

## The Beyond-Use Date Perception of Drugs in North Jakarta, Indonesia

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### Abstract

Beyond-Use Date (BUD) refers to the unsafe period of drug consumption and is calculated from the moment of opening the primary package. Meanwhile, Indonesia has no current related data, in terms of public awareness. Therefore, this research aims to assess the BUD perception of North Jakarta communities and pharmacists' roles in providing the relevant information. The data collection process employed a semi-structural interview across 6 districts in the research location between September–November 2019, followed by data transcription and thematic development. Based on 60 informants recruited by purposive sampling, three themes were obtained, including residual drug storage, pharmacists' contributions, and BUD awareness. Furthermore, about 97% of the respondents were completely unaware of the subject matter, while 100% denied having any form of sensitization from pharmacists. The perception of 50% were based on the expiration date labelled on the medications. In summary, North Jakarta community's views were possibly influenced by very poor BUD knowledge. Therefore, the role of pharmacists in educating patients and communities appears very essential.

**Keywords:** Drug-compounding, drug-stabilities, perception, pharmacists

## Persepsi mengenai *Beyond-Use Date* Obat pada Masyarakat Jakarta Utara, Indonesia

### Abstrak

*Beyond-Use Date* (BUD) merupakan waktu ketika sediaan obat tidak dapat digunakan lagi dan dihitung berdasarkan waktu pembukaan kemasan primer sediaan. Sampai dengan saat ini, tidak terdapat data tentang pemahaman masyarakat Indonesia mengenai BUD. Penelitian ini bertujuan untuk melihat persepsi masyarakat Jakarta Utara mengenai BUD, serta mengetahui peran apoteker dalam menyediakan informasi BUD. Data mengenai persepsi BUD diperoleh dari wawancara semi terstruktur yang dilakukan di 6 kecamatan yang terletak di Jakarta Utara pada September–November 2019, dan diikuti oleh proses transkripsi dan pengembangan tema. Dari 60 informan yang direkrut secara *purposive sampling*, didapatkan tiga tema yaitu penyimpanan sisa obat racikan, kontribusi apoteker terkait BUD, dan pengenalan terhadap BUD. Mayoritas informan (97%) tidak mengetahui tentang BUD, dan semua informan (100%) tidak pernah menerima informasi BUD dari apoteker. Sebagian dari informan memiliki persepsi bahwa BUD sama dengan masa kadaluarsa yang ada di kemasan pabrik. Kami menyimpulkan bahwa persepsi masyarakat Jakarta Utara mengenai BUD dapat disebabkan oleh pengetahuan tentang BUD yang rendah, dan peran apoteker dalam menginformasikan dan mengedukasi pasien dan masyarakat mengenai BUD sangat diperlukan.

**Kata kunci:** Apoteker, obat racikan, persepsi, stabilitas obat

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Submitted: 5<sup>th</sup> August 2020, Accepted: 30<sup>th</sup> July 2021, Published: 30<sup>th</sup> September 2021

## Introduction

Extemporaneous drug formulation is a preparation using traditional compounding techniques to produce a specific dosage specifically to meet a certain individual's needs, which dosage not commercially available.<sup>1-3</sup> Dermatologic products were the most frequent extemporaneous drug formulations being made.<sup>2</sup> In Indonesia, the number of extemporaneous drug formulations prescriptions is highly implemented. Andriani et al. found that 13.04% of prescriptions are extemporaneous compounding capsules, and 44.88% of them contained six or more drugs.<sup>4</sup> The use of extemporaneous drug formulations was more common in children. This phenomenon is caused by some factors, i.e., the need for drug dosage adjustment from adult form available in the market, the child's refusal to take solid forms, and the limitation of drug formulation availability in primary health care facilities and rural areas.<sup>3,5</sup> Mufarrihah et al. found that 99.76% of pediatric patients received crushed tablets, and 27.24% of them containing more than four drugs.<sup>6</sup>

Meanwhile, Hapsari et al. found that 97.67% of pediatric patients in Banyumas Regency, Central Java, Indonesia, received extemporaneous drugs, with the most common drug formulations were crushed tablet (88.36%) and suspension (8.06%).<sup>7</sup> The disruption of their original packaging's integrity causes changes in crushed tablet's stability and sterility and any other extemporaneous drug formulations. Therefore, the stability of drug forms that had been altered or torn from their primary packaging will not follow the expiration date but following Beyond-Use Dates (BUD).<sup>8</sup>

Beyond-Used Date (BUD) is set based on the time of the preparations, active ingredient's stability, and allowed sterility limits, considering active ingredient properties and its degradation mechanism, drug dosage form

and its components, microbe proliferation potency, container type, the right storage condition needed for the drug, and duration of required therapy.<sup>8,9</sup>

Based on the descriptions above, BUD is a crucial way to monitor the excellent quality of drugs, guaranteeing drug efficacy and safety. This research inquired the community perception in North Jakarta, Indonesia, about BUD, particularly in non-sterile extemporaneous preparations.

According to the United States Pharmacopeia (USP) and Ministry of Health Republic of Indonesia Regulations No. 35 the year 2014 about Pharmaceutical Service Standards, BUD is one of the information that must be added to the patient drug label. The pharmacist needs to counsel the patient about how to use, how they keep and discard the drugs, especially regarding BUD, related to drug storage and drug disposal.<sup>8,10</sup> Based on a cross-sectional survey in Indonesia, only about 43.75% of pharmacists practicing BUD without detailed information about this practice.<sup>11</sup> Therefore, we also want to assess people's perception of a pharmacist's contribution in providing BUD information related to extemporaneous drug preparation service.

## Methods

This study was conducted following the Helsinki Declaration of 1975. It had been reviewed by the ethical committee of the School of Medicine and Health Sciences, Atma Jaya Catholic University of Indonesia (AJCUI) with ethical clearance approval no. 07/05/KEP-FKUAI/2019.

### Study design

Qualitative with phenomenology study design, initiated by recorded semi-structural interviews, followed by data transcription and thematic development.

### Research team

The interviews were conducted by male and one female pharmacy students. Each of the interviewers had been trained by two professional clinical pharmacists on conducting good interview techniques. The interviewers had no relationship with each of the participants.

### Settings

Data were collected between September and November 2019. Data was collected in the public spaces, e.g.: malls or shopping centers in all districts in North Jakarta, which are Cilincing, Penjaringan, Kelapa Gading, Tanjung Priok, Pademangan, and Koja. All districts were included to be more representative of North Jakarta.

### Sampling

The sampling technique was done using non-probability sampling, which is purposive sampling. The samples of this study were collected based on inclusion criteria until reaching data saturation. There were ten informants' data collected from each district, with a total of 60 informants, assuming this number is sufficient to achieve data saturation. This number of informants was considered sufficient to represent the assessed community since repetitive and similar results were obtained during the interview, indicating data saturation. The inclusion criteria were people who live in North Jakarta and more than 18 years old.

### Data collection

Samples were obtained following the purposive sampling technique. Each informant had to fill out a form on demographic details and signed the consent forms. Samples that met all inclusion criteria became informants, who were semi-structurally interviewed face-to-face using a voice recorder. Data were collected until reaching data saturation.

### Interviews

Authors developed questions framework from in-depth literature reviews. Informants were given open questions about how they keep the extemporaneous drug formulations or drugs that have been torn open, the information they got from the pharmacist when they were procuring the drugs, their knowledge regarding the beyond-use date and its difference with an expiration date. The verification process was done during the interviews, and the principal researcher took field notes after the interviews.

### Analysis

Interview results were transcribed and then analyzed thematically by two researchers independently, continued by discussions to overcome discrepancies. In the results part, the themes detected from the interview transcripts were marked by adding quotations. The unnecessary conversation was being cut using sign /.../. A square bracket sign is used to accommodate terms not included in the parts of the theme for the readers to understand the conversations. The themes were translated from Bahasa to English, not word for word, but by the true meaning, to increase the conversations' comprehension.

### Results

About ten eligible people from each district (Cilincing, Penjaringan, Kelapa Gading, Tanjung Priok, Pademangan, and Koja) were selected as informants, creating a total of 60 informants whose interview results showed data saturation. Among the informants, there are 48 males and 12 females. Majority (n=37) of informants came from age group of 36 to 55 years. Their demographic data are presented in Table 1. Each informant was asked three main questions, and the answer was categorized into three themes as followed:

**Tabel 1 Demographic Data**

	Residence (% (n))					
	Cilincing (n=10)	Penjaringan (n=10)	Kelapa Gading (n=10)	Tanjung Priok (n=10)	Pademangan (n=10)	Koja (n=10)
<b>Gender</b>						
Male	70 (7)	90 (9)	90 (9)	60 (6)	90 (9)	80 (8)
Female	30 (3)	10 (1)	10 (1)	40 (4)	10 (1)	20 (2)
<b>Age Category (Years)</b>						
Young adult (18–35)	50 (5)	30 (3)	40 (4)	30 (3)	40 (4)	40 (4)
Middle-aged adult (36–55)	50 (5)	70 (7)	60 (6)	70 (7)	60 (6)	60 (6)
Older adult (>55)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

**Theme 1: Storage of remaining drugs**

During the interviews, the informants were asked about how they kept the remaining drugs (when the primary packaging have been torn) after they got fully recovered from sickness. The answers were ranging from not keeping the remaining drugs to keeping them without time limit. Most respondents only used one drug storage technique for all types of drug forms, be it a crushed tablet, syrup, or cream/ointment. Thus indicating that informants had low knowledge about the right storage for drugs.

- *Not keeping the remaining drugs*

“Well, if I am fully recovered, I will throw away the remaining drugs.”

- *Keeping the remaining drugs for not more than two weeks*

“Two weeks is the longest. After that, I will throw them away.”

- *Keeping the remaining drugs for not more than one month*

“For me, usually we take them [drugs] many times daily. If the drugs not finished, we will keep them for at least a month. Yes [keeping the drugs], just in case we still need them.”

- *Keeping the remaining drugs for not more than three months*

“I usually keep them for three months the longest. Longer than that, I will not take them again because I’m afraid they are not effective anymore. I keep them [the remaining drugs]. /.../ Yes, sometimes I have a relapse that requires me to continue taking the drugs, but if this is not the case, I won’t take them anymore.”

- *Keeping the remaining drugs for not more than six months*

“Usually, I keep them for six months, and I won’t take the drugs that have been kept for longer than that. I’m afraid, well, they won’t be effective anymore, how do I know that. If it is still far from the limit time, I will take them again, but if it is too close to the limit time, I won’t dare [taking the remaining drugs]. I keep them so they can still be used, just in case my family or brother or sister or my uncle needs them. Yes [for the family], for example, I got a cough, and I took effective drugs for it from public health care, or whatever, I can recommend those drugs, let them take those drugs.”

- *Keeping the remaining drugs up to drug’s expiration date*

“Depends on the expiration date. Yes, I would take them [the remaining drugs] again, [but] if they are not effective, then I would go to the doctor again.”

“Check the expiration date. If it’s still far

from it, then I'll take them [the remaining drugs] again for the same disease."

- *Finishing the drugs, no remaining drugs*

"Not long until they are finished. I would throw them away [if there were remaining drugs]"

- *Keeping them without time limit*

"Until they are finished. I would keep them [the remaining drugs] just in case the cough relapse."

- *According to what the doctor said*

"Well, I'll follow what the doctor says."

"Depends on what the doctors say in the [following] consultation. Sometimes the doctor might say the time limit."

#### Theme 2: Pharmacist's contributions

The informants were asked about what did the pharmacist say about storing medication. All informants said pharmacists did not give any BUD information when they were purchasing the drugs. Most of informations received was about the dosage and frequency of taking medication per day.

- *The pharmacist did not tell anything about the drugs storage*

"Never [tell me anything], just about how to use them, how many times a day I have to take them, but [I have] never been told about how long the drug should be stored."

"Nope [never been told by the pharmacist], just follow the instructions on the box."

"Never [tell me anything]. When I bought the drugs, I just bought them. After that, that's it."

- *The pharmacist only informed about where to keep the drugs*

"In the pharmacy, yes, they [the pharmacists] told me, [syrup] should be shaken first, then put in the fridge. I don't think they told me

about how to store capsule drugs."

"Sometimes they [pharmacists] do, but sometimes not. Usually, [they inform me] about where to keep the drugs, in the room temperature."

#### Theme 3: Familiarity with BUD

The informants were asked about their familiarity with BUD. Overall 97% did not know about BUD. About 50% thought that the expiration date was the same as BUD.

- *No idea about BUD*

"Well, I don't know. Usually, I only look at the expiration date."

"I only know about the expiration date. I don't know if it [the maximum time of drug storage] could be invalid."

- *Not sure about BUD*

"Sometimes, the risk of color change is written [on the drug brochure], but sometimes not. So, instead of becoming sick from taking the drugs, we should just throw them away."

"I have seen it on the drug's label. I knew it from somewhere when my family or I got sick, and the packaging has been opened, the drug will expire soon."

- *BUD is the same as expiration date stated in the drug packaging*

"Well, just follow what's written in the packaging."

"Just check the expiration date first before taking it [a drug]. Please don't take it right away."

- *Obtaining BUD information from doctor or relatives*

"I've heard it from the doctor or my co-worker. Usually a week [the BUD]"

- *Obtaining BUD information from the pharmacist's drug label*

"Usually, there is. I knew it from the



pharmacist's writing on the drug's label. It could be three weeks to a month."

## Discussion

Based on the answers to main question 1, the interesting part is that some informants stated that they would keep the remaining drugs not just for themselves but also for their relatives (friends/family). People may think that the drugs should be the same for the same indication regardless of each condition. This behavior is not relevant to the Patient-Centered Care concept, highlighting the importance of health care professionals and patients working together for the best patient outcome achievement.<sup>12,13</sup> Another interesting perception is that some of the informants would like to use the remaining drugs again. Despite going to health care facilities, some people prefer using the remaining drugs for the same condition, although different kinds of drugs might be needed for a better outcome. Two other informants suggest that they might follow the doctor's instructions about BUD. Regarding this issue, the pharmacist role might not be anticipated by the patients. According to Puspitasari et al., Indonesian pharmacists lacked involvement due to low expectations from the patients and doctors, especially in managing non-communicable diseases.<sup>14</sup>

General answers from main question 1 show that informants' knowledge regarding drug storage was low. This statement can be seen by how most informants generalized all types of drug dosage form: crushed tablet, syrup, cream/ointment, into one way of keeping the drug safe. Based on the United States Pharmacopeia (USP) Convention, non-sterile formulation without water content has BUD not more than six months since its preparation time or following the expiration date, which one is earlier. Oral formulation with water content has BUD not more than

14 days. Meanwhile, topical or dermal and liquid or semisolid mucosal preparations with water content have BUD not more than 30 days since preparations.<sup>8,15</sup>

Nevertheless, the informants' statements emphasize that the pharmacist role should be more increased, since the informants are more familiar with doctor's role. A pharmacist has the responsibility to inform BUD to the customer, and the informants' statements indicate the lack of a pharmacist's role in this area. Alfian et al. found that consumers need more drug information and more time to consult pharmacists.<sup>16</sup> Beyond that, according to Hermansyah et al., 60% of community pharmacists in Indonesia only work about 30 hours per week, which means 4.3 hours per day. Therefore the Indonesian community pharmacists not meeting ideal professional working hours, leading to the less visible role of the Indonesian community pharmacists and the unawareness of pharmacist existence.<sup>17</sup>

Another perception is that BUD information could be seen from the pharmacist's drug label. From this informant interview, the pharmacist only wrote BUD on the drug label but not informing the patient about BUD. Direct information about BUD is also needed to prevent misinterpreting label instructions. Misinterpreting drug label instructions is a common cause of medication error and affecting patients' health outcomes.<sup>18,19</sup> For extemporaneous preparations or products that have been torn, the labeling is not regulated and not standardized.<sup>1</sup> Therefore, patient misunderstanding of drug label instructions should be prevented.

Generally, most informants had no idea about BUD, and half of them believed that BUD and expiration date were the same thing. Some informants had no concern about their medicines, probably due to a lack of knowledge about the importance of drug safety. Those statements emphasize the importance of community education or

information about drug storage. Meanwhile, pharmacists' willingness to give information to the patients about drug storage, including BUD, is also important. The pharmacists' knowledge regarding BUD itself should be investigated, whether or not they fully understand the essential of BUD.

This study is the first preliminary project studying perception related to BUD of drugs in Indonesia. Further research about targeted intervention may be needed to educate community. In this study, we did not record informants' education and income level, which could be correlated to poor knowledge about BUD. There is another limitation in this study, since there is no specific Indonesian term to simplify and describe BUD, and people are not familiar with BUD, there might be a mistake in interpreting the expiration date definition by informants. Further clarification and investigation about the expiration date definition by the community are needed.

## Conclusions

This study showed a lack of knowledge of majority informants in North Jakarta about BUD. Pharmacist contributions are needed to enhance community's BUD understanding. Further investigations of pharmacist contribution in providing BUD information to the consumer are needed. An effective way to give the Indonesian community education on handling and storing drugs, including BUD, is also needed.

## Funding

This research is sponsored by Atma Jaya Catholic University of Indonesia (AJCUI).

## Conflict of Interest

The authors declared no potential conflicts of interest concerning the research, authorship,

and publication of this article.

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