

Analysis of reconstitution process, stability, stability of intravenous antibiotics in hospitalised patients in a private hospital

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ABSTRACT

Introduction: reconstitution of sterile preparations is a series of changes in the drug from its original condition to a new product by dissolving or adding other ingredients carried out aseptically by the pharmacy.

Aim: determine the suitability of the reconstitution technique, the suitability of stability (solvent type and solvent volume), and the suitability of the sterility of the reconstitution product.

Methods: data collection obtained by observation is carried out with the help of a checklist that is adapted to hospital standard operating procedures (SOPs), Inject-able Drug Guide, guidelines for mixing inject-able drugs, and preparations. 48 processes of reconstitution of intravenous antibiotics were carried out in hospitals that could be observed as samples.

Results: conformity to the preparation stage were 99%, the mixing stage was 73%, the labelling was 100%, and the labelling was 90%. In evaluating the stability of the solvent type category, the suitability of 100%. In the volume category of the solvent used, 90% were suitable, and 10% were unsuitable for the antibiotic's cefotaxime 1 gram, vancomycin 1 gram, and sulbactam + ampicillin Na 1 gram. From the sterility test results, the reconstitution of ceftriaxone intravenous antibiotic preparations showed that the bacterial preparations were free of microorganisms (sterile).

Conclusion: the personnel performing the reconstitution are nurses trained in intravenous antibiotic recovery. One of the factors that caused the reconstitution process not to be under the hospital's KSB was the lack of training and supervision from the hospital management. SPO recovery is not installed in an intravenous drug mixing room.

Keywords: antibiotics; reconstitution; stabilitas; sterility.



INTRODUCTION

Reconstitution of sterile preparations is a series of changes in the form of drugs from their original condition to a new product by dissolving or adding other ingredients carried out aseptically. Pharmacists in the Hospital Pharmacy Installation should carry out the reconstitution process (Krämer, Thiesen and Astier, [2020](#)). However, it is still carried out by health workers with limited facilities and knowledge. At the same time, pharmaceutical work requires special techniques with background knowledge, including sterility, physicochemical properties and drug stability, drug miscibility and the risk of drug exposure hazards (Abbas, Iqbal and Khan, [2022](#)). Intravenous antibiotics are an important part in the treatment of serious bacterial infections in hospitalized patients. They are used to treat infections that cannot be treated with oral antibiotics or that require immediate treatment (Landersdorfer and Nation, [2021](#)). Some critical aspects that need to be considered in compounding sterile preparations are personnel who perform compounding, supporting facilities and infrastructure, and compounding procedures. In addition, the conditions for managing the results of compounding sterile preparations also need to be considered to ensure that drug stability and quality are always maintained (Jeličić *et al.*, [2021](#)). Drug incompatibility is insolubility or precipitation that can be prevented and reversible. Incompatibility is divided into 2 parts: physical incompatibility if no precipitate, crystals, fog, or discoloration are visually detected. Chemical incompatibility occurs if, for at least 24 hours, no decomposition of active ingredients occurs by 10.00% or more (Leeuwerik *et al.*, [2023](#)).

The process of reconstitution and intravenous storage of antibiotics requires a high degree of precision. Errors in this procedure can reduce the effectiveness of antibiotics or even cause the risk of contamination that can harm the patient (Cousins, Otero and Schmitt, [2021](#)). The practice of reconstitution and intravenous antibiotic use can vary between hospitals, even within private categories. This can affect the quality and stability of antibiotics provided to patients. The stability of intravenous antibiotics is a key factor in ensuring that drugs remain effective and safe during use. Impaired stability can result in decreased effectiveness or even unwanted side effects in patients. Analysis of the process of reconstitution and stability of intravenous antibiotics relates not only to the effectiveness of treatment, but also to the safety of patients (Suprpto *et al.*, [2024](#)). The necessary measures to ensure the stability of antibiotics also contribute to reducing the risk of medication errors and their negative impacts (Menga and Hartaty, [2023](#)). Gaps in this context refer to areas where current knowledge or practice is insufficient or requires further research. Protocol alignment There is a need to review and compare protocols for reconstitution and intravenous storage of antibiotics used in private hospitals, especially in terms of alignment with clinical guidelines and drug safety standards (Dixon *et al.*, [2021](#)). There have been no in-depth studies evaluating intravenous antibiotic reconstitution practices thoroughly in private hospitals, including engineering, adherence to procedures, and quality monitoring of reconstituted drugs. Antibiotic stability needs further research on the stability of intravenous antibiotics during the reconstitution and storage process in private hospital environments, especially with variations in storage conditions that may differ. The study of how environmental factors in private hospitals, such as room temperature or humidity, can affect the stability of intravenous antibiotics during the reconstitution and storage process (Kiggundu *et al.*, [2022](#)).

Training of health workers evaluate the level of knowledge and skills of health workers involved in the reconstitution of intravenous antibiotics, as well as their impact on patient error and safety. Increased quality supervision needs to be improved quality supervision in the management of intravenous antibiotic reconstitution in private hospitals, including the use of assistive devices such as temperature or humidity monitoring devices (Mambula *et al.*, [2023](#)). The development of best practices will help improve the safety and effectiveness of intravenous antibiotic use in inpatients in private hospitals. The compounding of energy, infrastructure, and procedures for mixing sterile injectable preparations have not been in accordance with the Guidelines for Injectable Drug Mixing and Handling, in addition to physical incompatibility as

large as even though using solvents according to the literature. One of the Private Hospitals in Palembang has a Standard Operating Procedure (SOP) for handling sterile preparations. A decree of the hospital director delegates the authority of pharmaceutical services to prepare reconstituted drugs for sterile injection preparations to doctors and nurses. This is the reason for researchers to assess the suitability of handling reconstituted preparations based on the 2009 Ministry of Health guidelines and determine the stability and sterility of reconstituted products.

MATERIALS AND METHODS

This study was conducted from April to May 2022 at one of the private hospitals in Palembang with research permit number 0927/CHP-KEPK/VI-22. This study is concurrent observational, by directly observing the process of reconstitution of intravenous antibiotic preparations in the preparation room based on using a checklist sheet based on Standard Operating Procedures (SPO) made by the house, as well as direct observation of stability in the form of the type and volume of solvent. The sterility test of the reconstituted product was carried out at the Palembang Health Laboratory Centre.

Population and Sample

The population used in this study was the entire reconstitution process of intravenous antibiotic preparations carried out from April to May 2022 in inpatients at one of the private hospitals in Palembang. The sample in the study was determined using a purposive sampling technique, namely the entire population that met the inclusion criteria in the form of the reconstitution process of intravenous antibiotic preparations that could be observed directly. At the same time, the exclusion criteria are intravenous antibiotic preparations that have been reconstituted but not given to inpatients in the internal medicine ward.

Research Instruments

Instruments prepared by researchers in the form of reconstitution techniques based on standard operating procedures (SPO) made by one of the private hospitals in Palembang (preparation, mixing, labelling and etiquette), intravenous antibiotic preparation stability evaluation data sheets (drug name, solvent type, and solvent volume) and sterility evaluation data sheets of intravenous antibiotic preparation reconstitution products (drug name and sterility).

Research procedure

Preparatory stage the preparatory stage began with taking care of administrative files for research permit applications submitted to the director of one of the private hospitals in Palembang and conducting field studies in one of the private hospitals in Palembang. Then, formulate existing problems, set research objectives, and compile research instruments. Data collection stage, At this stage, data collection was carried out on the reconstitution process of intravenous antibiotic preparations (preparation, mixing, labelling and etiquette), stability evaluation (drug name, solvent type, and solvent volume), and sterility evaluation of intravenous antibiotic preparation reconstitution products (microorganism testing).

Processing stage

The data obtained were grouped and analyzed, including the reconstitution technique evaluation data sheet, the stability evaluation data sheet, and the sterility evaluation data sheet of the reconstitution product results of intravenous antibiotic preparations. The results are presented in percentage form for correct values given a score = 1 and incorrect values given a score = 0 using the equation below. % conformity = $x \times 100\%$

Data Analysis

Data were analyzed cumulatively as a percentage of patient demographics, suitability of reconstitution techniques, suitability of stability, and sterility description of reconstituted products.

RESULTS

Table 1 Research category data reconstitution engineering of intravenous antibiotic preparations

Assessment Categories	Number of conformities (N=48)	%	Median
Preparatory Stage			
Verify drug preparation according to drug preparation verification procedure 6 CORRECT (correct patient name, drug name, drug dosage, administration time, method of administration, drug does not expire)	47	98	99
1. Perform a double check based on the independent double check procedure.	47	98	
2. Write the label of the drug to be taken in the label provided: the name of the drug, solvent, date, time, name of the nurse and the paraf who prepared it.	48	100	
3. Prepare tools: medicine, syringe, solvent, patient identity label and equipment needed and place them on the work table	48	100	
Mixing Stage			
1. Prepare workbenches and disinfect according to public facility cleaning procedures	14	29	73
2. Perform hand hygiene according to hand hygiene procedures	47	98	
3. Using Personal Protective Equipment (PPE)	17	35	
4. Take the vial and open the vial by: <ol style="list-style-type: none"> a. Open the vial cover. b. Dispose of the vial cover in the drain box. c. Wipe the rubber part of the vial with 70% alcohol (alcohol swab) let it dry. d. Stand up the vial. 	48	100	
5. Suction the required solvent from the solvent colf according to the required amount, if the medicine in the vial is a powder	48	100	
6. Hold the vial 45°C, insert the syringe into the vial	48	100	
7. Insert the appropriate solvent into the vial, slowly turning motions to dissolve the drug	48	100	
8. Apply negative pressure by drawing the air in the vial into the syringe according to the desired volume	48	100	
9. Hold the vial in a position of 45°C,			

draw the solution into the syringe	48	100	
10. For intravenous (iv) infusion requests, inject the drug solution into the infusion vial at 45°C slowly through the infusion wall	3	6	
11. Covering the infusion bottle with sealer/parafilm	0	0	
12. For intravenous bolus requests, replace the needle with the appropriate size for injection	45	94	
13. Physical examination of injection drugs that have been prepared, if there are physical changes in drugs: color, viscosity, turbidity, cristilation then it should not be given to patients	48	100	
14. Put the drug that must be protected from light into black plastic / aluminum foil.	0	0	
15. Attach the patient's ID label and medication label to the syringe or infusion bottle by not covering the volume size	43	90	
16. When finished, throw all contaminated materials into the garbage box according to its category (sharp objects or household waste) and clean the workbench	48	100	
17. Remove PPE according to PPE removal procedures	17	35	
18. Perform hand hygiene in accordance with hand hygiene procedures	48	100	
19. Document the preparation of the drug in the drug list	48	100	
Labeling Levels			
1. Patient name	43	90	96
2. Medical Record No	43	90	
3. Drug name	48	100	
4. Solvent name	48	100	
5. Setup date	48	100	
6. Officer name	48	100	

In evaluating reconstitution techniques based on standard hospital operating procedures. In the category of preparatory stages, which meet 99% of the requirements. Consists of conformity at the point of preparation, namely verifying drug preparations according to 6 procedures for verifying CORRECT drug preparations (correct patient name, drug name, drug dosage, time of administration, method of administration, non-expired drugs) (98%), double checking based on self-double check procedures (98%), writing drug labels to be taken on available labels (drug name, solvent, date, time, nurse's name and initials of the person preparing) (100%), and organizing tools (medicines, syringes, solvents, patient identity tags and equipment needed and placed on the workbench) (100%). It is important to check the condition of the drug before reconstitution to ensure that there are no medication errors that could harm the patient.

Table 2: Stability suitability of intravenous antibiotic preparations

Drug Name	Setup	Route of administration	Belarusian type		Solvent Volume	
			Appropriate	No	Appropriate	No
Seftriakson	1 gram	IV	19	-	-	19
Seftazidime	1gram	IV	6	-	6	-
Sefotaksime	1 gram	IV	3	-	-	3
Sefotaksime	2 gram	IV(Drip)	1	-	-	1
Sefepime	1 gram	IV	5	-	5	-
Sefepime	1 gram	IV(Drip)	1	-	1	-
Meropenem	1 gram	IV	10	-	-	10
Doripenem	0,5 gram	IV(Drip)	1	-	-	1
Vancomycin	1 gram	IV	1	-	-	1
Sulbaktam + Ampicillin Na	1 gram	IV	1	-	-	1
Total			48		12	36

Table 3. Evaluation of Intravenous Antibiotic Dosage Types

Drug Name	Dose	Therapy Classes	n	%
Seftriakson	1 gram	Sefalosforin generasi III	19	39,58
Seftazidime	1 gram	Sefalosforin generasi III	6	12,5
Sefotaksime	1 gram	Sefalosforin generasi III	3	6,25
Sefotaksime	2 gram	Sefalosforin generasi III	1	2,08
Sefepime	1 gram	Sefalosforin generasi IV	6	12,5
Meropenem	1 gram	Beta Laktam Lainnya	10	20,83
Doripenem	0,5 gram	Beta Laktam Lainnya	1	2,08
Vancomycin	1 gram	Glikopeptida	1	2,08
Sulbaktam + Ampicillin Na	1 gram	Penicilin	1	2,08
Total			48	100

DISCUSSION

The researchers found that the personnel performing the reconstitution were nurses trained in intravenous antibiotic recovery. One of the factors that caused the reconstitution process not to be under the hospital's KSB was the lack of training and supervision from the hospital management. SPO recovery is not installed in an intravenous drug mixing chamber. In evaluating the reconstitution technique based on hospital standard operating procedures (SPO). In the preparation stage category, that fulfils 99% of the requirements. Consists of conformity at the preparation point, namely conducting drug preparation verification according to the 6 CORRECT drug preparation verification procedure (correct patient name, drug name, drug dose, time of administration, method of administration, unexpired drug) (98%), double checking based on independent double check procedures (98%), writing the drug label to be taken in the available label (drug name, solvent, date, time, nurse's name and initials of the person preparing) (100%), and organizing tools (drug, syringe, solvent, patient identity label and equipment needed and placed on the work table) (100%). It is essential to check the condition of the medicine before reconstitution to ensure that no medication error can harm the patient (Kuitunen *et al.*, 2021). The suitability of the preparation stage is carried out based on the guidelines for mixing injectable drugs and handling cytostatic preparations, including checking the condition of the drug received (33.33%), calculating the suitability of the dose and volume of solvent (1.75%), using solvents

that are by the literature (100%), making drug labels (93.86%), completing mixing documents (0%) and washing hands with soap (29.82%). In the category of mixing stages that fulfil the requirements with an average value of 73%. It consists of preparing the work table used and disinfecting according to public facility cleaning procedures (29%); the reconstitution process is not carried out in a sterile room or does not use Laminar airflow (LAF) and has a dual filtration system that has a high level of efficiency so that it can function as a filter for bacteria and exogenous materials in the air, maintain a constant airflow outside the environment and prevent the entry of contaminants into the LAF (Beaney *et al.*, 2020). Using Personal Protective Equipment (PPE) (35%), officers only use minimal PPE, namely masks and non-sterile gloves; officers should use protective clothing made of impermeable materials, not releasing fabric fibres with long sleeves cuffed and closed at the front (Tuncay *et al.*, 2021).

Reconstitution using the drip route may be done by sealing the infusion bottle with parafilm (0%) or not at all. Sealing using parafilm can avoid the entry of microorganisms into the reconstituted preparation. Medication errors are a great concern to health care organisations as they are costly and pose a significant risk to patients. Children are three times more likely to be affected by medication errors than adults with medication administration error rates reported to be over 70% (Marufu *et al.*, 2022). Putting drugs that must be protected from light into black plastic/aluminium foil (0%), attaching patient identity labels and drug netiquettes to syringes or infusion bottles by covering the volume size (90%), and finally removing PPE based on PPE removal procedures (35%), not all officers carried out the correct method (Smith and Larmené-Beld, 2023). The proper way to remove gloves, according to the Health Office 2009, should be to place the fingers of the glove on the outside of the cuff and lift the outer glove by pulling it towards the palm; the fingers of the outer glove should not touch the inner glove or skin repeat the procedure with the other hand, lift the outer glove so that the fingertips are on the inside of the glove, hold the raised glove raised from the inside until it is ultimately, discard the glove into a sealed bag (Marzal-Alfaro *et al.*, 2020).

In labelling, the conformity was 96%. Officers still have not attached drug etiquette to syringes or infusion bottles; sterile reconstitution preparations must be given etiquette with complete and transparent information to reduce the risk of errors in patient drug administration therapy. The study results of the stability of intravenous antibiotic preparations for solvent type and solvent volume are based on the Injectable and guidelines for mixing injectable drugs and handling cytostatic preparations. In the category of solvent type used, it is 100% correct, namely WFI (Water of injection) solvent for ceftriaxone, cefotaxime, cefazidime, cefepime, meropenem, doripenem, vancomycin and subactam + ampicillin Na. WFI solvents are compatible with water-carrying antibiotic preparations. In this study, the stability of the solvent is seen from the suitability of the volume and type of solvent used against the Guidelines for Mixing Inject-able Drugs and Handling Cytostatic Preparations of the Ministry of Health 2009. In the category of solvent volume, there is a mismatch (75%); the volume of solvent that is not suitable can cause differences in the concentration and toxicity of the resulting preparation and affect the effectiveness of the drug in inhibiting the growth of microorganisms (Ahmed *et al.*, 2022). Reconstitution of intravenous antibiotic preparations and the type and volume of solvent selection had been carried out properly, but aseptic techniques are still lacking. Sterility tests were carried out on samples of reconstituted products of intravenous antibiotic preparations (Ghert *et al.*, 2022). In this study, the most widely used antibiotic is the third-generation cephalosporin group, so sterility testing was carried out at the Palembang Health Laboratory Center (BBLK), which showed that the results of ceftriaxone intravenous antibiotic preparation products reconstituted by one of the private hospitals in Palembang with limited facilities and aseptic techniques that are not optimal to produce preparations that are free of microorganisms (sterile) (Rodriguez-Merchan and Ribbans, 2022). This is because the work of ceftriaxone antibiotics is to inhibit and kill germs. From the preparation and mixing stages, the reconstituted product's condition is still categorized as good in the sterility test (Li *et al.*, 2020).

The results of this study obtained the most extensive use of antibiotics is the third-generation cephalosporin group, as much as 60.41% consisting of ceftriaxone (39.58%), cefotaxime (8.33%) and ceftazidime (12.5%). Ceftriaxone has a longer half-life than cefotaxime and cefazidime (Fawaz, [2021](#)). Cephalosporins are generally less active against gram-positive cocci than the first generation but much more active against Enterobacteriaceae, including penicillinase-producing strains (Telles *et al.*, [2021](#)). Cefazidime's activity against gram-positive bacteria is not as good as cefotaxime. Its activity against *P. aeruginosa* clearly stands out, far exceeding cefotaxime (Akakuru, Iqbal and Wu, [2020](#)). The most considerable use of antibiotics was ceftriaxone (40.5%) with NaCl solvent. Ceftriaxone has a broad spectrum of activity, so it is the leading prescription choice. There is also research that the highest use of antibiotics is the third-generation cephalosporin group (65.15%) with WFI solvents. The analysis of parenteral antimicrobials shows that the third-generation cephalosporin antibiotic is ceftriaxone (Firesbhat *et al.*, [2021](#)).

CONCLUSIONS

The process of reconstitution of intravenous antibiotics plays an important role in the success of therapy and patient safety. Evaluation and improvement of reconstitution practices needs to be the focus. The stability of the drug during the process of reconstitution and storage must be maintained so that the effectiveness of therapy is not compromised. Further studies are needed to understand the factors affecting the stability of the drug. Harmonization of reconstitution protocols and intravenous storage of antibiotics with clinical guidelines and drug safety standards is important to avoid errors and improve adherence to correct procedures. Increased knowledge and skills of health workers involved in the reconstitution process will contribute to error reduction and improved patient safety. It is necessary to improve quality supervision in the management of intravenous antibiotic reconstitution, including monitoring of drug storage conditions and the use of appropriate aids. The need for a holistic approach in intravenous antibiotic management in private hospitals, with a focus on improving clinical practice, quality control, and training of health personnel to improve the safety and effectiveness of therapy in inpatients.

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Conflict of Interest

None declared

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