

Indonesian Pharmacists' Application of Beyond-Use Date Interventions to Patients and Its Contributing Factors: A Cross-Sectional Study

Hospital Pharmacy
2023, Vol. 58(6) 628–633
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DOI: 10.1177/00185787231179833
journals.sagepub.com/home/hpx



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Abstract

Background: Extemporaneous preparations are commonly used in Indonesia, hence, Beyond-Use Date (BUD) information needs to be delivered by pharmacists to patients to maximize drug stability and enhance safety. **Objective:** This study aims to evaluate BUD interventions carried out by Indonesian pharmacists. **Methods:** A cross-sectional design was used, while a validated and reliable questionnaire was given to the samples using the snowballing and purposive sampling methods. The sample criteria were Indonesian pharmacists who had experience serving patients' extemporaneous prescriptions and those that completed the questionnaire. The significance of the relationship between BUD interventions and samples' characteristics was evaluated using the Mann-Whitney *U* test. **Results:** From the 221 total respondents, the majority admitted that they always provide BUD labeling on crushed tablets 46%, syrup 50.7%, and ointment 49.6% extemporaneous preparations. Similarly, most of the respondents also affirmed that they always provided BUD verbal information to patients on crushed tablets 66.8%, syrup 68%, and ointment 64% extemporaneous preparations. However, the remaining pharmacists, ranging from 32% to 54%, acknowledged that they did not always deliver both BUD labeling and verbal information to patients. Compared to the community-based, hospital pharmacists provided BUD labeling more frequently on all extemporaneous formulations as demonstrated by $P < .05$. Additionally, pharmacists found to work in Jakarta and the surrounding areas provided substantially more BUD labeling on crushed tablets and ointment ($P < .05$) compared to other workplace. Adult pharmacists also provided BUD labeling on crushed tablet formulations more often than the middle-aged ($P < .05$). Only the crushed tablet preparation was associated with the provision of BUD verbal information ($P = .004$). **Conclusions:** Based on the results, not all pharmacists verbally inform patients about BUDs nor provide drug labeling on various extemporaneous preparations. The determinant factors contributing to BUD labeling provisions were the type of practice, workplace location, and age. For the provision of verbal information, the only determinant factor was the type of practice.

Keywords

Beyond-Use Date, Indonesian pharmacists, non-sterile compounding drugs

Plain language summary

Beyond-Use Date (BUD) is a date assigned by a pharmacist for a compounded medication that should not be used afterward. In order to avoid medication errors, it is important that pharmacists should always provide BUD labeling and verbal information regarding BUD to patients. The purpose of this study was to explore Indonesian pharmacists' practice in BUD intervention.

Implications for managed care pharmacy

The findings of the study showed there was a lack of awareness among Indonesian pharmacists regarding their responsibilities to provide BUD labeling and verbal

information to patients. The implication for managed care pharmacy is that the Indonesian policymakers must create a regulatory framework related to pharmaceutical care, especially on providing proper information about Beyond-Use-Date to patients.

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Introduction

Indonesian pharmacists are required to provide qualified and safe pharmaceutical care to patients. According to the Regulation of the Indonesian Ministry of Health on Pharmaceutical Service Standards in Hospitals, Pharmacies, and Primary Clinics, pharmaceutical care is a responsible service related to drug formulations for improving patients' quality of life.¹⁻³ To achieve this purpose, pharmacists must have good medicine managerial skills and clinical competencies to optimize the efficacy and safety of the drugs. However, the Beyond-Use Date (BUD) is not clearly stated in the regulations related to pharmaceutical care, despite its relation to the expiration time. According to United States Pharmacopeia, the Beyond-Use Date reflects the expiration time of extemporaneous preparations, and is determined based on the compounding dates.⁴ Consuming medications passed their BUD could interfere with the lower potency and efficacy and higher risk of toxicity due to lower stability. A case series and a case report indicate the emergence of acidosis and Fanconi's syndrome after taking degraded tetracycline tablets.^{5,6} Thus, the unstable drug might endanger the patients, and this shows the importance of BUD knowledge.

Extemporaneous preparations are commonly used in Indonesia, according to Hapsari et al,⁷ 97.6% of prescriptions in Banyumas Regency have at least one extemporaneous compounding. A cross-sectional study conducted in Yogyakarta found that 75% of prescriptions intended for children can only be carried out through extemporaneous compounding due to the non-availability of readily made dosage forms,⁸ hence, this re-emphasize that the knowledge of BUD is very important for patients.⁹ According to Cokro et al⁹ from a total of 60 informants, 97% know nothing about BUD, while 100% denied pharmacists' role in providing related information. Therefore, there is a need to study BUD interventions from the pharmacist angle, that is, providing BUD information on drug labels and verbally. This study aims to examine BUD interventions conducted by Indonesian pharmacists.

Methods

Study Design

A cross-sectional study was conducted using an online questionnaire to explore respondents' provision of BUD interventions on several non-sterile compounding and the related sociodemographic characteristics.

Study Setting

Pharmacists practicing in health center facilities, including hospital and community-based were included, considering that compounding can be performed in all healthcare settings among pharmacists in Indonesia.

Population and Sample

The snow-balling and purposive sampling methods were used for sample screening among Indonesian pharmacists. Indonesia has 32 386 pharmacists and their ratio to the general population is 1:7700.¹⁰ Consequently, in accordance with Charan and Biswas¹¹ the minimum required sample size ranged from 15 with 5% absolute error to 380 with 1%. The inclusion criteria were Indonesian pharmacists who can complete the questionnaire and had the experience of serving patients' extemporaneous prescriptions, particularly dry syrup, crushed tablets, and/or ointment dosage forms. Meanwhile, the exclusion criteria were pharmacy technicians and non-registered pharmacists. Information regarding the purpose of this study, the use of data for publication, and identity confidentiality were conveyed to prospective respondents before filling out the questionnaire.

Data Collection and Instrument

The online questionnaire was distributed through social media platforms including Facebook, Instagram, as well as messaging applications such as WhatsApp. The questionnaire was mainly distributed on Indonesian Pharmacists Association (IAI) WhatsApp groups. All respondents were asked for IAI membership numbers to confirm that they were pharmacists. The data collection was conducted from September to October 2021 using QuestionPro survey tool, while the online questionnaire consisted of 33 relevant questions divided into 2 sections, including sociodemographic and professional experience about Beyond-Use Date of some non-sterile compounding drugs available in Indonesia. These include ointment without moisture, dry syrup without preservatives, and crushed tablets. The questionnaire was initially validated through a peer-review process by clinical pharmacist experts to assess the face and content validity. Validity testing in this study was conducted using Pearson's correlation. When the correlation coefficient is greater than R table, the question is valid. Moreover, Cronbach's alpha was used to assess the reliability of the questions. A question is considered reliable when the Cronbach alpha value $\geq .6$. The validity and reliability testing results showed that all questions used in this study were valid and reliable.

Variables

This study generally provides information describing the profile of BUD interventions by Indonesian pharmacists. In addition, the relationship between the BUD interventions and dependent variables, including workplace location, type of practice, gender, and age groups were also investigated.

Table 1. Demographic Profile of the Pharmacists Respondents.

Pharmacist respondents characteristics	Frequencies	Percentage
Type of practice		
Hospital pharmacist	93	42.1
Community pharmacist	128	57.9
Workplace location		
Jakarta and the surrounding districts	118	53.4
Outside Jakarta and surrounding districts	103	46.6
Sex		
Male	43	19.5
Female	178	80.5
Age		
Adult (21-45 y old)	199	90
Middle-aged (≥ 46 y old)	22	10

Table 2. Descriptive Data of Pharmacists' BUD Interventions On Various Extemporaneous Dosage Forms.

Dosage form	BUD labeling and frequencies				BUD verbal information and frequencies			
	Never (%)	Seldom (%)	Sometimes (%)	Always (%)	Never (%)	Seldom (%)	Sometimes (%)	Always (%)
Crushed tablet	53 (26.2)	16 (7.9)	40 (19.8)	93 (46.0)	14 (6.9)	10 (4.9)	43 (21.3)	135 (66.8)
Syrup	39 (26.0)	9 (6.0)	26 (17.3)	76 (50.7)	8 (5.3)	4 (2.7)	36 (24.0)	102 (68.0)
Ointment	31 (22.3)	12 (8.6)	27 (19.4)	69 (49.6)	10 (7.2)	9 (6.5)	31 (22.3)	89 (64.0)

Data Analysis

The Mann-Whitney *U* test was used to gage the significant relation of BUD interventions with respondents' characteristics using the SPSS Statistics Base 22 software.

Ethics

This study was carried out following the Declaration of Helsinki in 1975 and in May 2021, approval was obtained from the ethics committee, Faculty of Medicine and Health Sciences, Atma Jaya Catholic University of Indonesia.

Results

Among the 221 respondents who completed the questionnaire, 202 (91.40%) had prior experience dispensing extemporaneous prescriptions in crushed tablet form, while 150 (67.87%) and 139 (62.90%) had prior experience with dry syrup and ointment form, respectively. Table 1 shows the characteristic information for the respondents. Regarding the type of practice, pharmacists who work in hospitals and community-based were comparable. Similarly, in terms of workplace, there were slight differences between respondents who worked in Jabodetabek (Jakarta and its surroundings) and outside, while the majority of the respondents were adult women.

The survey results revealed that the majority of pharmacists always use a BUD label for all extemporaneous preparations of crushed tablets, syrup, and ointment preparations

with values of 46%, 50.7%, and 49.6% respectively. Similarly, the majority of pharmacists stated that they always provide BUD verbal information on extemporaneous crushed tablets 66.8%, syrup 68%, and ointment preparations 64%, as shown in Table 2. However, the rest of the pharmacists, ranging from 32% to 54%, confirmed that they do not always provide both BUD labeling and verbal information. Approximately 26.2%, 26%, and 22.3% of the pharmacists did not provide BUD labeling on extemporaneous crushed tablets, syrup, and ointment preparations. Meanwhile, 6.9%, 5.3%, and 7.2% of the pharmacists did not provide verbal information respectively.

The bivariate analysis showed that type of practice correlated with BUD labeling on extemporaneous crushed tablet $P=.000$, syrup 0.001, and ointment 0.004 preparations. BUD labeling on crushed tablet preparation also correlated with workplace location $P=.046$ and age 0.024. Moreover, the labeling on ointment preparation correlated to workplace location $P=.022$. Regarding the provision of BUD Verbal information, only crushed tablets showed a correlation with $P=.004$. These results are presented in Table 3 and more detailed information on significant data can be seen in Table 4.

As shown in Table 4, more hospital pharmacists significantly implemented BUD labeling on crushed tablets, syrup, and ointment preparations with $P < .05$. Regarding the workplace location, pharmacists who worked in Jakarta and its surroundings appeared to significantly label BUD on crushed tablets and ointment preparations ($P < .05$). The results also showed that adults are more likely to label BUD on crushed tablets compared to middle-aged pharmacists ($P=.024$).

Table 3. Correlation Test Between BUD Interventions and Respondents' Characteristics.

	P-value of BUD labeling			P-value of BUD verbal information		
	Crushed tablet	Syrup	Ointment	Crushed tablet	Syrup	Ointment
Type of practice	.000*	.001*	.004*	.004*	.133	.243
Workplace location	.046*	.176	.022*	.796	.701	.891
Sex	.483	.397	.255	.214	.720	.268
Age	.024*	.287	.085	.371	.937	.924

*Significant correlation.

Table 4. Detailing Frequency and Percentage of Significant Data.

	Always	Sometimes	Seldom	Never	P-value
Type of practice	n (%)				
BUD labeling of crushed tablet					
Hospital pharmacist	54 (62.1)	15 (17.2)	5 (5.8)	13 (14.9)	.000*
Community pharmacist	39 (33.9)	25 (21.7)	11 (9.6)	40 (34.8)	
BUD labeling of syrup					
Hospital pharmacist	52 (76.5)	8 (11.8)	1 (1.5)	7 (10.3)	.001*
Community pharmacist	40 (48.8)	20 (24.4)	5 (6.1)	17 (20.7)	
BUD labeling of ointment					
Hospital pharmacist	43 (60.6)	13 (18.3)	5 (7.0)	10 (14.1)	.004*
Community pharmacist	26 (38.2)	14 (20.6)	7 (10.3)	21 (30.9)	
BUD verbal information of crushed tablet					
Hospital pharmacist	67 (77.0)	16 (18.4)	1 (1.2)	3 (3.4)	.004*
Community pharmacist	68 (59.1)	27 (23.5)	9 (7.8)	11 (9.6)	
Workplace location	n (%)				
BUD labeling of crushed tablet					
Jakarta and the surrounding districts	58 (53.7)	17 (15.7)	8 (7.4)	25 (23.2)	.046*
Outside Jakarta and surrounding districts	35 (37.2)	23 (24.5)	8 (8.5)	28 (29.8)	
BUD labeling of ointment					
Jakarta and the surrounding districts	44 (55.7)	17 (21.5)	7 (8.9)	11 (13.9)	.022*
Outside Jakarta and surrounding districts	25 (41.7)	10 (16.7)	5 (8.3)	20 (33.3)	
Age	n (%)				
BUD labeling of crushed tablet					
Adult	89 (48.1)	38 (20.5)	12 (6.5)	46 (24.9)	.024*
Middle-aged	4 (23.5)	2 (11.8)	4 (23.5)	7 (41.2)	

Discussions

The intervention results show that approximately half of the respondents did not always provide BUD labeling and verbal information. Moreover, about a quarter of the respondents do not even provide BUD labeling. All pharmacists are expected to have the ability to provide BUD interventions to the patients according to the drug dispensing Standard Operating Procedures (SOP) that applies at all health facilities.

Compliance with legal requirements and best practice standards must be achieved through the use of efficient SOPs,¹² hence, it is important for health facilities to have SOPs regarding BUD interventions. A qualitative study conducted in England and Wales found that community pharmacists have to follow several processes and it is impossible to comply with every procedure. Pharmacists' confidence in their ability to follow procedures is also impacted by a lack of staff, excessive tasks, and inadequate communication.¹³ Moreover, a

cross-sectional study conducted in 3 big cities in Indonesia showed that the majority of community pharmacists are aware of their responsibilities in providing pharmaceutical services, but they have obstacles in adhering to the rules and regulations.¹⁴ This is in line with the results obtained in this study, which indicated that more BUD labeling was carried out on all extemporaneous preparations in hospitals than in the community. Similarly, the percentage of pharmacists who verbally inform patients about crushed tablets' BUD in hospitals was higher than those in the community. The accreditation by hospitals might be one of the contributing factors to these results. According to an updated Hospital Accreditation Standard, BUD of extemporaneous preparations must be written on each of the drug label.¹⁵ Accreditation is an important tool to standardize the service process, and every hospital in Indonesia must be accredited.¹⁶ Although there were regulations governing the importance of accreditation at primary clinics and community health centers, according to Ministry of Health data in 2019, only 57% of community health centers have been accredited.¹⁷ To date, there are no regulations governing the application of accreditation in pharmacies. Consequently, it is possible that the service process in hospitals is carried out better than in pharmacies due to the absence of audit processes by external parties. The standardization process in other community-based services, for example, primary clinics and community health centers are also not optimum. This shows the positive impact of accreditation which ensures better patient-care procedures. This also emphasizes the importance of standardization process through regulations and its socialization to support the implementation of BUD interventions.

The bivariate analysis also showed the correlation between workplace location and BUD labeling interventions, where pharmacists in Jakarta and the surrounding districts used more BUD labeling on crushed tablets and ointment compared to other workplace locations. This is because Jakarta is a national economic center with massive development,¹⁸ hence, it is likely that various training and skill development are held in this location. A quasi-experimental study showed that pharmacy service training has a positive impact on increasing knowledge and improving clinical services.¹⁹ Therefore, pharmaceutical training is important to support pharmacists' work to provide rational therapy for patients. Based on the Indonesian Ministry of Education and Culture data, there are more pharmacy faculty or study program in Java including Jakarta compared to other locations.^{20,21} This can lead to unequal knowledge related to pharmacy, which might affect BUD interventions. Although, this discrepancy is expected to be minimized in the digitalization era, where seminars and workshops can be held online with the help of various digital applications. A cross-sectional study in Indonesia showed that not all pharmacists have adequate BUD knowledge and this can lead to negative impacts on pharmaceutical service and patients' drug safety.²²

This study re-emphasizes the importance of pharmacy training for pharmacists.

Based on the results, BUD labeling was conducted significantly by adult pharmacists compared to the middle-aged. However, there was a large difference in number between the 2 age categories. According to Central Bureau of Statistics data, in 2022, the most productive age in Indonesia ranges between 25 and 29.²³ This might contribute to the discrepancies in both age categories. Regarding the significant result, based on Gateway to Global Aging Data, about 0.5% to 19.8% of middle-aged between 55 and 65 years old suffered from disabilities in the year 2014 to 2015.²⁴ This can be a barrier to middle-aged pharmacists at work and become the contributing factor for the lack of BUD interventions.

Regarding the standardization of drug dispensing and storage processes, there are regulations that emphasize the importance of checking the expiration date regularly.^{1-3,25} Hospital Accreditation Standards arranged by Ministry of Health recently added the importance of BUD implementation, but without detailing explanations of the storage period of the drug.¹⁵ In other regulations in different settings, there is no explicit BUD explanation and no distinction between the terms of the expiration date and beyond-use date which can lead to misinterpretation by pharmacists regarding drug storage.^{26,27} This implies that pharmacists need to understand this distinction to support BUD interventions and enhance patients' drug safety.

Limitations

Detailed information was not extracted from pharmacists regarding the reasons for not providing BUD interventions, and this is the limitation of this study. This information is needed to acquire determination factors of not providing BUD-interventions for preventive or corrective actions.

Conclusions

Based on the results, not all pharmacists provided BUD labeling and verbal information to patients. Hospital pharmacists provided more BUD labeling on all extemporaneous preparations and verbal information on crushed tablets significantly compared to the community based. Moreover, pharmacists working in Jakarta and the surrounding districts were found to significantly provide more BUD labeling on crushed tablets and ointment extemporaneous preparations compared to other workplace locations. Adults significantly provided more BUD labeling on crushed tablets preparations compared to the middle-aged.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the Research and Community Service Institutions, Atma Jaya Catholic University of Indonesia (AJCU), with grant number 0700/III/LPPM-PM.10.01/05/2021. The funds obtained were used for the data collection process.

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Supplemental Material

Supplemental material for this article is available online.

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