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Original Article

Implementation of Aseptic Dispensing for Non-Cytostatic Injectable Drugs in the Internal Medicine Inpatient Ward of 'X' hospital, West Java

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ABSTRACT

Aseptic Dispensing activity is a procedure to minimize pharmaceutical preparations from the threats of pyrogens and contaminants. This study aims to determine the implementation of aseptic dispensing for non-cytostatic injectable drugs and the sterility of intravenous mixed preparations in the Internal Medicine Inpatient Ward of 'X' hospital, West Java for the period January - February 2022. This was a descriptive observational prospective study with a cross sectional approach. Researchers made direct observations of dispensing personnel, room and equipment as well as the process of aseptic dispensing activities including the stages of preparation, mixing, storage and disposal as well as sterility test of aseptic dispensing products. Based on the study results, it was obtained that of the 150 intravenous mixed preparations collected, there were 40 activities of diluting intravenous preparations, 100 activities of packaging into ready-to-use preparations and 10 activities of mixing intravenous preparations into infusion fluids, room suitability by 74%, preparations arrangement procedure by 68%, mixing procedure by 44%, storage procedure by 100% and disposal procedure by 63%. It can be concluded that the aseptic dispensing of non-cytostatic injection drugs in the internal medicine inpatient ward of 'X' hospital, West Java was not in accordance with the guidelines, especially at the mixing procedure stage (≤50). Compliance of dispensing personnel and room cleanliness during the process of mixing intravenous preparations need to be considered. The result of the identification of contamination during the aseptic dispensing activity of non-cytostatic injectable drugs showed that 1 in 150 samples (0.66%) was contaminated.

Keywords: Aseptic Dispensing, Non Cytostatic Injectable Drugs, Sterility Test, Contamination.

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INTRODUCTION

Dispensing of sterile preparations is a form of pharmaceutical service carried out in health service facilities which can be defined as procedures that change the form of a drug from its original condition into a new product by dissolving or adding other ingredients aseptically by pharmacists[1].

Dispensing of sterile preparations must be performed centrally in the Hospital Pharmacy Department. To ensure the safety, quality, benefits and efficacy of the drugs prepared and delivered to patients, hospitals are required to prepare and dispense drugs in a safe environment for patients, staff and the environment or so called aseptic dispensing[2,3].

Aseptic Dispensing is a procedure to minimize pharmaceutical preparations from the threats of pyrogens and contaminants. Such

method includes the stages of preparation, mixing, storage and disposal. Each stage is closely related to the availability of human resources (HR), equipment and room, so that the correct technique in mixing parenteral preparations is required. Aseptic means free of microorganisms and bacteria which can reduce the risk of exposure to officers. Contaminants may be carried into the aseptic area from medical devices, pharmaceutical preparations, or personnel. Sterile preparations mixing must consider product protection from contamination by microorganisms. Sterile preparations mixing requires trained human resources, appropriate facilities and equipment as well as specific management procedures. Non-Cytostatic Injectable Drug refers to a parentral preparation or sterile solution intended for parenteral use (administered intravenously) made by mixing one or more parenteral products into one container. The scope of sterile preparation dispensing includes non-cytostatic injectable drugs (iv-admixture), preparation of parenteral nutrition, cytotoxic mixing and dispensing of eye drop preparations[4].

Many inpatient patients are prescribed parenteral preparations because they are more appropriate for emergencies, have a quick onset and considered the appropriate treatment for uncooperative patients with oral drug preparations. One of constraints in sterile preparations mixing is the risk of contaminants which may lead to further risks of embolism and phlebitis. To avoid the presence of hazardous substances in intravenous preparations, an aseptic dispensing technique is needed so as not to cause adverse effects for patients and healthcare workers on duty.

Several previous studies showd that there was 1 contamination out of 43 intravenous preparation mixing (2.3%) carried out in the treatment ward[5]. Another study showed that the preparation to dispensing in the ICU and NICU wards had not been carried out according to the guidelines for injectable drugs mixing and cytostatics management. Among 110 Aseptic Dispensing, the levels of suitability of the preparation stage, mixing stage, storage stage and disposal stage were 87.77%, 49.09%, 80% and 98.18%, respectively[6]. A study on bacterial contamination in single dose vials and repeated dose vials showed that only 1 of the 92 preparations made in treatment room was contaminated[7].

Unsterile mixing has health impacts such as nosocomial infections. Dispensing of sterile preparations for patients with internal disease requires special care since they have a lot of drug use. Therefore, the level of aseptic dispensing activity is higher than other treatment wards. The impelemtation of aseptic dispensing for non-cytostatic injectable drugs at 'X' hospital, West Java had never been evaluated. Such fact has prompted researchers to make observations on dispensing of sterile preparations as an evaluation and basis for further development to optimize and improve pharmaceutical services, especially in terms of dispensing personnel, dispensing infrastructure, and quality sterile preparations products in the hospital. This study was conducted to determine the implementation of aseptic dispensing of non-cytostatic injectable drugs and the sterility of intravenous preparation products. Therapeutic suitability and the quality of the formulation are two important things to achieve optimal therapy for internal medicine patients. Until now, researchers have not obtained and found research data published in Indonesia that directly observed all aseptic dispensing activities of non-cytostatic injectable drugs, which include dilution of sterile preparations, packaging into ready-to-use preparations and mixing into infusion fluids and all aseptic dispensing products were tested for sterility.

METHOD

This study was conducted in a descriptive observational manner with prospective data collection. The current study was conducted at 'X' hospital, West Java, and has obtained ethical approval from the Research Ethics Committee of the Yarsi University Research Institute through a letter number 035/KEP-UY/BIA/II/2022. Inclusion samples were aseptic dispensing activities: dilution of sterile preparations, packaging into ready-to-use preparations and mixing into infusion fluids which were carried out in the Internal Medicine Room in January - February 2022 from Monday to Sunday at 08.00 - 22.00 WIB. All activities were directly observed by researchers. On the other hand, the exclusion criteria were sterile preparations containing cytostatics, sterile preparations in original packaging (Insulin, Fondafarinux inj) and mixing of antibiotics. The specified sample size involved 150 samples.

The incidental sampling technique was applied. The study instrument involved the 2009 Indonesian Ministry of Health Republic of Indonesia's Basic Manual for Sterile Preparations, an observation sheet (checklist) intended for dispensing personnel, room, equipment as well as process of aseptic dispensing activities consisting of 4 stages (preparation, mixing, storage and disposal). A Sterility Test was applied for the results of the aseptic dispensing activities at the Bogor Biopharmaca Study Center. Data were analyzed descriptively and qualitatively regarding the dispensing personnel, room and equipment, as well as regarding the process of aseptic dispensing activities by using the Guttman Scale. Certain variable was considered suitable if the percentage was ≥50% and not suitable if ≤50%. Secondary data derived from the process of aseptic dispensing activities were interpreted using categories by Arikunto, 2006, namely very good (80%-100%), good (66%-79%), moderate (56%-65%), poor (40%) -55%) and failed (≤40%).

RESULTS

Table 1 showed that there were 5 dispensing personnel who carried out aseptic dispensing activities. Furthermore, most of personnel were in the age category of <35 years by 3 people and were female by 3 people. 1 person had Bachelor of Nursing education. Based on years of service, most of personnel had been working <10 years by 3 people. Such findings indicated that the aseptic dispensing activities in the internal medicine inpatient ward at 'X' hospital, West Java was carried out entirely by nurses. There was no role for pharmacists or pharmaceutical technical staffs in dispensing injectable drugs either in the form of dilution of intravenous preparations (A), packaging into ready-to-use preparations (B), mixing intravenous preparations into infusion fluids (C). In addition, nurses performed injectable drugs dispensing based on previous experience and did it every day, although they rarely took part in training regarding injectable drugs dispensing.

Table 1. Data on dispensing personnel.

Dispensing Personnel	Gender	Age (Years)	Education	Years of Service	Profession
1	Male	34	Bachelor of Nursing	5	Nurse
2	Female	28	Diploma III of Nursing	6	Nurse
3	Female	40	Diploma III of Nursing	17	Nurse
4	Male	35	Diploma III of Nursing	11	Nurse
5	Female	33	Diploma III of Nursing	8	Nurse

Table 2. Number of Sampling Activities.

Dispensing Personnel	Number of Aseptic Dispensing Activities		
	January	February	Total
1	9	21	30
2	11	19	30
3	7	23	30
4	14	16	30
5	1	29	30
Total Activities			150

Table 2 showed that the number of sterile preparation activities for each dispensing personnel was 30. The activities were assessed according to the work schedule of dispensing personnel in the field. From 5 dispensing personnel, a total sample of 150 aseptic dispensing activities was obtained. The number of samples in January was less than in February since the study started in mid-January.

Table 3. Suitability of the Room for Aseptic Dispensing Activities.

No	Room	Number of Activities (N = 150)				Category
		Suitable		Not Suitable		
		n	%	n	%	
1	Clean room, specifically for processing sterile preparations	150	100	0	0	Very Good
2	All doors and windows were always closed	25	17	125	83	Failed
3	No sink	150	100	0	0	Very Good
4	No permanent shelves or blackboards	150	100	0	0	Very Good
5	Floor was disinfected daily using hypochlorite	150	100	0	0	Very Good
6	Easy-to-clean wall	0	0	150	100	Failed
7	Work table was far away from the door	150	100	0	0	Very Good

Table 3 revealed 2 procedures that were not in accordance with the guidelines, namely all doors and windows were always closed with a suitability percentage of 17% and easy-to-clean wall with a suitability percentage of 0%. Implementation of aseptic technique in a space with criteria of clean room, the floor was disinfected daily using hypochlorite and the work table was far qway from the door showed a suitability percentage of 100%. In contrast, the unavailability of sink for washing, permanent shelves or blackboards showed a suitability percentage of 100% Such findings indicated that the process of sterile preparation dispensing was still not able to apply the provisions of aseptic dispensing to protect against possible contamination.

Table 4. Suitability of Procedures for Sterile Preparations Arrangement.

No	Procedure	Number of Activities (N = 150)				Category
		Suitable		Not Suitable		
		n	%	n	%	
1	Hand disinfectant	136	91	14	9	Very Good
2	Wore mask, gloves, goggles and cap	68	45	82	55	Poor

Table 4 showed that the procedures for sterile preparations arrangement regarding hand disinfectants had a suitability percentage of 91%. On the other hand, wearing masks, gloves and protective eyewear and cap showed a suitability percentage of 45% which was not in accordance with the guidelines. Such finding indicated poor aseptic practice in the arrangement of sterile drug preparations.

Table 5. Suitability of Procedures for Sterile Preparations Mixing.

No	Mixing Procedure	Number of Activities (N = 150)				Category
		Suitable		Not Suitable		
		n	%	n	%	
1	Clean room, specifically for processing sterile preparations	150	100	0	0	Very Good
2	All doors and windows were always closed	25	17	125	83	Failed
3	No sink	150	100	0	0	Failed
4	No permanent shelves or blackboards	150	100	0	0	Failed
5	Floors were disinfected daily using hypochlorite	150	100	0	0	Failed
6	Easy-to-clean wall	0	0	150	100	Failed
7	Work table was far away from the door	150	100	0	0	Very Good
8	Gauze was disposed into the sealed bag	150	100	0	0	Very Good
9	Took off personal protective equipment	103	69	47	31	Very Good

Table 5 revealed a minimum suitability of the 9-stage mixing. The dominant mixing suitability was only found at the point of disposing of all contaminated material amd all gauze into a closed bag by 100%. Meanwhile, at the other stages, the minimum category by 30% was found for cleaning the work area by washing with detergent and rinsing with distilled water, repeated 3 times, and finally by rinsing with distilled water and cleaning the workbench with distilled water followed by 70% alcohol.

Table 6. Suitability of Procedures for Sterile Preparations Storage.

No	Storage procedure	Number of Activities (N = 150)				Category
		Suitable		Not Suitable		
		n	%	n	%	
1	Protected from direct light, using carbon paper/black plastic bags or aluminum foil	150	100	0	0	Very Good
2	Storage temperature was 2 - 8 º C in the refrigerator (not Freezer)	150	100	0	0	Very Good

Table 6 showed that the 2 procedures at the storage stage met the standards with a percentage of 100%. The storage temperature was in accordance with the requirement for preparation made in the inpatient room, namely 2-8°C, with a percentage of 100%. Preparations were stored in a place that was protected from direct light and used carbon paper/ black plastic bags or aluminum foil for lipid preparations. Temperature checking and recording were performed by nurses on duty effectively with a percentage of 100%. Storage stage of injection preparations in the internal medicine inpatient room of "X" hospital, West Java was in accordance with the SOPs with a percentage of 100%.

Table 7. Suitability of Waste Disposal Procedures.

No	Waste Disposal Procedure	Number of Activities (N = 150)				Category
		Suitable		Not Suitable		
		n	%	n	%	
1	Wore PPE	120	80	30	20	Very Good
2	Placed waste in closed disposal container (sharp waste such as syringes, vials, ampoules were placed in unpenetrable container)	150	100	0	0	Very Good
3	Put a warning label on the outside of the bag	35	23	115	77	Failed
4	Took waste to disposal	30	20	120	80	Failed
5	Washed hands	140	93	10	7	Very Good

Table 7 showed that in the disposal stage procedure consisted of 5 points, only placed waste in a closed disposal container (sharp waste such as syringes, vials, ampoules were placed in unpenetrable container) had a percentage of 100%. Such finding indicated that the procedures for the waste managemenet had not been optimally carried out and were not in accordance with the applicable SOPs.

Table 8. Results of Sterility Test.

Dispensing Personnel	Product Activities	Results of Sterility Test*	
		Steril	Unsteril
1	30	30	0
2	30	30	0
3	30	29	1
4	30	30	0
5	30	30	0

Table 8 showed that there was 1 contaminant out of 30 aseptic dispensing activities from Personnel 3, while the other sterility test results did not find any contaminant. Such finding indicated that there was 1 contaminated sample out of all the samples of aseptic dispensing activities.

DISCUSSION

1. Dispensing Personnel and Aseptic Dispensing Activities.

The study findings showed that there were 22 dispensing personnel was 22 people, and 5 personnel were responsible for dispensing sterile preparations. Pharmacists are preferred to be responsible for drug dispensing to ensure the quality of the preparations produced. Based on previous study, dispensing of sterile preparations carried out by pharmacists better quality of products quality compared to those produced by non-pharmaceutical workers.

According to the Indonesian Pharmacist Competency Standards, the pharmacist is responsible for ensuring that the mixing of sterile preparations in hospitals is in accordance with Good Preparation Practices (GPP) so that sterility, solubility and stability of products are guaranteed. Inaccuracy in intravenous mixing in terms of aseptic procedures, mixing techniques, dissolution, and storage can cause precipitation of the drug which may further cause blockage in the injection device and endanger the patient. Dispensing personnel must be trained regarding the implementation of aseptic techniques. Despite adequate facilities and infrastructure, without sufficient capabilities in aseptic dispensing, the product will not be protected from contamination[6].

Other research further revealed that dispensing personnel in the children's ward of a hospital in Istanbul, Turkey, did not have specific education and training regarding the preparation and administration of injectable drugs, which resulted in preparations with inappropriate doses and concentrations as prescribed[8]. Another opinion also explains that dispensing personnel must be trained in the implementation of aseptic techniques as the key factor to guarantee a product that is free of contamination.

2. Suitability of Aseptic Dispensing Procedures based on the Basic Guidelines for Sterile Preparation Dispensing

The internal medicine inpatient ward at 'X' hospital, West Java did not have LAF. Aseptic mixing procedures are performed according to the standards of the Indonesian Ministry of Health, regarding matters to be considered in dispensing sterile preparations. The inpatient ward was always closed and git sufficient natural lighting from sunlight or light. The floor was disinfected every day using wipol liquid which contains cresol as a disinfectant.

The preparation room used was a special room that was the cleanest and specifically intended for sterile preparations only. Another thing that must be considered during the dispensing of sterile preparations is that the work table must be far from the door. In addition, the distribution of drugs and equipment for dispensing sterile preparations should not go through passboxes since dispensing in such hospital was not carried out in a special room that can guarantee drug sterility.

The study showed that the facilities and infrastructure available at "X" Hospital were inadequate for dispensing ceftriaxone injection. During the observation, the dispensing of ceftriaxone injection was only carried out in the nurse's room which was not equipped with a special air conditioning system or particle and microbial control. Laminar Air Flow (LAF) was also not available at “X” Hospital[7]. Another study showed that the infrastructure and procedures for mixing sterile injection preparations at hospitals in the Cilacap area

were not in accordance with the Guidelines for Injectable Drugs Mixing[9].

It is recommended that dispensing of sterile preparations is carried out in the LAF in a special room consisting of a preparation room, dressing room, intermediate room, and a sterile room, with a special air conditioning system that can limit the number of particles and microbes[10,11].

Other study also explained regarding the risk of bacterial contamination of mixed intravenous preparations prepared in the nursing ward and pharmacy showed that the frequency of contamination for drugs prepared in the nursing ward was higher than those prepared in the pharmaceutical environment namely 3.7% vs 0.5%[12,13]. Furthermore, some critical aspects of sterile preparations do not meet the requirements according to guidelines such as dispensing personnel and infrastructure[14].

3. Procedures for Sterile Preparations Arrangement.

Procedures for sterile preparations arrangement includes washing hands and using Personal Protective Equipment (PPE). Personal Protective Equipment (PPE) are equipment that must be used while working to maintain the safety of the workers as well ass people around them. Table 4 showed that the procedures for sterile preparations arrangement regarding hand disinfectants had a suitability percentage of 91%. On the other hand, wearing masks, gloves and protective eyewear and cap showed a suitability percentage of 45% which was not in accordance with the guidelines. Such finding indicated poor aseptic practice in the arrangement of sterile drug preparations. One of the things that triggers non-compliance with the use of PPE is the inadequacy of the facilities available in the internal medicine inpatient ward at "X" hospital, West Java.

4. Procedures for Sterile Preparations Mixing.

At the mixing stage, personal protective equipment (PPE) must be used. Several things to be considered while mixing sterile preparations include the controlled stages of mixing which functions to minimize microbial contamination. While mixing sterile preparations, it is necessary to pay attention to certain conditions, such as protection of the product from contamination by microorganisms, protection of personnel and the environment against exposure, stability of the preparation, and non-mixing of the preparation. Therefore, to avoid unwanted things, the preparation must be performed in a special (sterile) room, in a disciplined and careful manner along with adequate knowledge and skills to prevent unwanted risks[1].

The high incidence of nosocomial infections in hospitals is one of the reasons for the importance of implementing aseptic techniques by healthcare workers, especially nursing staff as a preventive measure to prevent the entry of microorganisms into the patient's body[15]. Based on observation, the practice of sterile preparations mixing was not in accordance with the SOPs and this condition may increase the risk of microorganisms contamination and the spread of infection. Such infection rate can often arise due to the high number of patients and limited time in mixing drugs, lack of knowledge of human resources about aseptic dispensing, and incomplete facilities for carrying out aseptic dispensing. Another factors regarding aseptic dispensing were the availability of equipment and room[16]. The procedures for sterile preparations mixing in the internal medicine ward of “X” hospital, West Java, was in accordance with the SOPs with a percentage of 43.55%.

5. Procedures for Sterile Preparations Storage.

Storage is an activity of securing medicines received so that they are safe and protected from physical or chemical damage. Storage functions to maintain the stability of the drug and its quality is guaranteed. The storage conditions that should be considered to maintain stability and quality of the drug include humidity, sunlight, and temperature or heat[17].

6. Procedures for Waste Disposal/Management.

According to Minister of Health Decree Number 1204 of 2004 concerning Hospital Environmental Health, good management of waste disposal may kill or inhibit cell growth[18]. Waste needs to be collected in a strong, leak-proof and labeled container. Health waste is paotentially hazardous and microorganisms can infect hospital patients, personnel and the public[19].

According to the theory of the Health belief model, human resources may feel to be threatened if they do not comply with using PPE (masks, handscoons, gowns) during dispensing practices[20]. Suitability of hand washing procedure which only obtained a value of 93.33% indicated a risk of contamination after managing waste. Obviously, the management of injection preparations waste in the internal medicine ward of "X" hospital, West Java, was not in accordance with the SOPs.

CONCLUSION

Implementation of aseptic dispensing for non-cytostatic injectable drugs based on the work procedures for sterile preparations in internal medicine inpatient ward of 'X' hospital, West Java revealed that dispensing personnel, rooms and equipment as well as procedures for mixing sterile preparations were not in accordance with the Basic Guidelines for Sterile Preparation Dispensing and Guidelines for Injectable Drugs Mixing and Cytostatics Management so as to affect the quality of the sterile preparations produced. Compliance of dispensing personnel and room cleanliness during the process of mixing intravenous preparations need to be considered. In addition, the compliance of dispensing personnel with aseptic activity procedures also affects the products of intravenous preparations. The result of the identification of contamination during the aseptic dispensing activity of non-cytostatic injectable drugs showed that 1 in 150 samples (0.66%) was contaminated.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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