EVALUATION OF THE DETERMINATION AND IMPLEMENTATION OF BEYOND-USE DATE (BUD) TO NON-STERILE EXTEMPORANEOUS COMPOUNDED MEDICINES BY PHARMACISTS IN SUKOHARJO INDONESIA

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ABSTRACT

Objective: This research aims to evaluate pharmacists' determination and implementation of Beyond-Use Date (BUD) for extemporaneously compounded medicines from non-sterile drugs and the factors that influence it.

Methods: This research is a non-experimental cross-sectional study that used a validated questionnaire with the cluster sampling method applied to select pharmacists. The data were analyzed statistically using the Mann-Whitney, Kruskal Wallis tests and Spearman Correlation.

Results: Of the 181 pharmacists who participated, 161 (89.0%) were aged 26–45 years, 160 (88.4%) were women, 118 (65.2%) were married, and 173 (95.6%) had a bachelor's degree with a profession. Around 75%–77% of respondents calculate BUD on the extemporaneous compounded and mark BUD on the drug label or medicine packaging. Around 80% of pharmacists inform patients about BUD, but only 65% ensure patients understand it. Age, marital status, education level, length of work experience, and income significantly influence the determination and implementation of BUD ($P<0.05$). Knowledge has a significant relationship with pharmacists' attitudes ($r = 0.836$) and behavior ($r = 0.646$) towards BUD

Conclusion: The role of pharmacists in determining and implementing BUD in extemporaneously compounded medicines needs to be improved to ensure maximum drug quality, safety, and optimal therapy.

Keywords: Extemporaneous compounding, Beyond use date, Pharmacist, Expired date

INTRODUCTION

Beyond Use Date (BUD) is the date or time when the medicine, formulated into a sterile or non-sterile preparation after being opened in the primary packaging, may not be used, stored, or distributed [1]. BUD, which differs from the manufacturer-determined expiration date, indicates the stability of drugs in extemporaneous compounding [2]. In general, the BUD is not listed on the drug packaging, so not everyone knows when the BUD for a drug is. Therefore, before medication is given to patients, it is necessary to provide education regarding the BUD of the medication they will consume to prevent errors in medication management [3]. BUD also determines the time limit within which a medicinal preparation remains stable, which must have chemical, physical, microbiological, therapeutic, and toxicological characteristics that do not change from when it is produced until during the storage and use period. BUD is very important because it will affect the effectiveness of the drug [4].

In research, Priyoherianto *et al.*, 2023, revealed that the level of public knowledge regarding BUD in Indonesia is still relatively low. This is confirmed by the research results, which showed that the majority of people did not know about BUD, and most did not receive BUD information from pharmacists or pharmaceutical technical personnel [5]. So, some people have the perception that BUD is the same as the expiry date. Furthermore, in research by Cokro *et al.*, 2022 which was conducted in North Jakarta, it was stated that around 97% of pharmacists did not know BUD. Meanwhile, the majority of respondents never received BUD information from pharmacists. The perception of 50% of respondents was based on the expiration date stated on the drug packaging. It can be concluded that the views of the people of North Jakarta are likely influenced by very minimal knowledge of BUD. Therefore, the role of pharmacists in providing information and education to patients and the public seems very important [6].

Based on the existing problems, it is necessary to research to determine and evaluate the level of knowledge, attitudes, and practice of pharmacists in implementing BUD in daily practice, determine the factors that influence the implementation of BUD, and determine the correlation between knowledge, attitudes, and implementation of BUD in pharmacies Sukoharjo Regency.

MATERIALS AND METHODS

Study design

This is quantitative observational research using a cross-sectional design. Respondents were given a questionnaire which contained four sections. The first is demographic data, the second is about knowledge, the third is attitude, and the fourth is respondent practice in implementing BUD. Research data collection was carried out in September-December 2023 at pharmacies in Sukoharjo Regency, Central Java, Indonesia.

Research tools

The instrument used in this research was a questionnaire. The research questionnaire was compiled from primary references such as United States Pharmacopeia (USP) (2022), Ministry of Health (2021), and Indonesian Drug and Food Control Agency (2019) and secondary references, namely Christina (2012), Pertiwi *et al.* (2021), and Kusuma *et al.* (2020) [1, 2, 4, 7, 8, 9]. Validity and reliability tests were carried out before being used in this research to test the validity of the question items.

Sample

The sample used meets the inclusion criteria. Inclusion criteria were the pharmacists, pharmacists willing to be respondents, and pharmacists who worked in Sukoharjo Regency pharmacies. The exclusion criteria were pharmacists who did not answer the questionnaire completely. The minimum number of samples used in this research was 181 people, calculated using the Slovin formula [10].

Data collection

Sampling was carried out using a purposive sampling technique. Questionnaires were distributed directly to several pharmacists in Sukoharjo Regency pharmacies, and cellphones with the WhatsApp

application were also used as a means of distributing the questionnaire link, laptops to compile and process data via Google forms, and SPSS for Windows 25.0 software to manage the data obtained.

Data analysis

Univariate analysis was used to obtain an overview of the percentage of demographic data, knowledge, attitudes, and practice of pharmacists toward BUD. In this study, bivariate analysis was also carried out. A normality test is needed when carrying out bivariate analysis. Data is said to be normally distributed if it has a significance value>0.05. The Kolmogorov-Smirnov test was used to

determine whether the data was normally distributed because it had more than 54 respondents [11]. The normality test results in this study showed that all variables obtained a value<0.05, meaning they were not normally distributed. Data analysis used the Spearman rank test because the data was not normally distributed. Unpaired numerical comparative testing was also carried out on two groups that were not normally distributed using the Mann-Whitney test and on groups of more than 2 using the Kruskal-Wallis test [11].

RESULTS AND DISCUSSION

One hundred eighty-one pharmacists participated in this study. Demographic data is described in Table 1.

Table 1: Demographic characteristic respondents (n=181)

Demographic data	Number	Percentage (%)
Age (year)		
<26	6	3.3
26-45	161	89.0
46-65	13	7.2
>65	1	0.6
Gender		
Female	160	88.4
Male	21	11.6
Marital Status		
Single	58	32.0
Married	118	65.2
Divorced	5	2.8
Educational Background		
Bachelor-profession	173	95.6
Master degree-profession	8	4.4
Duration of working experience (year)		
<3	48	26.5
>3	133	73.5
Monthly income (Million rupiah)		
≤ 2	2	1.1
2-3	43	23.8
3-4	76	42.0
>4	60	33.1

Based on table 1, most respondents were aged 26-45 y, amounting to 84.3%. According to Tobing and Sinaga, 2021, the age range of 26-45 y is the mature age, where at that age, a person will have a good mindset and ability to perceive so that it will greatly influence his attitudes and practice [12]. In this study, the majority of respondents were female, reaching 89%. According to Lestari and Hanun, 2020, women are labeled as more skilled and painstaking workers than men. Apart from that, women are considered more obedient or easier to manage and less demanding or more accepting of circumstances [13, 14]. Most of the respondents were married. Married employees certainly have greater demands, especially in the family economy, because they have more needs [15, 16].

Most of the respondents had a bachelor's degree, 98.4%. According to Damayanti and Sofyan, 2022, the higher a person's level of education,

the higher their knowledge and the better their attitude and behavior. Knowledge can be obtained from education and experience while working [17, 18]. Most respondents have worked for more than three years (66.9%). The longer the work period obtained, the more work experience will increase compared to other colleagues [19]. Most respondents earned an income of more than IDR 4 million. This means that most respondents earn more than the minimum wage for work in Sukoharjo Regency. The length of professional practice influences a large income, and other allowances are assessed based on the experience gained. Work experience can influence the amount of income earned because the longer a person works, the more extensive experience and skilled work attitude can help pharmacies earn more income [20]. The level and description of pharmacists' knowledge, attitudes, and practice in implementing BUD can be seen in table 2-5.

Table 2: The level of knowledge, attitude, and practice toward BUD

Kategori	Number of questions	Range of score	Total score (%) (mean±SD)	Level (%)		
				Low (<56%)	Moderate (56-75%)	High (>76%)
Knowledge	22	0-100	79.33±18.82	10.5	16.0	73.5
Attitude	22	0-100	80.00±19.77	9.4	11.6	78.5
Practice	20	0-100	77.00±16.57	9.9	17.1	72.9

Based on table 2, more than 60% of respondents have good knowledge, attitudes, and practices in implementing BUD. It is known that using a drug that has passed its expiration date means

using a drug whose stability is no longer guaranteed. This study is in line with studies conducted in previous research [19-22]; knowledge related to BUD was in the good category.

Table 3: Responses to the questionnaire on BUD knowledge

Domain	Statements	Correct		Incorrect	
		n	%	n	%
Definition of BUD and ED	Q1. The expiry date (ED) is a date that has been determined when an item can no longer be used because it exceeds the estimated shelf life of the item.	154	85.1	27	14.9
	Q2. Beyond use date (BUD) is the expiry time of a drug after the preparation is formulated	154	85.1	27	14.9
	Q3. The expiration date or ED is the benchmark for stopping the use of the drug	156	86.2	25	13.8
	Q4. Determination of the BUD for medicinal preparations based on the dosage form	117	64.6	64	35.4
	Q5. ED is found on drug packaging	156	86.2	25	13.8
	Q6. ED and BUD are the same terms in drug storage	122	67.4	59	32.6
BUD parameters	Q7. Medicines that have changed color, smell, and taste should no longer be consumed	164	90.6	17	9.4
	Q8. Liquid medicines such as syrup that have turned cloudy, thick, have sediment, are separated, and the packaging has become foggy should no longer be consumed	139	76.8	42	23.2
	Q9. Hardened ointments can still be used	152	84.0	29	16.0
	Q10. Repacking products and multidose packaged medicines are of solid dosage form medicine products that do not require BUD	156	86.2	25	13.8
Determination of BUD	Q11. Amoxicillin dry syrup that has been dissolved requires BUD	144	79.6	37	20.4
	Q12. The BUD for drugs that need to be mixed before use is determined based on the information on the drug packaging	123	68.0	58	32.0
	Q13. Compound drugs are preparations consisting of several drugs with stability and physicochemical characteristics	141	77.9	40	22.1
	Q14. Compounded drugs have a shorter BUD than the ED of each formulation ingredient	147	81.2	34	18.8
	Q15. Mixed medications such as ointments, creams, pastes, and gels can be used until the 35th day if the ED medication lasts more than 35 days.	141	77.9	40	22.1
	Q16. The dry syrup can be used for more than 14 days after reconstituting	142	78.5	39	21.5
	Q17. When the container is opened, the usage time limit does not change	142	78.5	39	21.5
	Q18. Pulveres have a maximum BUD of 180 days if the ED medication is more than 180 days	152	84.0	29	16.0
	Q19. The suppository has a BUD of more than 90 days	132	72.9	49	27.1
	Q20. If there are several drugs in one formulation, the shortest BUD for the drug is used	155	85.6	26	14.4
	Q21. Polio vaccine can be stored at room temperature	132	72.9	49	27.1
	Q22. Injection preparations stored at freezing temperatures (<10) have a maximum BUD of 45 days	138	76.2	43	23.8

Tabel 2: Responses to the questionnaire on BUD attitude

Domain	Statements	SA		A		DF		D		SD	
		N	%	N	%	N	%	N	%	N	%
BUD education	Q1. I will provide information beyond-use date (BUD)	98	55.1	55	30.4	20	11.0	7	3.9	1	0.6
	Q2. I feel the need to provide education about BUD	85	47.0	69	38.1	14	7.7	10	5.5	3	1.7
	Q3. I feel the need to ensure that the patient understands the information related to BUD that I provide	82	45.3	71	39.2	14	7.7	12	6.6	2	1.1
BUD parameters	Q4. I will maintain the characteristics required to minimize the risk of contamination or degradation of drugs	80	44.2	66	36.5	19	10.5	11	6.1	5	2.8
	Q5. I will consider possible ways that physical or chemical characteristics that can change over time can be minimized	61	33.7	73	40.3	27	14.9	14	7.7	6	3.3
Determination of BUD	Q6. I will give special marks to drugs with fast BUD	55	30.4	79	43.6	25	13.8	17	9.4	5	2.8
	Q7. I will pay attention to the expiration date of the medicine every time I store it	63	34.8	82	45.3	14	7.7	16	8.8	6	3.3
	Q8. I will calculate the BUD in the concoction drug	53	29.3	94	51.9	14	7.7	16	8.8	4	2.2
	Q9. I feel it is necessary to show the patient the expiry date of the medicine on the medicine packaging	56	30.9	92	50.8	14	7.7	14	7.7	5	2.8
	Q10. I am worried if the patient takes medication through the BUD	52	28.7	87	48.1	19	10.5	16	8.8	7	3.9
	Q11. I will record the expiry date of the concocted medicine	51	28.2	87	48.1	20	11.0	14	7.7	9	5.0
	Q12. I will look for BUD information from the drug manufacturer	55	30.4	84	46.4	28	15.5	7	3.9	7	3.9
	Q13. I will determine the BUD based on the information on the packaging for preparations that need to be mixed	44	24.3	90	49.7	22	12.2	12	6.6	13	7.2
	Q14. I will store powder preparations and capsules in a damp place	52	28.7	88	48.6	23	12.7	11	6.1	7	3.9
	Q15. I will inform the patient that amoxicillin dry syrup, when mixed with water, can be consumed for a maximum of 7 d	70	38.7	64	35.4	24	13.3	16	8.8	7	3.9
	Q16. I will not use pulveres medicine that has clotted	55	30.4	90	49.7	19	10.5	10	5.5	7	3.9
	Q17. I will inform the patient that the measles vaccine has a BUD of 6 h when stored in the refrigerator at a temperature of 2–8 °C	66	36.5	75	41.4	19	10.5	15	8.3	6	3.3
	Q18. I will use USP in determining the BUD	54	29.8	84	46.4	23	12.7	14	7.7	6	3.3
	Q19. I feel the need to pay attention to factors that can influence the BUD	45	24.9	101	55.8	19	10.5	10	5.5	6	3.3
	Q20. I feel it is necessary to prohibit patients from consuming medication through their BUD	51	28.2	93	51.4	16	8.8	17	9.4	4	2.2
	Q21. I will look for the latest information regarding vaccine BUD from the vaccine manufacturer's brochure	44	24.3	93	51.4	26	14.4	12	6.6	6	3.3
	Q22. I will give a vaccine that I have stored at a frozen temperature for more than 45 d	47	26.0	64	35.4	31	17.1	30	16.6	9	5.0

SA: Strongly Agree, A: Agree, DF: Doubtful, D: Disagree, SD: Strongly Disagree

Table 4 shows that the majority of respondents have a positive attitude towards BUD. However, around 15%-21% of respondents were doubtful regarding statements No. 4, 11-18, and 22. Attitude is a pharmacist's belief regarding beyond use date, which is accompanied by certain feelings and provides a basis for making a response or behaving in a certain way of his choosing. This study is in line with a study conducted by Kurniawan *et al.*, 2023 where the majority of pharmacists had a positive attitude towards BUD. A positive attitude can help patients or the public avoid the dangers of expired medicines [22].

Tabel 5: Responses to the questionnaire on implementation of BUD

Domain	Statments	A		O		ST		SD		N	
		F	%	F	%	F	%	F	%	F	%
Information of BUD	Q1. I provide information related to beyond-use date (BUD)	70	38.7	85	47.0	16	8.8	6	3.3	4	2.2
	Q2. I provide education about BUD	76	42.0	81	44.8	11	6.1	8	4.4	5	2.8
	Q3. I remind patients to save leftover paracetamol medication so it can be used again until the expiration date (ED)	57	31.5	45	24.9	24	13.3	40	22.1	15	8.3
	Q4. I ensure that the patient understands the information about BUD that I provide	59	32.6	75	41.4	23	12.7	18	9.9	6	3.3
BUD parameters	Q5. I maintain the characteristics required to minimize the risk of contamination or degradation of drugs	62	34.3	79	43.6	23	12.7	10	5.5	7	3.9
	Q6. I consider possible ways that physical or chemical characteristics that can change over time can be minimized	66	36.5	85	47.0	12	6.6	11	6.1	7	3.9
Determination of BUD	Q7. I give special marks to drugs with fast BUD	61	33.7	88	48.6	17	9.4	9	5.0	6	3.3
	Q8. I pay attention to the ED of the medicine every time I store it	75	41.4	77	42.5	11	6.1	10	5.5	8	4.4
	Q9. I calculate the BUD in the concoction of drugs	66	36.5	85	47.0	13	7.2	8	4.4	9	5.0
	Q10. I show the patient the ED of the medicine on the medicine packaging	74	40.9	75	41.4	11	6.1	13	7.2	8	4.4
	Q11. I note the ED of the concocted medicine	67	37.0	73	40.3	21	11.6	11	6.1	9	5.0
	Q12. When determining BUD, I consider ED and BUD as one of the drugs mixed in the formulation	84	46.4	17	9.4	18	9.9	42	23.2	20	11.0
	Q13. I am looking for BUD information from the drug manufacturer	62	34.3	79	43.6	19	10.5	13	7.2	8	4.4
	Q14. I determine the BUD based on the information on the packaging for preparations that need to be mixed first	63	34.8	88	48.6	10	5.5	14	7.7	6	3.3
	Q15. I use the oldest drug, BUD, in one formulation that contains several drugs	99	54.7	22	12.2	14	7.7	25	13.8	21	11.6
	Q16. I informed the patient that amoxicillin dry syrup, when mixed with water, can be consumed for a maximum of 7 d	72	39.8	74	40.9	14	7.7	16	8.8	5	2.8
	Q17. I provide information to patients that the measles vaccine has a BUD of 6 h when stored in the refrigerator at a temperature of 2-8 °C	69	38.1	66	36.5	15	8.3	16	8.8	15	8.3
	Q18. I use USP in determining the BUD	64	35.4	69	38.1	27	14.9	12	6.6	9	5.0
	Q19. I prohibit patients from taking medication through their BUD	91	50.3	67	37.0	7	3.9	11	6.1	5	2.8
	Q20. I administered a vaccine that I stored at a frozen temperature for more than 45 d	81	44.8	14	7.7	21	11.6	29	16.0	36	19.9

A: always, O: Often, ST: Sometimes, SD: Seldome, N: Never

Table 6: Relationship between demographic data and knowledge, attitudes, and practices in implementing BUD

Variable	N	Knowledge		Attitude		Practice	
		mean *rank*	p-Value	mean *rank*	p-Value	mean *rank*	p-Value
Age (year)**							
<26	6	5.58	<0.001	6.67	<0.001	8.17	<0.001
26–45	161	91.01		92.37		92.32	
46-65	13	123.92		107.96		106.65	
>65	1	173.50		155.50		172.50	
Gender*							
Female	160	89.07	0.169	89.59	0.319	88.45	0.071
Male	21	105.69		101.71		110.40	
Marital Status**							
Single	58	85.72	0.016	91.19	0.020	58	0.036
Married	118	90.55		87.87		118	
Divorced	5	164.50		161.50		5	
Background Education*							
S1-apt	173	88.28	0.001	87.66	<0.001	88.57	0.004
S2-apt	8	149.81		163.19		143.56	
Working experience (year)*							
<3	48	64.49	<0.001	63.09	<0.001	55.77	<0.001
3	133	100.57		101.07		103.71	
Monthly Income (Millian rupiah)**							
<2	2	6.75	0.002	7.00	<0.001	7.00	<0.001
2-3	43	71.94		66.09		57.77	
3-4	76	103.37		111.53		117.17	
>4	60	91.80		85.65		84.47	

*Mann–Whitney; **Kruskal–Wallis

Table 5 shows that most pharmacists have good practice in implementing BUD. This study is in line with the study conducted by Anggiani *et al.*, 2023, where pharmacists already have positive behavior towards beyond-use date [23]. However, in this current study, 31.5% of pharmacists almost never and 9.4% never provide information to patients about storing leftover paracetamol so that it can be used later. Paracetamol is a symptomatic drug where the drug can be stopped if recovered, and the drug can be used again if patients are sick as long as the drug has not expired. Around 10-18% of pharmacists do not ensure that the patient understands BUD, do not show the patient the expiry date of the medicine on the medicine packaging, and do not inform the patient that amoxicillin dry syrup when mixed with water can be consumed for a maximum of 7 d. In line with the previous study, most patients did not receive information regarding BUD or ED from pharmacists [6].

Based on the Spearman correlation test results, correlation values were obtained of 0.836 and 0.646 with a p-value of<0.001, meaning that knowledge has a significant correlation with attitudes and behavior. The correlation value shows a positive correlation with very strong strength. A positive correlation coefficient means that the higher the respondent's level of knowledge, the higher the attitude and behavior. This study is in line with a study conducted by Kurniawan et al., 2023 where knowledge has a significant contribution to forming attitudes and practice among pharmacists regarding BUD [22]. The relationship between demographic data and knowledge, attitudes, and practice in implementing BUD can be seen in table 6.

Based on table 6, some factors have a significant relationship between demographic data and knowledge, attitude, and practice about BUD are age, marital status, background education, working experience, and monthly income. Efforts are needed to increase knowledge through outreach and counseling related to BUD. In Indonesia, there are no regulations governing the inclusion of BUD in drug labels, so pharmacists need to convey information about BUD to the patients so they better understand and realize the importance of BUD [24, 25].

CONCLUSION

Based on research results from 181 pharmacists in Sukoharjo regency, it is known that the majority is known that the majority are aged between 26-45 y (89.0%), female (88.4 %), married (65.2%), and the level of education was bachelor's degree-profession (95.6%). Most respondents had knowledge, attitudes, and practices in the good category (>72%). Knowledge, attitudes, and practices toward BUD are correlated with each other. Age, marital status, level of education, length of work, and income are significantly related to knowledge, attitudes, and practices of BUD implementation.

ACKNOWLEDGMENT

FUNDING

AUTHORS CONTRIBUTIONS

HK: conceptual or design of the work, analysis, interpretation of data, critical for important intellectual content, and final approval of the version to be published. MRSH: collected data, analyzed, drafted the work, revised, and gave final approval for the version to be published.

CONFLICT OF INTERESTS

The authors declare no conflict of interest.

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