Research Article
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Evaluation of Mixed Intravenous Preparation in Patients at the Hospital "X" Samarinda's Intensive Care Unit (ICU)

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Keywords: Mixed intravenous preparation, Intensive Care Unit (ICU), Sterile dosage, Drug physical quality.

Abstract: Mixing intravenous preparation, especially in patients' intensive care unit (ICU) at the hospital, requires special attention on their higher medication errors, such as nosocomial infection and incompatibility drugs. The personnel, facilities, infrastructure, and mixing process must be carefully considered when preparing sterile mixtures. This study aims to calculate the percentage of suitability for the mixing process for intravenous preparations based on the Basic Guidelines for Dispensing Sterile Preparations, Guidelines for Injectable and Cytostatic Drugs in 2009, and the Handbook of Injectable Drugs Edition 16th for Intensive Care Unit (ICU) patients at the hospital “X” Samarinda. The research is descriptive research using sheets of observational data collection. The research subjects are mixing facilities, infrastructure, and procedures. We found as many as 215 processes of mixing intravenous preparations in the ICU, showing that nurses carried out 100% of compounding, 100% of the infrastructure did not have a clean room, LAF, and pass box, 53% carried out the mixing process according to procedures, and physical quality tests. Drug preparations follow the Handbook of Injectable Drugs Edition 16th. The preparations produced are clear and free of foreign particles.

Introduction

According to the Regulation of the Minister of Health, No. 72 of 2016 concerning pharmaceutical service standards in hospitals includes clinical pharmacy services, namely mixing sterile preparations, which can only be done in hospitals with facilities for mixing sterile preparations. The mixing of sterile preparations is carried out at the pharmacy installation using an aseptic technique to ensure the sterility of the drug. The purpose of mixing sterile preparations is to ensure that the drug is received as needed and to ensure the sterility of the drug (1).

Based on the Ministry of Health of the Republic of Indonesia in 2009 regarding the Basic Guidelines for Dispensing Sterile Preparations and Guidelines for Mixing Injectable and Cytostatic Drugs, sterile preparations must be mixed in pharmacy installation in hospitals to avoid nosocomial infections and the occurrence of medication errors. Mixing of sterile preparations is a series of changes in the form of the drug from its original condition into a new product by dissolving or adding other ingredients carried out aseptically by pharmacists in health care facilities (2). Aseptic mixing of sterile preparations has several requirements that must be met, namely a clean room, LAF, cabinet, and competent personnel who meet the requirements as mixing officers. Hospital pharmacy installation must also establish a team for product quality assurance and mixing sterile preparations to ensure quality and minimize errors (3).

Unsterile mixing negatively impacts patient health, such as nosocomial infections, which are a serious problem in hospitals because they can increase morbidity and mortality for contaminated patients (4). The incidence of nosocomial infections that often occur at the Setjonegoro Regional General Hospital, Wonosobo Regency is phlebitis, surgical wound, and pressure sores (5). In addition to nosocomial infections, drug incompatibility can also cause serious problems where chemical degradation of drugs occurs, resulting

in reduced drug effectiveness and can cause toxicity (6). This study aims to calculate the percentage suitability of the mixing process for intravenous preparations based on the Basic Guidelines for Dispensing Sterile Preparations, Guidelines for Injectable and Cytostatic Drugs, and the 16th edition of the Handbook of Injectable Drugs in ICU patients at "X" Hospital Samarinda.

The results of the study are expected to be an evaluation of Hospital "X" in Samarinda to improve and improve various aspects of mixing sterile preparations that are not appropriate and maintain things that follow the Book based on the Basic Guidelines for Dispensing Sterile Preparations, Guidelines for Injecting and Cytostatic Drugs in 2009 and Handbook of Injectable Drugs 16th edition.

Methodology

This research was conducted with a descriptive observational method with a cross-sectional approach. The data collection technique was carried out by accidental sampling during the observation period, every Monday – Friday in June – August 2022. The data was taken on a data collection sheet based on the 2009 Basic Manual for Dispensing Sterile Preparations, the Guidebook for Mixing Injectable and Cytostatic Drugs in 2009, and the 16th edition of the Handbook of Injectable Drugs. Observations were made on mixing intravenous preparations related to various aspects, namely compounding personnel, supporting facilities and infrastructure, drug preparation procedure, mixing procedure, and drug physical quality test results. All samples that met the inclusion criteria were used in the study.

The inclusion criteria in this study were the observed compounding process for intravenous preparations and classified into the three most widely used drugs for ICU patients at "X" Samarinda Hospital. The exclusion criteria in this study were compounding intravenous preparations, which were classified into the three most widely used drugs for ICU patients at Hospital "X" Samarinda. Still, the researcher did not observe the entire process.

Result and Discussion

This study involved 215 mixing processes carried out in the ICU room of Hospital "X" Samarinda for 50 patients. Data is taken from 08 June 2022 – 08 August 2022, every Monday to Friday. The most frequently mixed drugs were ceftriaxone 102 times (47%), omeprazole 67 times (31%), and tramadol 46 times (22%).

Compounding Personnel

The process of mixing sterile preparations is carried out by pharmacists who have attended training and continuing education under the responsibility and supervision of pharmacy installation in hospital pharmacists (2). Based on the results of observations made by researchers, the process of mixing sterile preparations is still fully (100%) carried out by nurses who have attended training and continuing education. This is due to the ICU's unavailability of pharmacists or special pharmacy personnel. Compounding personnel involved in mixing sterile preparations can be seen in Table 1.

Research conducted by Berdot et al. (2016) shows that training may not necessarily reduce the number of errors. Still, at least it can increase nurses' awareness about the possibility of medication errors (7). There is 34 nursing staff in the ICU, with one person preparing sterile preparations in the morning. At the same time, the mixing personnel is the nurse responsible for each patient or 8 people for eight beds in the afternoon.

Table 1. Compounding personnel in the intensive care unit (ICU).

No.	Demographic Classification		Amount	Percentage (%)
1	Human Resources	Pharmacists or Pharmacy Technicians	0	0
		Nurse	34	100
	Total		34	100
2	Gender	Male Female	10 24	29 71
	Total		34	100

Facilities and Infrastructure

The process of mixing intravenous preparations is not carried out in a clean room but in a special room mixing drugs, and the mixing process is not carried out under the LAF but is carried out on a workbench which is first wiped with 70% alcohol. This is feared to increase the risk of microbial contamination during the mixing process of sterile preparations (2). Mixing intravenous preparations using a clean room can be the best strategy to reduce the level of contamination of intravenous mixing solutions (4). An aseptic technique is an important procedure used in mixing sterile preparations so that before mixing the drug, the compounding personnel must wear complete personal protective equipment (PPE). Available facilities and infrastructure can be seen in Table 2.

Based on observations made by researchers, compounding personnel in the ICU room at hospital "X" Samarinda have worn complete PPE, namely protective clothing, masks, and gloves. The primary purpose of using PPE is to protect compounding personnel from exposure to drugs and to the product against contamination from compounding personnel (8). The distribution of drugs in the ICU of hospital "X"

Samarinda is not through the inbox. Still, it uses a medicine box because the mixing of drugs is not carried out in a clean room and is adequate to ensure the sterility of the drug.

Table 2. Compliance with facility and infrastructure criteria for compounding sterile preparations.

No.	Compounding Criteria	Number of Conditions Following Standard (2)	Number of Observed Conditions	Percentage (%)
1.	Has a special room and special equipment for compounding.	0	215	0
2.	Compounding is done under LAF.	0	215	0
3.	Taking medical devices and medicines from the pass box.	0	215	0
	Total	0	645	0

Drug Preparation Procedure

Completeness of Necessary Documents and Drug Condition

The preparation procedure aims to prevent medication errors in patients that lead to medication errors. The drug preparation procedure can be seen in Tables 3 and 4.

Table 3. Compliance of the necessary document.

No.	Compounding Criteria	Number of Conditions According to Standard (2)	Number of Observed Conditions	Percentage (%)
1	Correct Medicine	215	215	100
2	Correct Patient	215	215	100
3	Correct Dosage	215	215	100
4	Correct Route	215	215	100
5	Right Time to Give	215	215	100
	Total	1,075	1,075	100

Before preparing the medication, nurses conducted a thorough verification of the requested documentation to confirm the accuracy of essential details, including the patient's identity, prescribed drug, dosage, administration route, and scheduled administration time. Once the documentation was validated, the nurses retrieved the necessary medication from the storage cupboard, where drugs were organized according to the patient's bed number. During this retrieval process, the nurses diligently checked the medication's name, quantity, and solvent, ensuring precision in the preparation. Simultaneously, they calculated the appropriate dosage tailored to the specific patient's needs. Notably, the verification process did not extend to checking the batch number and expiration date of the drug at this stage. The responsibility for checking the batch number and expiration date fell under the domain of the pharmacy staff, stationed at the pharmacy installation. This division of tasks was implemented to prevent any potential harm or compromise to the medications received by the ICU nurses. By entrusting this crucial step to the pharmacy staff, the healthcare facility aimed to maintain the integrity of the pharmaceuticals and uphold the highest standards of medication safety within the ICU.

Table 4. Compliance with compounding criteria for accurate medication preparation.

No.	Compounding Criteria	Number of Conditions Following Standard (2)	Number of Observed Conditions	Percentage (%)
1	Medicine name	215	215	100
2	Amount of Medicine	215	215	100
3	Medicine Batch Number	0	215	0
4	Expired Date	0	215	0
5	Calculating Appropriate Dosage	215	215	100
6	Calculating the Volume of Solvent Used	215	215	100
	Total	860	1,290	67

Drug Labels Compliance

According to the Guidelines for Mixing Injectable and Cytostatic Drugs, the drug label contains the patient's name, medical record number, treatment room, a dose of administration, method of administration, storage conditions, date of manufacture and expiration date of the mixture (2). The drug labels compliance can be seen in Table 5. Drugs in sterile compound dosage forms must be labeled with complete clear labels with complete and clear information to reduce the risk of errors in therapy (2). According to the Guidelines for Mixing Injectable and Cytostatic Drugs, the drug label contains the patient's name, medical record number, treatment room, a dose of administration, method of administration, storage conditions, date of manufacture and expiration date of the mixture (2). According to observations, 38% of the labeled procedure did not follow the guideline since the drug label only included the drug name, solvent, reconstitution time, dose strength, and BUD date.

Table 5. Compliance with medication labeling criteria for sterile preparations.

No.	Compounding Criteria	Number of Conditions Following Standard (2)	Number of Observed Conditions	Percentage (%)
1	Patient's name	0	215	0
2	Medical Record Number	0	215	0
3	Ward	0	215	0
4	Dosage	215	215	100
5	Way of giving	0	215	0
6	Storage Condition	0	215	0
7	Manufacture Date	215	215	100
8	Beyond Use Date	215	215	100
	Total	645	1,720	38

Table 6. Compliance with compounding criteria for sterile preparations.

No.	Compounding Criteria	Number of Conditions Following Standard (2)	Number of Observed Conditions	Number (%)
1	Using Personal Protective Equipment (Protective clothing, gloves, and disposable masks).	215	215	100
2	Perform decontamination and disinfection.	215	215	100
3	Turning on LAF.	0	215	0
4	Prepare the LAF workbench by providing a liquid absorbent mat in the LAF.	0	215	0
5	Prepare garbage disposal bags in LAF for used drugs.	0	215	0
6	Disinfect gloves with 70% alcohol	215	215	100
7	Taking medical devices and medicines from the pass box.	0	215	0
8	Perform aseptic mixing.	0	215	100
9	The technique of transferring drugs from ampoules/vials according to the procedure.	215	215	100
10	Transfer of medication to another vial/infusion bottle according to the procedure.	215	215	100
11	Taking the right volume of medication.	215	215	100
12	Give appropriate labels for each syringe and infusion containing the mixed drug.	215	215	100
13	Wrap in black bags or aluminum foil for medicines that must be protected from light.	0	215	0
14	Remove the container containing the syringe or infusion through the pass box.	0	215	0
15	Dispose of all traces of drug mixing in a special disposal container.	215	215	100
	Total	1,720	3,225	53

Mixing Procedure

Some aseptic techniques that can be used to minimize the occurrence of contamination and nosocomial infections are to wash both hands before compounding. The mixing procedure can be seen in Table 6.

Based on observations made by researchers at the mixing stage, nurses used aseptic procedures by washing hands before mixing and 100% using complete Personal Protective Equipment (PPE). Still, when mixing, the vial and ampoule caps were not disinfected before opening. The technique of mixing vial preparations nurses carry was still not following the Manual for Dispensing Sterile Preparations. After observing the situation, the nurse agitates the vial while keeping the needle inside. The limited availability of equipment and infrastructure in the mixing room, such as the lack of Laminar Air Flow (LAF), means that

the needle is kept in the vial during the mixing process to avoid contamination of the syringe. Then to dissolve the powder, it is enough to rotate the vial slowly until all the powder is dissolved (2). This is to prevent the powder from sticking to the rubber vial, which causes the drug not to dissolve completely. Shaking should be done at the 90o position because the contact between the substance and the solvent is greater, and the substance can be dissolved well. Shaking should not be done too vigorously, as this may cause the powder to remain at the bottom of the vial cap (2).

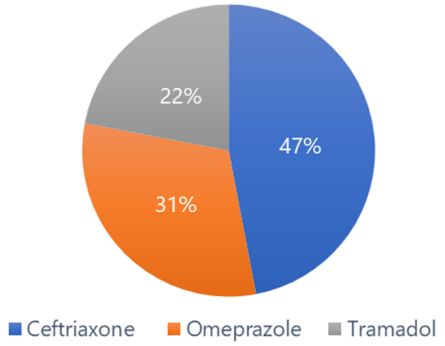

Figure 1. The most frequently mixed drugs in the installation.

Table 7. Prescribed drugs physical quality.

No.	Medicine name	Parameter	Information from literature (10)	Observation result
1.	Ceftriaxone	Foreign particles	Free of foreign particles	Free of foreign particles
		Solution color	**Light yellow**	**Light yellow**
		Lucidity	Solution must be clear	Solution must be clear
2.	Omeprazole	Foreign particles	Free of foreign particles	Free of foreign particles
		Solution color	**Colorless**	**Colorless**
		Lucidity	Solution must be clear	Solution must be clear
3.	Tramadol	Foreign particles	Free of foreign particles	Free of foreign particles
		Solution color	**Colorless**	**Colorless**
		Lucidity	Solution must be clear	Solution must be clear

Observing the standard protocol outlined in the Manual for Dispensing Sterile Preparations, the nurse utilized a J-motion technique to transfer the drug solution from the neck of the ampoule before transferring it into the syringe. The ampoule was held at a 45-degree angle during the process. In addition, the use of disposable syringes and needles is recommended to prevent contamination. From the results of observations, all mixing sterile preparations have used single-use syringes and syringes. Still, when administered to patients, the used syringes are not replaced with new syringes.

Waste in mixing sterile preparations is classified as medical waste that must be disposed of in a special place to avoid polluting, harming, and preventing misuse. Disposal of waste, especially drug packaging (vials or broken ampoules) and syringes, must be disposed of separately because it requires a different waste treatment process from other types of waste (9). Based on the results of observations made, 100% of compounding personnel have disposed of the remaining medical waste from the mixing process to the special disposal site provided.

Drug Physical Quality

Through visual observations of three samples of the most commonly mixed drugs in the ICU room at Hospital "X" Samarinda, researchers found that all of these preparations were physically compatible. The type of drugs used for these frequently mixed drugs, as outlined in the 16th edition of the Handbook of Injectable Drugs, is presented in Figure 1. The danger of the presence of visible drug powder particles in solution can cause embolism if they are not completely dissolved when administered. The insoluble drug particles can stick to blood vessels and cause blockages (2). Drug physical quality test results can be seen in Table 7.

In 102 ceftriaxone preparations, the solution was light yellow, clear, and had no foreign particles. In 67 preparations of omeprazole and 46 preparations of tramadol, the resulting solution was colorless and clear, and there were no foreign particles. There is no BUD information on the mixed preparations because the mixing results are not stored but are given directly to the patient (10).

Conclusion

Mixing intravenous preparations in the ICU room at Hospital "X" Samarinda still does not meet the Basic Manual for Dispensing Sterile Preparations criteria and the Guidebook for Mixing Injectable and Cytostatic Drugs. Still, the resulting intravenous preparations follow the 16th edition of the Handbook of Injectable Drugs regarding foreign particles, solution color, and clarity.

Declarations

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Conflict of Interest

The authors declare no conflicting interest.

Data Availability

The unpublished data is available upon request to the corresponding author.

Ethics Statement

Not applicable.

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Not applicable.

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