatively good, with an average score of 81.91. The implementation of GCP in Samarinda City pharmacies was also found to be relatively good, with an average score of 77.91. However, there was no significant relationship between the level of knowledge and the implementation of GCP (P value = 0.896). The cross-tabulation of the Odd Ratio (OR) yielded a value of 0.992, indicating that a higher level of knowledge slightly reduces the risk of poor implementation of GCP among pharmacists. **Conclusion:** While pharmacists in Samarinda City demonstrate a good understanding of GCP and its implementation, this study found no significant correlation between their level of knowledge and the practical application of GCP in their daily work. Further research may be needed to explore other factors influencing the implementation of GCP in pharmacies.

Keywords: *Good Compounding Practice (GCP); Implementation; Knowledge Level; Pharmacy*

INTRODUCTION

Compounding is the process of preparing customized drug formulations by mixing pharmacologically active ingredients with pharmaceutical additives to meet the specific needs of patients (Mattison, *Parker &* Jackson, 2020). This involves combining, mixing, or altering ingredients to create a drug that is tailored to individual requirements. Compounded drugs are often modified from existing forms or created by mixing active ingredients into new preparations, such as poultices (Toha *et al*., 2022). They are also produced when commercially available drugs are not suitable or unavailable (Gudeman *et al*., 2013). Pharmacists play a critical role in compounding, as they must ensure that the medicinal products

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meet the unique needs of patients. This process must be performed meticulously by qualified medical personnel or pharmacists following established standard operating procedures (SOPs) or standard formulations to produce high-quality drug products that ensure patient safety (Dooms & Carvalho, 2018). In Indonesia, the practice of drug compounding remains common among doctors. However, concerns have arisen due to the occurrence of adverse events, such as pharmaceutical problems and drug interactions (Rochjana *et al*., 2019). To address these issues, GCP guidelines have been established. GCP provides detailed instructions on how to properly compound drugs for human or animal administration, covering aspects such as personnel, compounding processes, facilities, equipment, material storage, and documentation (General Chapters, 2020). The quality of compounded drugs in Indonesia largely depends on the expertise of pharmacists. It is essential that pharmacists master the skills required for effective drug compounding (Pignato & Birnie, 2014). However, research has shown that the implementation of compounding practices in Indonesia is less than optimal. Issues identified include insufficient knowledge among compounding personnel, the use of multifunctional compounding tables, lack of documentation, and the failure of many compounders to use Personal Protective Equipment (PPE) during the compounding process (Dewi & Wiedyaningsih, 2012). Given these challenges, further research is necessary to assess the understanding and implementation of GCP among compounders in pharmacies. This research will help identify and address the problems currently encountered in the compounding process within pharmacies.

METHODOLOGY

This type of research is descriptive correlation with cross-sectional research design. Direct data collection in the form of questionnaires given to pharmacists, namely data reviewed from demographic data, level of knowledge about GCP, implementation of GCP and obstacles to implementing good drug compounding practices. The sampling technique used in this study used a total sampling technique, from 250 pharmacists in Samarinda City pharmacies, 120 pharmacists were obtained who met the inclusion criteria. The tool used in this study is a questionnaire made by researchers based on USP 34 chapter 795, the National Association of Pharmacy Regulatory Authorities regarding good compounding practice and Regulation of the Minister of Health of the Republic of Indonesia Number 73 of 2016 concerning Pharmaceutical Service Standards in Pharmacies which will be given to pharmacists in Samarinda City Pharmacies. This study used 2 questionnaires, namely a questionnaire regarding pharmacists' knowledge of GCP and a questionnaire regarding the implementation of GCP by pharmacists in pharmacies. The material for this research is data from pharmacists' answers to the pharmacist's level of knowledge about GCP and its implementation. Researchers determine the topics discussed in the GCP and develop these topics into several questions. Researchers used 2 questionnaires, namely a questionnaire regarding pharmacists' knowledge about GCP and a questionnaire regarding the implementation of GCP by pharmacists in pharmacies. Data analysis in this study was univariate analysis, univariate analysis was grouped using Microsoft excel. The questionnaire used to measure the level of knowledge of pharmacists was a multiple-choice type questionnaire using a single choice question form with options a, b, and c. The questionnaire used to determine the implementation of GCP was a questionnaire with a Guttman scale, with the criteria "Yes" or "No". Bivariate analysis used in this study to determine whether or not there is a correlation between demographic characteristics of knowledge and implementation. To determine the analysis to be used, the sample will be tested with the chi square test which is used to analyse nominal data. If the P value is <0.05, there is a significant relationship between the two variables tested (McCrum-Gardner, 2008). The odd ratio (OR) value is used to see how much the relationship between the two variables is tested. Odd ratio can be used if two variables have a significant relationship or P value <0.05 (Szumilas, 2010).

RESULTS AND DISCUSSION

Demographic Data:

The characteristics of the respondents in this study used to describe the sociodemographic characteristics of respondents were gender, year of graduation, place of work and length of work. This is expected to provide a fairly clear picture of the respondents' conditions and research objectives at

the Samarinda City pharmacy. The total percentage based on the characteristics of the respondents is as follows:

Table 1: Percentage of Respondents by Year of Graduation, Length of Service, GCP Training

Year of Pharmacist Graduation	**Number of Respondents**	**Percentage (%)**
2005-2009	7	6%
2010-2014	23	19%
2015-2019	51	42%
2020-2023	39	33%
Total	120	100%
Length of Service	**Number of Respondents**	**Percentage (%)**
<1 Year	17	14%
1-3 Year	44	37%
4-7 Year	44	37%
8-10 Year	12	10%
>11 Year	3	2%
Total	120	100%
Training GCP	**Number of Respondents**	**Percentage (%)**
Yes	31	26%
No	89	74%
Total	120	100%

Based on table 1, Characteristics of respondents based on graduation year are grouped based on a span of 5 years, because every 5 years there is a change in the competence of the Pharmacist profession. The year of graduation of respondents to become a pharmacist is mostly between 2015-2019, namely 51 people. While between 2005-2009, 2010-2014, 2020-2023 were 7, 23, and 39 people. Based on length of work, 44 respondents have worked at the pharmacy for 1-3 years. Furthermore, 17 respondents have only worked at the pharmacy for less than 1 year. In the 4–7-year time range, there were 44 respondents. Then, as many as 12 respondents have worked for 8- 10 years. Meanwhile, the period above 11 years only consisted of 3 respondents. The length of work of respondents needs to be known because a person's knowledge is influenced by that person's experience. The longer the working period, the more experience and knowledge will be obtained (Sulistya, Pramestutie & Sidharta, 2017). Based on the results of GCP training by pharmacists in Samarinda City pharmacies, it shows that as many as 89 respondents have never received training on Good Compounding Practice (GCP) after graduating from college. While only 31 respondents had received good compounding training after graduating from college. In a study conducted by on good compounding training, the results showed an increase in participants' knowledge after being given training materials (Rahayu & Yulyuswarni., 2020). Before training, the difference was very far, compared to after being given a good compounding theory. Therefore, training is very important because it is a process to shape and equip pharmacists by increasing skills, abilities and knowledge (Kasmir, 2019).

Pharmacist Knowledge of Good Compounding Practice (GCP):

Accurate knowledge is essential for pharmacists to carry out the compounding process. The assessment of a pharmacist's knowledge includes definitions, personnel, compounding procedures, equipment, stability, and facilities in the pharmacy. Based on research conducted with 120 respondents, the level of pharmacists' knowledge about GCP in pharmacies in Samarinda City was evaluated. The following are the results of the recapitulation of pharmacists' knowledge levels regarding GCP in these pharmacies.

Table 2: Recapitulation of Pharmacists' Level of Knowledge About GCP

No	Respondent	Knowledge level			
		Good		Not enough	
		N	%	N	%
1.	Man	28	23	0	0
2.	Woman	90	75	2	2

Based on table 2, the good category for male respondents is 23% (n= 28) and the good category for female respondents is 75% (n= 90). Respondents in the less category were 2% (n= 2). The answer results were categorized into 2, namely "Good" (56%-100%) and "Poor" (<56%). The average value of Pharmacists' knowledge level regarding Good Compounding Practice (GCP) is 81.91 so it is included in the "Good" category.

Implementation of Good Compounding Practice (GCP) in the Pharmacy:

The role of the Pharmacist is of particular concern because the Pharmacist has the expertise and authority as the person responsible for pharmaceutical work in the pharmacy. To ensure the safety, quality and effectiveness of compounded medicines, pharmacies that receive prescriptions for compounding medicines must implement or follow guidelines for dispensing good medicines. One of the guidelines that can be used is USP and Regulation of the Minister of Health of the Republic of Indonesia Number 73 of 2016 concerning Pharmaceutical Service Standards in Pharmacy. The following are the results of the answers to the implementation of Good Compounding Practice (GCP) in Samarinda City pharmacies:

Table 3: Recapitulation of GCP Implementation in Pharmacies

No	Respondent	GCP Implementation			
		Good		Not enough	
		N	%	N	%
1.	Man	28	23	0	0
2.	Woman	91	76	1	1

Based on table 3, the good category for male respondents is 23% (n= 28) and the good category for female respondents is 76% (*n*=91). Respondents in the less category were 1% (n= 1). The answer results were categorized into 2, namely "Good" (56%-100%) and "Poor" (<56%). The average value of Good Compounding Practice (GCP) implementation in pharmacies is 77.91 so it is included in the "Good" category.

Relationship between Demographic Characteristics and Pharmacists' Knowledge and Implementation of Good Compounding Practice (GCP):

The analysis is used to determine whether or not there is a correlation between demographic characteristics and knowledge and its implementation is chi square. The chi square test is used to analyze nominal data. If the P value is <0.05 then there is a significant relationship with the two variables tested. The results of the analysis are as follows:

Table 4: Relationship Between Pharmacists' Level of Knowledge and Implementation of Good Compounding Practice (GCP)

Variable	GCP Implementation		P (*Value*)	*Confidence Interval*		OR	Ket
	Good	Not enough		*Lower*	*Upper*		
Knowledge level			0.896	0.975	1.008	0.992	No connection
Good	117	1					
Not enough	2	0					

Based on table 4, the P value obtained for the knowledge level variable associated with GCP implementation has a value that exceeds 0.05. These results indicate that the knowledge level variable does not have a significant influence on GCP implementation. Cross tabulation results of Pharmacists

with good knowledge and implementation were 117 people, Pharmacists with good knowledge and poor implementation were 1 person. There were 2 pharmacists with poor knowledge and good implementation, there were no pharmacists with poor knowledge and poor implementation. The cross-tabulation results of the Odd Ratio (OR) in table 12 are 0.992, which shows <1, so the level of knowledge reduces the risk of low pharmacists implementing GCP.

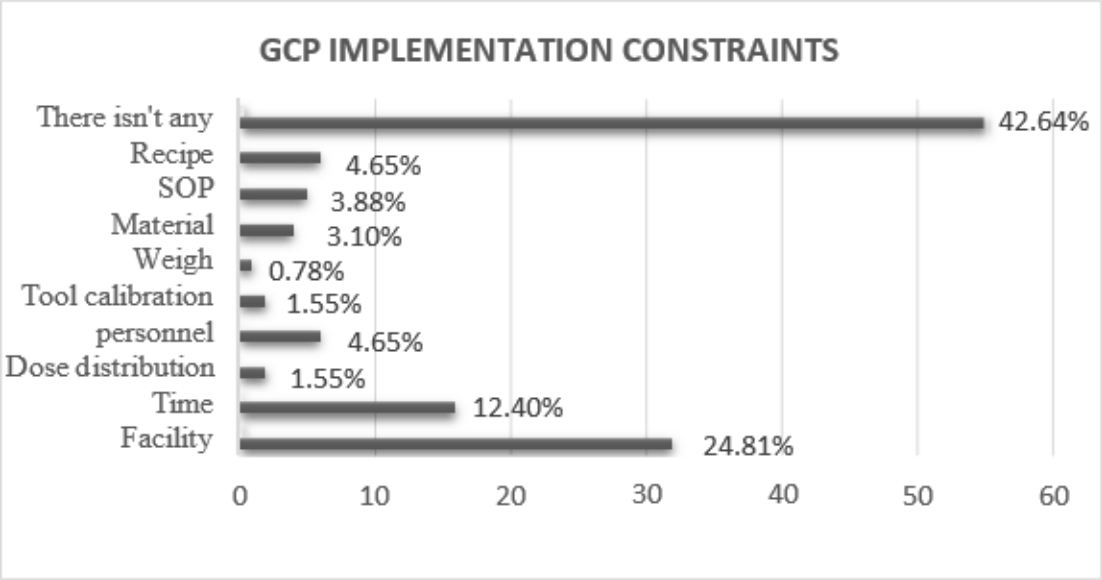

Figure 1: Pharmacists' Obstacles in Implementing GCP

Based on Figure 1, the biggest obstacle for pharmacists in implementing Good Compounding Practice (GCP) is facilities with a percentage of 24.81% with a total of 32 respondents. The most frequently encountered facility problems include rooms that are not separated from medicine storage rooms and other rooms because the rooms are narrow and inadequate. In the compounding room, at least compounding equipment, drug scales, mineral water for diluent, drug spoons, drug packaging materials, refrigerator, room thermometer, blank prescription copies, labels and drug labels are provided. The room is arranged to provide sufficient light and air circulation and can be equipped with air conditioning (Minister of Health of the Republic of Indonesia, 2016). Then in Figure 4, the obstacle for pharmacists in implementing Good Compounding Practice (GCP) is time with a percentage of 12.40% with a total of 16 respondents. The standard waiting time is determined in the Minister of Health Regulation through the minimum service standard, namely, compounded medicine service ≤60 minutes (Minister of Health of the Republic of Indonesia, 2016). The efficiency of waiting time at pharmacies providing prescriptions is caused, in part, by the queue of patients visiting the pharmacy (Yuliana *et al.,* 2021). Therefore, pharmacists have difficulty implementing Good Compounding Practice (GCP) because patients can't wait and weighing and dispensing medicines takes a long time.

In Figure 1, another obstacle faced by pharmacists is personnel with a percentage of 4.65% with a total of 6 respondents. The obstacles faced by respondents include personnel still lacking discipline in using Personal Protective Equipment (PPE) when dispensing medicine and not paying attention to SOPs. Lack of understanding and attention to Standard Operating Procedures (SOP) can cause problems in managing medicines and providing services to patients (Putra, 2021 Mensa *et al.,* 2024). Furthermore, another obstacle is prescriptions with a percentage of 4.65% with a total of 6 respondents. The obstacles faced by respondents were difficulty reading physical prescriptions and the large number of compounded prescriptions, resulting in a lack of attention to proper medication compounding. Obstacles to the implementation of Good Compounding Practice (GCP) that are not often encountered include SOP (3.88%), materials (3.10), weighing (0.78%), equipment calibration (1.55%), dose distribution (1.55%), and respondents who stated there were no obstacles in implementing Good Compounding Practice (GCP) were 42.64%.

CONCLUSION

This study indicates that pharmacists in Samarinda City have a strong understanding of Good Compounding Practice (GCP), with an average knowledge score of 81.91, categorizing their knowledge as "Good." However, significant barriers hinder the effective implementation of GCP. Inadequate facilities were the most common challenge, reported by 24.81% of respondents, particularly due to insufficient dedicated compounding spaces. Time constraints also posed a challenge, affecting 12.40% of pharmacists, as patient flow can impede careful dispensing. Moreover, issues with personnel discipline regarding Personal Protective Equipment (PPE) and adherence to Standard Operating Procedures (SOPs) highlight the need for ongoing training and better compliance. Given that many pharmacists have not received GCP training post-graduation, continuous professional development is essential. To improve GCP implementation, pharmacy management and regulatory bodies should focus on addressing these obstacles by enhancing training opportunities and improving physical facilities. This will foster safer compounding practices and ultimately enhance patient care and safety. Future research should further explore the relationship between these barriers and the practical application of GCP in Indonesia.

Conflict of Interest

The authors declare that they have no competing interests.

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