

Training on Determining Beyond Use Date (BUD) on Pharmacy Practice at Surabaya Health Vocational School

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ABSTRACT

All drugs must be injected immediately after being prepared because the life of the drug can be shorter and it no longer refers to the Expiration Date (ED). If the medicine is not injected immediately, then to maintain the quality of the medicine before the BUD limit is to give the medicine vial a mark of the date and time the medicine was prepared and it must be stored according to storage requirements. The method used theoretical presentation, question/answer, discussion and practice offline in one of Surabaya Health Vocational School classrooms. The results are the community service activities through training on determining the Beyond Use Date (BUD) in Pharmacy practice at the Surabaya Health Vocational School received a positive response and the participants were very enthusiastic. It is hoped that there will be special standards established by the Surabaya Health Vocational School to help provide understanding regarding determining the Beyond Use Date (BUD) in the pharmaceutical practice and further collaboration with the Health Service, Community Health Center or Hospital on an ongoing basis.

INTRODUCTION

In pharmaceutical practice, before a drug is injected into a patient, the drug needs to be prepared according to the dosage form (such as a solution), packaging type (single dose vial/multidose vial or prefilled syringe) and instructions from the manufacturer (Rational Bulletin, 2012). Some drugs in solution form require a reconstitution process (mixing with a diluent or solvent provided by the manufacturer). Meanwhile, drug solutions in prefilled syringe packaging can be used immediately (Department of Health and Human Services Centers for Disease Control and Prevention, 2011). All drugs must be injected immediately after being prepared because the life of the drug can be shorter and it no longer refers to the Expiration Date (ED). The time period or date after the preparation of the drug where after this time the drug can no longer be used is known as the Beyond Use Date (BUD). In other words, BUD is the time limit for using a medicinal product after it has been formulated or prepared or after the primary packaging (such as bottle, blister, ampoule) has been opened or damaged (RSUD Banjarnegara, 2021).

The BUD between drug products varies and the latest information regarding the BUD of drugs can be obtained from the manufacturer's brochure. If the drug is not injected immediately, then to maintain the quality of the drug before the BUD limit is to provide the drug vial with a mark on the date and time the drug was prepared and must be stored according to storage requirements (National Center for Immunization and Respiratory Disease, 2012). The determination of BUD requires an in-depth understanding of the physicochemical properties, stability, use of the drug and compliance with the guidelines set by regulatory authorities. The determination of BUD on the container of most drugs is regulated by each country's regulations such as USP, The National Association of Boards of Pharmacy (NABP) recommends that BUD be included on the drug label. However, in Indonesia, the timing and inclusion of BUD is still not regulated in a special (separate) regulation (Anggianingrum et. al., 2023). However, knowledge of BUD remains the responsibility of a professional to provide information to patients. The use of drugs by patients who have passed their BUD period can mean that the drug has stability that is no longer guaranteed (Kurniawan et. al., 2023). Therefore, it is important to educate health workers and the public so that knowledge about the use and management of drugs seen from their BUD increases so that they can avoid their bad impacts. To support this, community service is carried out by being a resource person in the Training on Determining Beyond Use Date (BUD) in Pharmacy Practice at the Surabaya Health Vocational School as an effort to increase understanding of applicable drug regulations and guidelines, awareness of the importance of drug stability, service quality and development.

technical skills provided by graduates of the Surabaya Health Vocational School.

IMPLEMENTATION AND METHODS

Community service through training in determining the Beyond Use Date (BUD) in Pharmacy practice at the Surabaya Health Vocational School is carried out offline . This training activity was carried out by a committee formed by the Surabaya Health Vocational School and was held on February 15 2024 and February 16 2024 (for 2 days). This training activity was located in one of the Surabaya Health Vocational School classrooms with a total of 25 Surabaya Health Vocational School students participating together with resource persons as material presenters and the committee as assistants/moderators. The timeline of training activities for determining the Beyond Use Date (BUD) in Pharmacy practice at the Surabaya Health Vocational School is shown as follows:

1. Preparation

These activities include:

- a. Coordination of resource persons with the Surabaya Health Vocational School as the organizer of training activities for determining the Beyond Use Date (BUD) in Pharmacy practice at the Surabaya Health Vocational School.
- b. Preparation of training schedules and plans which make the training duration, activity agenda and time allocation clear and detailed so that it can be ensured that the training runs smoothly and efficiently and provides sufficient time for participant understanding and discussion.
- c. Procurement of equipment and facilities where several facilities are needed to carry out research including classrooms, projectors, whiteboards and markers. Also ensure the availability of the technology needed for the presentation if necessary.
- d. Preparing training materials involves identifying the main concepts that will be conveyed to participants, selecting appropriate teaching methods and developing material that is easy to understand and relevant to pharmacy practice.
- e. Determining training participants means selecting how many participants from the Surabaya Health Vocational School will participate in training activities.

2. Training and Practice

These activities include:

- a. The opening of the training was led by a committee from the Surabaya Health Vocational School and introduced resource persons as presenters

of material on determining Beyond Use Date (BUD) in pharmaceutical practice.

- b. The resource person explained the training material with the theme "determining the Beyond Use Date (BUD) in Pharmaceutical Practice" as an effort to develop understanding and technical skills for Surabaya Health Vocational School students, where in the future Surabaya Health Vocational School graduates will work in the health sector, it is very necessary to think about the impact of determining BUD for patients.
- c. After presenting the material, the resource person allowed participants who took part in the training to ask questions regarding obstacles and what they did not understand after receiving the material from the resource person.
- d. After all the questions were collected, the resource person answered the questions one by one and started a discussion in class to liven up the atmosphere to make it more interactive and understand the material more effectively.
- e. After participants begin to understand what they did not understand before, the resource person will provide questions for participants to answer and determine directly how BUD is actually determined. Participants will receive feedback from the resource person regarding their answers and the resource person will measure the percentage of their understanding regarding determining BUD in pharmacy practice.
- f. After completing it, the resource person closed the event by providing messages and impressions during this training activity.

The method used in community service through "Training on Determining Beyond Use Date (BUD) in Pharmacy practice at the Surabaya Health Vocational School is a theoretical presentation, question/answer, discussion and practice carried out offline in one of the Surabaya Health Vocational School classrooms which is attended by The total number of participants was 25 students from the Surabaya Health Vocational School along with resource persons and the Surabaya Health Vocational School training committee.

The equipment used by the resource person in presenting material related to training on determining the Beyond Use Date (BUD) in Pharmacy practice at the Surabaya Health Vocational School is a projector, laptop, writing tools (markers and erasers), and internet access.

The materials used for training in determining the Beyond Use Date (BUD) in Pharmacy practice at the Surabaya Health Vocational School are presentation materials in the form of powerpoints , examples of medicines in packaging, and copies of reading materials for participants.

RESULTS AND DISCUSSION

In community service through training activities to determine *the Beyond Use Date* (BUD) in Pharmacy practice at the Surabaya Health Vocational School, Dr. Teguh Setiawan Wibowo, MM, M.Sc., M.Farm., Apt and Sri Bintang Sahara Mahaputra Kusuma Negara, S.Farm., M.Farm., Apt as resource persons in explaining the theory related to determining the *Beyond Use Date* (BUD). After the training participants entered the room, the resource person began the training presentation by explaining the SP *Compounding Standards* and *Beyond Use Date* (BUD). The interviewee explained that USP published updates to the USP General Chapter on compounding of non-sterile and sterile preparations as well as new standards for compounding radiopharmaceuticals on June 1 2019. Updates to these chapters include updates to the BUD, reflections on advances in science and clinical practice, clarifying topics -topics that are not consistently understood, and incorporate input from stakeholder engagement and from more than 8,000 public comments received during the public comment process. The BUD in the updated chapters is not significantly revised from the official chapters <795> (last revised in 2014) and <797> (last revised in 2008), and most of the revisions reflect expanded guidance regarding stability considerations and sterility for non-sterile and sterile preparations. Official <795> (last revised in 2014) includes water containing oral formulations = 14 days, water containing topical/dermal and mucosal fluids and semi-solids = 30 days and non-aqueous formulations = 6 months. Meanwhile Revised <795> (published June 1 2019), unpreserved liquid water = 14 days, preserved liquid water = 35 days, non-liquid dosage forms = 90 days, and solid dosage forms = 180 days. The resource person also mentioned that there were new factors that needed to be considered when determining the BUD. This revised chapter changes the categorization of Mixed Sterile Preparations (CSP) from microbial contamination risk levels (i.e. low, medium, and high risk levels) to CSP Category 1 and Category 2. The risk level of microbial contamination is determined based on the specific conditions listed for each risk level. Category 1 and Category 2 are differentiated primarily based on the conditions of manufacture, the possibility of microbial growth, and the period of use. Category 1: CSP is usually set up in an unclassified Segregated Compounding Area (SCA) and has a shorter BUD. Category 2: CSP is prepared in a clean room and has a longer BUD. Comparing the BUD between the official <797> and the revised <797> where the storage period in the official chapter is similar and sometimes longer than the BUD in the revised chapter in general and a longer BUD is permitted in certain circumstances based on additional requirements in engineering control, environmental monitoring , and release testing. After explaining the rules for these changes, the resource person explained that drugs have effectiveness and safety according to standards when their stability is

maintained during storage until they are used by patients or health workers. A medicinal product is said to be stable during storage until use if its physical, chemical, microbiological, toxicological and therapeutic characteristics remain the same as the specifications/conditions set by the manufacturer. The source added that if the stability of the drug decreases, there will be a decrease in the efficacy of the drug and the safety of the drug. In other words, drug stability is correlated with the drug's expiration date and decreasing drug stability indicates that the drug's expiration date is getting faster. Then, the source explained that BUD is said to be medicine that has been opened from its primary packaging, mixed or dissolved so that the expiration date is not the same as that stated on the medicine packaging. BUD is very different from ED which is the expiration date of the drug (when it is still intact or not opened from the primary packaging). The interviewee was of the opinion that the role of pharmacists and pharmaceutical vocational personnel must be to convey BUD information which is very important because it is closely related to the effectiveness and safety of drugs. The resource person said there are factors that influence stability (namely temperature, pH, light, solvent, humidity, packaging, and mixing room), signs of damage to the drug in the dosage form, how to control drug stability, methods for determining BUD, and how to determine BUD based on leaflets non-sterile and sterile compounded preparations. The resource person also gave an example of calculating from what date it was packaged and what date it was opened so that the BUD can be determined. After the explanation regarding BUD calculations was completed, the resource person opened a question/answer session for matters that the participants did not understand. After that, the speakers discussed it together. Then, if the participants' understanding is deemed sufficient, the session continues with the practice of determining the BUD individually by each participant. After the practicum is finished, the resource person closes the session.

During the training activity for determining *the Beyond Use Date* (BUD) in Pharmacy practice at the Surabaya Health Vocational School, the training participants with a total of 25 students at the Surabaya Health Vocational School were not familiar with determining the *Beyond Use Date* (BUD) as an effort to prevent the use of drugs whose stability was already established. not guaranteed or expired and what they know is usually the expiration date of the drug (*expiration date* / ED) so it takes time to research and receive information related to determining *the Beyond Use Date* (BUD) of the drug. Then, the training participants in determining *the Beyond Use Date* (BUD) in Pharmacy practice at the Surabaya Health Vocational School were very enthusiastic about learning how to determine the BUD. Some documentation related to the training process

for determining *the Beyond Use Date* (BUD) in Pharmacy practice at the Surabaya Health Vocational School is shown in the following image.



Figure 1 Participants in the Training on Determining *Beyond Use Date* (BUD) at the Surabaya Health Vocational School
(Source: Personal Documentation)

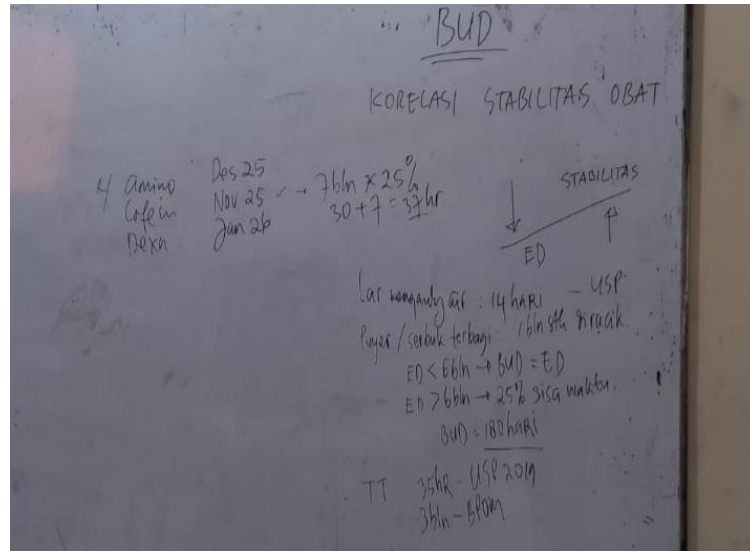


Figure 2 How to Determine the Beyond Use Date (BUD) in Pharmacy practice
(Source: Personal Documentation)

CONCLUSIONS AND RECOMMENDATIONS

Community service activities through training on determining the *Beyond Use Date* (BUD) in Pharmacy practice at the Surabaya Health Vocational School to increase understanding of applicable drug regulations and guidelines, awareness of the importance of drug stability, service quality and development of technical skills related to determining the *Beyond Use Date* (BUD) in Pharmacy practice is *offline* and carried out in one of the Surabaya Health Vocational School classrooms which is attended by a total of 25 Surabaya Health Vocational School students along with resource persons and committee members from the Surabaya Health Vocational School. This training activity was carried out on 15 February 2024 and 16 February 2024 (for 2 days) which included theoretical explanations, questions/answers, discussions and practice which received a positive response and was enthusiastically welcomed by the participants present. It is hoped that there will be special standards established by the Surabaya Health Vocational School to help provide understanding regarding determining the *Beyond Use Date* (BUD) in pharmaceutical practice and further collaboration with the Health Service, Community Health Center or Hospital on an ongoing basis.

Based on the results of the training activity on determining the *Beyond Use Date* (BUD) in Pharmaceutical practice at the Surabaya Health Vocational School above, it is hoped that graduates of the Surabaya Health Vocational School, especially Clinical Pharmacy graduates, can apply the knowledge provided by the resource person regarding determining the *Beyond Use Date* (BUD) in Pharmaceutical practice as efforts to prevent the use of drugs whose stability is not guaranteed or have expired and increase understanding and

development of their technical skills so that the benefits can be felt by patients who visit health centers/services.

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