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Research Article

Knowledge And Practice Of Non-Sterile Good Compounding Practice (GCP) In Samarinda City Community Health Center: Analysis Of Implementation By Pharmacists

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Abstract

Good Compounding Practice (GCP) is a guideline for proper drug compounding, providing detailed instructions on applying good compounding practices to prepare drug formulations intended for human use. Poor compounding can compromise quality, including issues with uniformity of content/potency and weight, physical, chemical, and biological stability, as well as the risk of drug interactions and side effects. The compounding process involves several steps, including preparation, mixing, assembly, packaging, and labeling according to the physician's prescription. This study aims to assess the level of pharmacists' knowledge about GCP, the implementation of GCP, and the relationship between pharmacists' knowledge of GCP and its implementation. This research is non-experimental with a cross-sectional design. The study subjects are pharmacists in Samarinda City, focusing on their knowledge of GCP, the implementation of GCP, and the relationship between the level of knowledge and its implementation. The sampling technique used is total sampling, and data analysis to determine the correlation between knowledge and implementation uses chi-square analysis. The results indicate that the level of pharmacists' knowledge about Good Compounding Practice (GCP) and its implementation in Puskesmas is categorized as "Good." The average knowledge score is 83.26, while the implementation score is 82.

Keywords: Compounded Medicines, Good Compounding Practice, Knowledge Level, Implementation, Puskesmas

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1 Introduction

Health services at Community Health Centers (Puskesmas) are highly dependent on the crucial role of pharmaceutical services. These services encompass the management of pharmaceutical preparations and medical consumables, as well as the provision of clinical pharmacy services. According to regulations stipulated by the Regulation of the Minister of Health of the Republic of Indonesia, the management and implementation of pharmaceutical services are carried out by specifically qualified health professionals, namely pharmacists [1]. The presence of pharmacists in Puskesmas is essential to improve service quality, develop drug-related services, and implement pharmaceutical policies aimed at promoting rational drug use within primary healthcare settings [2]. Pharmaceutical preparations can be obtained through two main approaches: compounding and manufacturing processes conducted by pharmaceutical industries. Both compounded and manufactured medicines must comply with established standards of quality and safety before being administered to patients [3]. Compounded medicines are pharmaceutical products that undergo modification from existing dosage forms into new formulations and involve the mixing of drugs or active pharmaceutical ingredients to produce new preparations, such as powders (pulveres). Compounding is also performed when commercially available dosage forms are not accessible [4]. Compounded medicines are commonly prepared in various dosage forms, including liquid, solid, and semi-solid formulations. One of the most frequently prescribed compounded dosage forms is pulveres (powders), as well as liquid formulations such as syrups [5]. The role of the pharmacist is to ensure that compounded medicines meet established standards of quality, safety, and effectiveness [6].

The compounding process involves several stages, including preparation, mixing, assembling, packaging, and labeling of medicines or medical devices in accordance with prescriptions issued by licensed medical practitioners [7]. Pharmaceutical compounding has become a matter of concern, as it is frequently associated with unintended events, including medication errors [8].

In Indonesia, pharmaceutical compounding is often carried out based on the individual experience of the compounder, primarily due to limited regulatory oversight by the National Agency of Drug and Food Control (BPOM) regarding compounding practices [9]. In contrast, several European countries, such as the Netherlands, Germany, Ireland, and Switzerland, have established national regulations that specifically govern pharmaceutical compounding. These regulations ensure the proper implementation of compounding methods and guarantee the quality and safety of compounded preparations by pharmacists [10].

The benefits of this study include enhancing the researcher's understanding of Good Compounding Practice (GCP) and issues related to compounded medicines, providing insights for pharmacists and Community Health Centers (Puskesmas) regarding GCP and its implementation, and serving as an additional reference for future, more in-depth research on Good Compounding Practice (GCP) for students and researchers.

2 Method

This study employed a descriptive correlational design with a cross-sectional approach. Data were collected directly using a questionnaire administered to pharmacists, covering demographic characteristics, level of knowledge regarding Good Compounding Practice (GCP), implementation of GCP (proper compounding practices), and barriers to the application of good compounding practices.

The study was conducted from May to August 2024. The study population consisted of pharmacists working at Community Health Centers (Puskesmas) in Samarinda City. A total sampling technique was applied, resulting in a study population of 26 pharmacists.

Data analysis was performed using univariate and bivariate analyses, with the Chi-square test employed to examine associations between variables. The data collected were primary data obtained directly from respondents through the questionnaire.

The questionnaire used to assess pharmacists' knowledge consisted of multiple-choice questions with three response options (a, b, and c), from which respondents were required to select one correct answer.

Doi: 10.30872/jtpc.v9i3.322

Correct responses were assigned a score of 1, while incorrect responses were assigned a score of 0. The categorization of knowledge levels was modified based on the classification proposed by Arikunto [11]. For data interpretation, the results were presented in percentage form using the following formula:

$$\text{Skor} = \frac{\text{Jumlah jawaban benar responden}}{\text{Jumlah soal dalam kuesioner}} \text{ x } 100\%$$

The questionnaire used to assess the implementation of Good Compounding Practice (GCP) was based on the Guttman scale, with response options of "Yes" or "No." The questionnaire scoring was conducted by comparing respondents' answers with the GCP guidelines. The responses were classified into two categories: "Good" if 75–100% of the answers were correct, and "Poor" if the proportion of correct answers was less than 75%.

The part of the method is not copied directly from the thesis.

The method is collection work from implementation of research, starting from implementation ways of data recruitment until data analysis.

3 Result and Discussion

The analysis used to determine the presence or absence of correlations between demographic characteristics and both knowledge and its implementation was the Chi-square test. The Chi-square test was applied to analyze nominal data. A p-value of less than 0.05 indicated a statistically significant association between the variables tested. The results of the analysis are presented below [12].

Table 1 Association Between Demographic Characteristics and Level of Knowledge

Characteristics	**Level of Knowledge**		**P (*Value*)**	**Notes**
	Good	**Low**		
Year of Graduation			0,352	No significant association
2004-2014	11	2		
2015-2023	9	4		
Length of Service			0,731	No significant association
<5 Years	8	2		
>5 years	12	4		
GCP Training			0,612	No significant association
Yes	11	9		
No	4	2		
Gender			0,173	No significant association
Male	5	0		
Famale	15	6		

Table 1 presents the results of the bivariate analysis examining the association between various demographic characteristics—such as year of graduation, length of employment, GCP training, and gender—and pharmacists' level of knowledge regarding Good Compounding Practice (GCP). The results of the Chi-square test indicated that there were no statistically significant associations between these

Doi: 10.30872/jtpc.v9i3.322

demographic characteristics and pharmacists' knowledge of GCP, as all obtained p-values were greater than 0.05.

These findings suggest that demographic factors such as length of employment, year of graduation, or participation in GCP training do not significantly influence pharmacists' knowledge of GCP. In other words, pharmacists' knowledge of GCP appears to be relatively uniform across different demographic groups and is not significantly affected by these variables.

Table 2 Association Between Demographic Characteristics and Pharmacists' Implementation of Good Compounding Practice (GCP)

Characteristics	**GCP Implementation**		**P (*Value*)**	**Notes**
	Good	**low**		
Year of Graduation			1,000	No significant association
2005-2014	12	1		
2015-2023	12	1		
Length of Service			0,727	No significant association
<5 Years	9	1		
>5 Years	15	1		
GCP Training			0,819	No significant association
Yes	14	1		
No	10	1		
Gender			0,473	No significant association
Male	5	0		
Famale	19	2		

Table 2 evaluates the association between pharmacists' demographic characteristics and the implementation of Good Compounding Practice (GCP) in Community Health Centers (Puskesmas). The results of the Chi-square analysis indicate that there is no statistically significant association between demographic characteristics—such as year of graduation, length of employment, GCP training, and gender—and the implementation of GCP, as all p-values exceeded 0.05.

These findings suggest that pharmacists' demographic backgrounds do not significantly influence the implementation of GCP in practice. Instead, other factors, such as institutional policies, availability of facilities, and individual awareness, may play a more substantial role in influencing GCP implementation.

Doi: 10.30872/jtpc.v9i3.322

Table 3 Association Between Pharmacists' Level of Knowledge and the Implementation of Good Compounding Practice (GCP)

Variabel	GCP Implementation		P (*Value*)	Notes
	Good	Low		
Level of Knowledge				
Good	19	1	0,347	No significant association
Low	5	1		

Table 3 analyzes the relationship between pharmacists' level of knowledge regarding Good Compounding Practice (GCP) and its implementation. The results of the analysis indicate that there is no significant association between knowledge and the implementation of GCP, with a p-value of 0.347, which is greater than 0.05. This finding suggests that although higher levels of knowledge are generally expected to lead to better implementation, knowledge alone is insufficient to ensure optimal application of GCP. Other factors, such as inadequate facilities, constraints in the implementation of standard operating procedures (SOPs), or other practical barriers, may also influence pharmacists' ability to apply their knowledge in daily practice.

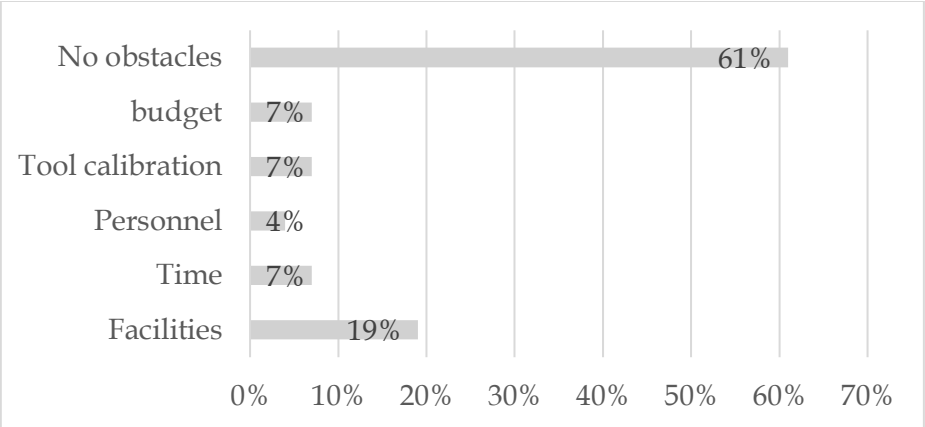

Figure 1 Barriers Faced by Pharmacists in Implementing Good Compounding Practice (GCP)

Figure 3 shows the obstacles pharmacists face in implementing Good Compounding Practice (GCP). In implementing Good Compounding Practice (GCP), pharmacists face several obstacles divided into several categories:

1. Facilities (19%)

The primary facility-related constraints include limited space within community health centers (Puskesmas), where compounding areas are often not separated from drug storage areas, as well as inadequate equipment, such as compounding tables that are not made of stainless steel materials as required by GCP standards.

2. Compounding Personnel (49%)

Significant issues in this category include staff non-compliance, such as failure to use appropriate personal protective equipment (PPE) and difficulties in adhering to standard operating procedures (SOPs). In addition, many staff members demonstrate a lack of awareness regarding the importance of proper GCP implementation.

Doi: 10.30872/jtpc.v9i3.322

3. Other Issues (7%)

Additional constraints include limited budget allocation for equipment calibration and suboptimal time management during the compounding process, which may adversely affect the quality of compounded medicines.

4. No Constraints (61%)

Despite the identification of various challenges, the majority of respondents (61%) reported experiencing no significant barriers in implementing GCP. This finding suggests that these pharmacists may have adapted well to existing SOPs and facilities or have successfully overcome challenges within their working environments.

Demographic characteristics such as year of graduation, length of work experience, and participation in Good Clinical Practice (GCP) training are theoretically expected to be associated with pharmacists' level of knowledge. More recent graduates and pharmacists with longer professional experience tend to have greater exposure to formal education, continuing professional development, and practical experience, which may enhance their understanding of GCP principles [13].

Furthermore, GCP training programs are specifically designed to improve knowledge and compliance with ethical standards and clinical research practices. The absence of a significant association observed in this study is likely influenced by the limited sample size and the homogeneity of respondent characteristics [14].The content of result and discussion made in one unified whole. The result is not raw data, however using data which was processed/analysed with the method was setting. Discussion is result comparison that obtained with concept/theory already exists.

4. Conclusion

Based on research conducted in Samarinda City, it can be concluded that the level of pharmacists' knowledge about Good Compounding Practice (GCP) in Community Health Centers and its implementation is in the "Good" category. The average pharmacists' knowledge score reached 83.26, while the implementation score was 82. However, this study found that there was no significant relationship between pharmacists' knowledge level regarding GCP and their level of implementation.

5. Declarations

5.1 Acknowledgements (Optional)

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5.2 Author contributions

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5.3 Ethics

Ethical Clearance Number 272/EC/KEPK-S1/08/2024 From The Ethical Committee Medical Research Universitas Muhammadiyah Lamongan

5.4 Conflict of Interest

There is no conflict of interest in this article.

5.5 Funding Statement

Financing is done independently

6. Bibliography

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