ISSN: 2085-675X (Print)
ISSN: 2354-8770 (Electronic)

**Jurnal Kefarmasian Indonesia**
Available online at https://jkefarind.com/index.php/jki
*Original Research Article*
JKI

# Mother's Knowledge of Expiration Dates, Beyond-Use Date (BUD), and Storage Conditions for Compounding and Non-Compounding Drugs

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ARTICLE INFO

*Article history:*
Received 05 December 2023
Revised 19 February 2024
Accepted 23 February 2024
Published online 29 February 2024

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DOI: https://doi.org/10.22435/jki.v14i1.6634

**Citation:** Isnenia I, Julaiha S. Mother's Knowledge of Expiration Dates, Beyond-Use Date (BUD), and Storage Conditions for Compounding and Non-Compounding Drugs. Jurnal Kefarmasian Indonesia. 2024;14(1):74-83

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## ABSTRACT

Patients can obtain various pharmaceutical dosage forms, both compounded and non-compounded. The expired date is no longer a benchmark when the patient or pharmacist opens the primary packaging in preparation but uses the Beyond-Used Date (BUD). Beyond-used date (BUD) has a shorter time than the expiration date. Storage conditions in the household play an important role in the quality of the drug and its feasibility for consumption. This study aimed to compare knowledge about the expired date, BUD, and drug condition storage in two groups, compounding and non-compounding. This research was quantitative, with a cross-sectional design. The sample of this study was the mothers of pediatric patients who received outpatient treatment at one of the primary health centers. The sampling technique was carried out purposively. Data were collected through interviews in September-October 2021. The results of this study show that the respondents are predominantly in the range of 26-45 years, senior high school education, status as housewives, and insurance. The level of knowledge of both the non-compounding groups in the three aspects is greater than that of the compounding group. There is a significant difference in the compound and non-compounding groups in the knowledge of expired date (p=0.000) and BUD (p=0.000). There is no significant difference in knowledge of storage conditions (0.347). This study concludes that there is a significant difference in knowledge between the two groups in expired date and BUD, where the compounding group has greater good knowledge.

***Keywords***: Beyond-use date; Compounding; Drug storage; Expiration dates

## INTRODUCTION

The prevalence of unused medication at home has increased dramatically in the past decade, with a range of 31.6%-95.5%.[1] The large number of households storing leftover medication can be due to various reasons, such as feeling better/healthier, low compliance, as well as the mindset that leftover medicines will likely be used someday if there are limited costs or ways to obtain them.[2,3,4]

Research conducted by Alnahas showed that 76.1% of respondents kept the remaining leftover medicine until it expired, and 2.8% continued to use the medicine even though it had expired.[4] In other research, 83% of households stored drugs in the unsafe category, namely expired, and the name of the expiry date (crushed tablets-compounded and tablets) was not identified.[5] The presence of expired medicine is not only dangerous for

ISSN: 2085-675X (Print)
ISSN: 2354-8770 (Electronic)

patients but can also endanger children at home.[6]

The expiration date is a marker of drug safety as long as the drug has not been opened in its original primary packaging. If the primary packaging is opened by the patient or pharmaceutical staff in the case of adding water to an oral suspension, adding medication to an intravenous admixture container, mixing ingredients to make a topical cream, mixing crushed tablets, and even repackaging the medication from the original container then the expiration date is not a benchmark. These changes in conditions make the Beyond Used Date (BUD) a benchmark, while the BUD is not always listed.[6,7] In a study, most informants stated that the BUD was the same as the expiry date determined by the manufacturer.[8]

About 95% of respondents in one study showed that they did not know about BUD, and 100% did not receive information on BUD from pharmacists.[8] The storage condition was one of the most important factors influencing medicine home storage. The research carried out shows that attention has been paid to temperature, but the value is still small, below 20%, and for attention to humidity, only 7.8%.[9]

Insufficient knowledge regarding drug safety markers, especially BUD, will lead to the potential for poisoning, ineffective therapy, and accumulation of drug waste at home. Children are a group that is vulnerable to drug use.[10] Prescribing medicines for children is more complicated than for adults because manufactured products are not all suitable for them, including dosage difficulty for swallowing solid manufactured form (tablets, capsules, etc).[11] According to research conducted in 4 pharmacies in the Umbulharjo sub-district, Yogyakarta City, it shows that mixing crushed tablets-compounded is the most prescribed dosage form, followed by syrup and tablets. The emergence of this form is due to the limitations of the availability of commercial products or individualized dosage is required.[12] The actual stability of the drug in the final compounded medicine is not known so to minimize the risk of a compounded medicine degrading, short-term expiry dates are used unless stability studies have been conducted and indicate otherwise. Microorganisms could potentially be introduced during the reformulation of non-sterile products. Including preservatives dan keeping in the refrigerator sometimes as a choice.[13]

There are no studies that describe knowledge on the three aspects of drug safety, as well as a comparison of knowledge in the compounded and non-compounded groups. This is important considering that no one monitors when the medicine is in the household except for the knowledge brought by the patient. This study aimed to compare knowledge about the expiration dates, BUD, and drug condition storage in two groups, compounding and non-compounding. It is hoped that the results obtained can be used as material for consideration in educating patients regarding drug safety.

## METHODS

### Research design

This research is quantitative-analytical, non-experimental, with a cross-sectional design. This research involved two groups of respondents: the compounded group and the non-compounded group. The compounded group were respondents with mixing crushed tablets-compounded. The non-compounded group was respondents with one of the following dosage forms, syrup, topical ointment, eye drops, and dry syrup.

### Population and sample

The population in this study were 179 mothers of children who sought treatment at the community health center in September-October 2021. Samples were taken based on calculations using the unpaired categorical test sample formula to obtain the results of 80 patients for each group. Researchers visited potential respondents after receiving a prescription from the pharmacy. Respondents were divided into certain groups in the order of

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ISSN: 2354-8770 (Electronic)

compounded groups, then non-compounded groups. The inclusion criteria in this study were the mother of a child patient (≤ 12 years), receiving medication belonging to the sample group, being willing to conduct an interview, and being able to communicate in Indonesian. The exclusion criteria in this study were respondents who did not complete the interview.

**Research instrument**

This research uses an interview method using a list of questions. One of the drugs belonging to the compounded or non-compounded (syrup/dry syrup/ointment/eye drops) group that the respondent received was used as a tool to answer the questions. Researchers translate respondent's answers into answer options available in the list of interview questions.

The research was carried out at one of the community health centers in Bandar Lampung City from September to October 2021.

**Data analysis**

Each respondent's answer is transcribed in the answer options from the list of questions. If the question is open, the respondent's answer is checked for correctness using information listed on drug packaging and literature. If it is correct, it is given a score of 2, wrong 1, and no 0. The data is then processed to display descriptive data regarding the characteristics of the respondents and the distribution of answers. Determination of the level of knowledge is obtained from the score divided by the total score of all questions multiplied by 100%. The level of knowledge is divided into good (≥76%), moderate (56-75%), and low (≤55%). and analyzed using the chi-square test to determine comparison between knowledge in the two unpaired groups. Characteristics between the two groups were compared using Chi-square. Mann Whitney test was used to assess comparison answers from each question at expired date, BUD, and storage conditions.

**Ethics approval**

This research has received ethical approval from the Tanjungkarang Health Research Ethics Committee with Number 225/KEPK-TJK/IX/2021.

## RESULTS AND DISCUSSION

Based on Table 1, the respondents in this study were mothers of pediatric patients. The average age of respondents was 33 years (with a range of 19 years to 52 years). About 98.75% of respondents were of childbearing age (15-49 years). The education level of respondents was highest in the high school group, with most of them being housewives. Most patients pay for medical treatment using health insurance. Health insurance helps people face the inability to finance health services. The insurance in this research is that respondents are members of BPJS and JKN Bandar Lampung City. With insurance membership and a supportive health service system, people can immediately seek treatment before the severity increases without thinking about the cost of treatment at that time. This can be seen from the utilization of health service facilities, both first and advanced, which increased by 153% in four years (2014-2018).[14]

The three security aspects looked at in this research are knowledge of expiration, BUD, and storage conditions. Respondents in the 100% compounded group could not indicate the expiration date because this information was not available. In the non-compounded group, expiration date information could be easily identified by 78.75% of respondents. About 11.25% of respondents still made mistakes in determining the expiration date, namely, not mentioning the date/month but mentioning the manufacturing date. The error in reading the expiration date can reach 47.62% (Table 2). Most respondents (> 80%) in the two groups had the correct answer that when the drug has been opened, the BUD is not the same as the expiration date and is not the same for all drug dosage forms (Table 3). The level of knowledge was good in the two groups,

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**ISSN: 2354-8770 (Electronic)**

with a high percentage (>90%) of respondents knowing how to store the medicine to be used, namely placing it at room temperature, and the medicine can change if the storage conditions are wrong (Table 4). The results of this research in Table 5 show that there is a significant difference in knowledge regarding expiration dates and BUD between the compounded group and the non-compounded group (p=0.000), and there is no significant difference in knowledge regarding storage conditions (p=0.347).

**Table 1.** Characteristics of Respondents

| Characteristics | Compounding Group n(%) | Non-Compounding Group n(%) | p-value |
|---|---|---|---|
| Age (years) | | | 0,172 |
| Late teens (17-25) | 8 (10.0) | 8 (10.0) | |
| Early adulthood (26-35) | 48 (60.0) | 34 (42.5) | |
| Late adulthood (36-45) | 23 (28.8) | 35 (43.8) | |
| Early Elderly (46-55) | 1 (1.2) | 3 (3.8) | |
| Education | | | 0,560 |
| elementary school | 7 (8.8) | 6 (7.5) | |
| junior high school | 11 (13.8) | 9 (11.2) | |
| senior High School | 55 (68.8) | 48 (60.0) | |
| Diploma | 0 (0.0) | 4 (5.0) | |
| Bachelor | 7 (8.8) | 13 (16.2) | |
| Work | | | 0,978 |
| housewife | 76 (95.0) | 70 (87.5) | |
| entrepreneur | 1 (1.2) | 4 (5.0) | |
| Employee | 3 (3.8) | 6 (7.5) | |
| Financing | | | 0,786 |
| Insurance | 72 (90.0) | 73 (91.2) | |
| Non-Insurance | 8 (10.0) | 7 (8.8) | |

**Table 2.** Distribution of Expiration Date's Answers

| Question | Answer | Compounding | Non Compounding | p-value |
|---|---|---|---|---|
| The expiration date is the only marker of a safe time limit for using the drug. | Wrong<br>Right | 25 (31.25)<br>55 (68.75) | 35 (43.75)<br>45 (56.25) | 0,104 |
| Can you show me the expiration date of this medicine? | Unavailable<br>Wrong<br>Right | 80 (100)<br>0 (0)<br>0 (0) | 8 (10)<br>9 (11.25)<br>63 (78.75) | 0,000 |
| Is the time limit for using the drug always the same as the expiration date? | No<br>Yes | 61 (76.25)<br>19 (23.75) | 64 (80)<br>16 (20) | 0,567 |
| When is the usage time limit for the drug if it is still in the original packaging from the factory? | Until the expiration date<br>After the expiration date | 80 (100)<br>0 (0) | 79 (98.75)<br>1 (1.25) | 0,317 |

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**Table 3.** Distribution of Beyond-Use Date (BUD) 's Answer

| Question | Answer | Compounding | Non Compounding | p--value |
|---|---|---|---|---|
| Do drugs that have been opened from their original seal/packaging have the same usage time limit as the stated expiration date? | Yes<br>No | 11(13.75)<br>69 (86.25) | 13 (16.25)<br>67 (83.75) | 0,659 |
| Do the different forms of medicine (tablets/puyer/syrup/salp/ dry syrup/etc) that have been unsealed/packaged have the same usage time limit? | Yes<br>No | 9 (11.25)<br>71 (88.75) | 8 (10)<br>72 (90) | 0,798 |
| The existence of information on the packaging indicating the usage time limit | Unavailable<br>No | 0 (0)<br>80 (100) | 8 (10)<br>72 (90) | 0,156 |
| What is the usage time limit of the drug from the packaging information? | Unavailable<br>Wrong<br>Right | 0 (100)<br>0 (0)<br>0 (0) | 72 (90)<br>2 (2.5)<br>6 (7.5) | 0,004 |
| Did you get information about the usage time limit of the drug from the pharmacy staff? | Yes<br>No | 8 (10)<br>72 (90) | 33 (41.25)<br>47 (58.75) | 0,000 |
| If the respondent obtains information on the time limit for drug use from the pharmacy staff, the information submitted by the respondent? | Right<br>Wrong<br>Unavailable | 0 (0)<br>8 (10)<br>72 (90) | 23 (28.75)<br>10 (12.5)<br>47 (58.75) | 0,000 |

**Table 4.** Distribution of Storage Conditions's Answer

| Question | Answer | Compounding | Non Compounding | p-value |
|---|---|---|---|---|
| Can storage conditions (light, temperature) shorten the shelf-life of the drug? | Yes<br>No | 64 (80)<br>16 (20) | 66 (82.5)<br>14 (17.5) | 0,686 |
| What are the good conditions for storing this medicine? | Right<br>Wrong | 75 (93.75)<br>5 (6.25) | 72 (90)<br>8 (10) | 0,387 |
| Can the wrong storage conditions change the drug (changes in color/taste/smell)? | Yes<br>No | 75 (93.75)<br>5 (6.25) | 77 (96.25)<br>3 (3.75) | 0,470 |

**Table 5.** Distribution of Knowledge Levels

| Aspect | Knowledge level | | | | | | |
|---|---|---|---|---|---|---|---|
| | Compounding Group | | | Non-Compounding Group | | | |
| | Low | Moderate | Good | Low | Moderate | Good | p-value |
| Expiration Dates | 14 (17.5) | 66 (82.5) | 0 (0.0) | 1 (1.2) | 21 (26.2) | 58 (72.5) | 0.000 |
| BUD | 14 (17.5) | 66 (82.5) | 0 (0.0) | 11 (13.8) | 51 (63.8) | 18 (22.5) | 0.000 |
| Storage Conditions | 2 (2.5) | 4 (5.0) | 74 (92.5) | 0 (0) | 5 (6.2) | 75 (93.8) | 0.347 |

ISSN: 2085-675X (Print)
ISSN: 2354-8770 (Electronic)

The level of good knowledge regarding expiration in the non-compounded group was greater than in the compounded group. The expiration date is the safe time limit set by the manufacturer under appropriate storage conditions during testing at the factory. For non-compounding drugs, this information is always on the primary packaging and secondary packaging of the drugs. In the group of compounded medicines, this information is not available on the primary packaging (commonly used paper) or secondary packaging (plastic along with the medicine label from the health center). People are still mistaken in determining expiration information on packaging. The reason is because the packaging has too small writing, the use of foreign languages, and the writing is close to each other (between manufacture and expiration date).[15]

There were respondents in the non-compounded group who stated that there was no information on expiration dates (10%) on tablet dosage forms that had been removed from their primary packaging, which came from large containers (bottles of 1000 tablets). The same thing applies to the compounded group; there is no expiration date information written on the medicine packaging/label. The majority (> 55%) of respondents in the two groups knew that the expiration date was the only marker of the safe time limit for using a drug. If the primary packaging of the drug has been opened, the safety limit for drug use is based on the BUD, which is calculated from the opened packaging and dosage forms.[9]

Good-level knowledge regarding BUD in the non-compounded group is greater than in the compounded group. However, the percentage of good-level knowledge regarding BUD in the non-compounded group is still much lower than knowledge regarding the expiration date. This could be due to the lack of BUD information compared to the expiration date. There was no BUD information in the compounded group on primary/secondary drug packaging (100%), and in the non-compounded group, only 10% had BUD information. This information is written for seven days on the dry syrup antibiotic preparation. Apart from the lack of written information on the packaging of compounded and non-compounded medicines, the delivery of verbal information by pharmaceutical staff is also still minimal.

More than 50% of respondents in both groups stated that they did not receive BUD information, with a larger percentage in the mixed group. This can be caused by the duration of administration of prescribed medication ranging from 3 days to 12 days, with the estimated drug running out before BUD is reached. Etiquette/label is a written medium as a means of providing drug information to patients.[16] The minimum information that can be written is the patient's name, prescription number, prescription date, how to use it as requested in the prescription, as well as instructions and other information.[16,17] Label standards in America contain the information component when the drug is no longer used (discharge after) or BUD, not the expiration date. Label modifications in the form of information type and writing method can improve patient compliance.[18]

In this study, there was minimal use of labels (paper) separately from plastic drug packaging from health care facilities or factory primary packaging. The type of information written becomes limited when only plastic medicine packaging or factory primary packaging is used as a medium for written information. The type of information in the group of compounded medicines and non-compounded tablets without original factory packaging is the patient's name and instructions for use written on the plastic medicine packaging. Likewise, with drugs in the non-compounded group, which still have the original factory primary packaging, information is written directly on the primary or secondary packaging of the drug, with the type of information most

ISSN: 2085-675X (Print)
ISSN: 2354-8770 (Electronic)

often written being the instructions for use and the patient's name.[1,2,19] Apart from that, many of these drugs come from doctor's prescriptions.

The lack of information regarding BUD for compounded medicines can be caused by a lack of knowledge of pharmaceutical staff and because pharmaceutical staff have not applied knowledge related to BUD to patients. Research shows that technical pharmacy staff tend to have more theoretical knowledge and less actual application of BUD when they work.[20] Another research showed that pharmacists wrote the BUD on the label without providing verbal information about the BUD to the patient. This verbal information is necessary to prevent misinterpretation of the information on the label. This misinterpretation is the cause of medication errors.[8]

Patient safety is the responsibility of health workers, especially when the patient is at home. With minimal assistance from health workers, all information related to effectiveness and safety should be conveyed either verbally or in writing. The lack of BUD information known to patients means that the expiration date is still a benchmark for storing medicines, which is indicated by the high number of medicines stored until the expiration date.[1,2,19] Prescription number, prescription date, how to use as requested on the prescription, instructions, and other information. This regulation does not explicitly have to include BUD. This could be the reason why the public does not recognize BUD information or is still minimally written/conveyed by pharmaceutical staff.[17]

The dry syrup dosage form is the dosage form for which the BUD is written the most compared to ointment and powder formulations. In this study, no BUD information was written on the mixing crushed tablets-compounded label, and only 36.24% was conveyed orally.[21] Pharmacists, as the last line of contact when patients obtain medicine, also provide minimal education and have minimal knowledge of BUD, especially regarding mixing crushed tablets-compounded and topical preparations.[8,22] Pharmaceutical organizations in several countries have seen BUD as important. The FDA has even created guidelines on how to determine the BUD of sterile and non-sterile preparations. USP labeling standards have been determined to include an expiration date or BUD. BUD information must be included on the prescription drug label with timing based on the manufacturer or USP.[23]

The third aspect of drug safety is storage conditions. The level of good knowledge in the two groups has a high percentage (>90%) and is not statistically significantly different. Respondents know how to store medicines, namely placing them at room temperature, and the medicine can change if the storage conditions are wrong. Respondents tend to have good knowledge that incorrect storage can shorten the time limit for drug use. The time limit for drug use becomes shorter due to improper storage due to an increase in the speed of drug degradation.[24]

Research conducted in Saudi Arabia shows that a large proportion of the sample practices good drug storage, namely reading instructions, storing before the expiry date, and storing in the original packaging.[25] This is different from other studies, which show that the number of respondents is still high (42.9%) who do not read the storage conditions on the medicine packaging.[19] The consequence of complying with storing according to the packaging recommendations is that people still receive quality medicines, and the use of these medicines is still appropriate. Many environmental factors influence the quality of drugs, such as temperature, humidity, and light. Changes in temperature change not only chemical stability but also physical stability and appearance, for example, the melting of suppositories and disintegration of tablets. Regarding humidity, some drugs are hygroscopic, such as acarbose. Some drugs are deliquescent at a more severe hygroscopic level, which usually occurs in sugar-coated tablet dosage forms effervescent.[9]

ISSN: 2085-675X (Print)
ISSN: 2354-8770 (Electronic)

The lack of knowledge regarding expiration dates and BUD is a problem in health services. The public must be provided with knowledge regarding drug safety standards by pharmaceutical personnel. It is also necessary to pay attention to the completeness of the educational written information on medicine labels, considering that there are no medicine-taking supervisors in the household. Pharmacy personnel should also ensure that patients have adequate knowledge of the information provided, either verbally or in writing. This research takes data directly on medicines that patients have just received at the health center so that the information from the patient's existing knowledge is the latest, not from knowledge from the past, which is quite long. It is hoped that the results of this research can be used to modify the written information media that patients will receive. Improvements can take the form of label formats, adding other media that patients can bring, and installing general information media that all patients can access. This written media can be an alternative if it is not possible to provide adequate information orally. The lowest satisfaction with pharmaceutical services at community health centers was found in the aspect of availability of facilities including the presence of drug brochures.[14]

The limitations of this research are, firstly, it was only carried out at one community health center, so it could not compare aspects of differences in pharmaceutical- staff and format/information on labels with the knowledge obtained by patients. Second, no investigation has been carried out regarding the provision of information on drug storage conditions from pharmacists or pharmaceutical technicians. Third, the collection of answers was carried out through interviews, and the answers were translated by the researcher into answer options so that their validity and reliability were not tested. The questionnaire is based on theory and research regarding medication use, storage, and disposal.

## CONCLUSION

There was a significant difference between the two groups in knowledge regarding aspects of the expiration date and beyond the used date. Pharmacists are expected to be able to innovate types of information on labels or different forms of information media from labels that can contain drug information.

### Conflict of Interest

The authors declare no conflict of interest.

### Authors' Declaration

The authors hereby declare that the work presented in this article is original and that any liability for claims relating to the content of this article will be borne by them.

### Acknowledgments

The authors are grateful to the Public Health Center in Bandar Lampung City for the encouragement and permission to collect data.

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