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MEDICATION ERROR PREVENTION USING HEALTHCARE FAILURE MODE AND EFFECT ANALYSIS AT CLINICAL PHARMACY INSTALLATION

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Abstract

Medication error is the second most common patient safety incident worldwide. Medication errors can be defined as unintentional failures in medication services that have the potential to cause harm to patients. Maintaining safe health services is highly dependent on the ability of service providers to proactively conduct patient safety risk analysis, one of which is using the Healthcare Failure Mode and Effect Analysis (HFMEA) method. This study was aimed at obtaining the HFMEA design as an effort to prevent medication errors at Company X Clinical Pharmacy Installation. The research method used is qualitative research with a specific type of Operations Research. Data collected by in-depth interviews, observation, secondary data analysis, and focus group discussion. The results of this study found factors that cause medication errors to occur from organizational factors and staff factors. These results then analyzed for the HFMEA design which obtained 11 risks that required attention and then 14 action plans are made to overcome them. This study successfully developed HFMEA design to prevent medication error in Company X Clinical Pharmacy Installation.

Keywords: *Healthcare Failure Mode and Effect Analysis (HFMEA); medication error; medication error prevention; patient safety; pharmacy installation*

1. Introduction

Maintaining patient safety and preventing patient safety incidents is one of the biggest challenges in public health. Patient safety incidents are one of the leading causes of death and disability worldwide, especially in low and middle-income countries (World Health Organization, 2021). According to WHO, there were 134 million patient safety incidents which then caused 2.6 million deaths in low-income countries (World Health Organization, 2019). In Indonesia, according to National Patient Safety Committee, there has been approximately 7465 patient safety incident cases throughout Indonesia in 2019, which 38% of them were near misses (Komite Nasional Keselamatan Pasien, 2020)

Medication errors are the second most common patient safety incident (18.3%) after errors during surgery (World Health Organization, 2017)Medication error can be considered as a global

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problem, where the prevalence varies throughout the world (World Health Organization, 2016). A study in the UK stated that 5% of all prescriptions made in primary care settings had prescription errors; a study in Sweden stated that the occurrence rate of medication errors was 42%; and study in Mexico found that 58% of prescriptions contained errors (Avery et al., 2012; Gandhi et al., 2003; Zavaleta-Bustos et al., 2008). In Indonesia, the prevalence of medication errors also varies. A study found 307 cases of medication errors at the Baubau City Hospital and found 190 cases of medication errors at Santa Anna Kendari Hospital in 2014 (Hartati, Lolok, Fudholi, & Satibi, 2014).

Medication errors can be caused by various factors, such as a poorly designed medication system, inadequate human resources in quality and quantity, and a bad work environment. Medication errors cause massive economic losses, which reaches $42 billion USD or more than 634 trillion rupiah each year (Donaldson, Ricciardi, Sheridan, & Tartaglia, 2021). The high level of losses incurred indicates that it is necessary to prevent medication errors.

Maintaining a safe and reliable healthcare system is highly dependent on the ability of the service providers to proactively identify the risk for patient safety incidents occurrence (VHA National Center for Patient Safety (NCPS), 2021) In 2001, Health Care Failure Mode and Effect Analysis (HFMEA) is developed, which is an adaptation and development to the Failure Mode and Effect Analysis (FMEA) method (Derosier, Stalhandske, Bagian, & Nudell, 2002) HFMEA is a tool to proactively evaluating and analyzing health risks, which then can be used to prevent patient safety incidents (VHA National Center for Patient Safety (NCPS), 2021). HFMEA can identify the most urgent risks to address and design solutions with high success rate. HFMEA has been proven to be used successfully in several studies, one of which is Hung et. al. (2015) in Salsabila (2021), which confirmed that the use of HFMEA was able to eliminate specimen rejection cases from 0.92% in 2010 to 2013 (Salsabila, Masyitoh, Sjaaf, & Partakusuma, 2021). Adding to this, basically the HFMEA method is an FMEA method that has been adapted to health services, which in several studies has been proven to improve the quality of health service delivery, improving processes, and minimizing the incidence of medication errors by identifying hidden risk (Chanamool & Naenna, 2016; Costa P. C., 2020). In accordance with the success of HFMEA at several studies in reducing patient safety risks, this method is the right tool to proactively reduce medication error.

The Health Ministry of Indonesia stated that every health clinic is obliged to undergo accreditation, where one of the standards is improving patient safety (Kementerian Kesehatan RI, 2021). Based on the unstructured interviews conducted by the researcher, there were several case of medication error near misses, in drug preparation and drug administration services at Company X Clinical Pharmacy Installation. The pharmacy installation also do not have an official records and reports regarding these near miss cases as a learning process and prevention of medication errors in the future. The implementation of HFMEA design at Company X clinical pharmacy installation is the right step to proactively improve quality and patient safety during healthcare service, specially to prevent medication error incidents, where relevant and needed preventive and corrective action can be conducted. This study has several novelties from previous studies in pharmacy installations, where the preventive design used in the analysis of medication error is HFMEA, which is a development of the FMEA, also the level of healthcare facilities analyzed is clinics. (Anjalee, Rutter, & Samaranayakee, 2021; Jain, 2017; Khani-Jazani et al., 2015; Namaghi, Jahangiri, Riahi, & Gharebagh, 2019). The main purpose of this study is to obtain the precise, relevant, and needed HFMEA design in preventing medication error at the Company X Clinical Pharmacy Installation in 2023.

2. Method

This study was conducted using a qualitative research design with a specific type of operations research. This study was conducted at Company X's clinical pharmacy installation from April to May 2023. This study has passed the ethics review from the Research and Community Engagement Ethical Committee, Faculty of Public Health Universitas Indonesia (No: Ket-158/UN2.F10.D11/PPM.00.02/2023). Before data collection, written informed consent was obtained from each informants. The confidentiality of the informants was secured by replacing all personal identifiers.

The data collected in this study using in-depth interview, observation, focus group discussions, and secondary data analysis. In-depth interviews with guidelines were done to 6 informants that selected through purposive sampling and snowball sampling. The criteria of the informants are having knowledge about the pharmacy installation service procedure and policies, also getting involved directly or non-directly in the pharmacy installation services. In-depth interviews were done to collect data about organizational policies, HR management, drug management, facilities and infrastructure, staff knowledge,

staff performance, staff communication, and staff behavior, that can lead to medication errors in Company X's Clinical Pharmacy Installation. Observations with guidelines are done to observe pharmacy installations' facilities and infrastructure, also pharmacy installation service procedure. Secondary data analysis with guidelines were done to all policy documents, standard operational procedure, and reports regarding process of medical services at the Pharmacy Installation, patient safety, and medication error prevention at Company X Clinical Pharmacy Installation. Focus group discussion with guidelines was done with 3 informants that selected through purposive sampling. Focus group discussion was done to conduct the final HFMEA design. The collected data then processed and analyzed through data reduction, presentation, and conclusion drawing, then validated with method and source triangulation.

Data collection begin with in-depth interview, observation, and secondary data analysis to collect information about organizational factors, which include organizational policies, HR management, drug management, facilities and infrastructure; also staff factors which include staff knowledge, staff performance, staff communication, and staff behavior, that can lead to medication errors in Company X's Clinical Pharmacy Installation. The collected data then processed, analyzed, and then used to create HFMEA design in HFMEA worksheet with focus group discussion.

3. Result and Discussion

Medication Error Organizational Risk Factors

1. Organizational Policy

While ensuring that existing policies and SOPs can be accepted and properly implemented, it is necessary to socialize them (Herdiana, 2018). In-depth interviews with several informants found that the SOPs socialization was still considered ineffective because it was only by email. This can contribute to medication errors, which ineffective socialization is an obstacle when achieving high quality medical services with minimal risk (Arundina & Widyaningrum, 2020). More effective socialization can be achieved by arranging offline meetings to allow more interactive discussions. Then, pre-tests and post-tests were also held to measure officers' understanding of the socialized policies or SOPs (Permatasari, 2020).

2. Human Resource Management

Education and training provided to health workers can reduce the incidence of medication errors (World Health Organization, 2016)In-depth interviews with several informants found that there had been training in the Pharmacy Installation, but not specifically for patient safety and prevention of medication errors. Sometimes participants are not focused because the training is held with online meetings and during service hours. This shows that the training held is not optimal and can contribute to medication errors (Brigitta & Dhamanti, 2020). To overcome this, Company X can organize training about patient safety and medication error prevention to increase staff's competence and awareness regarding medication error, since it can maximize the staff's potential in prevent and minimize the risk of medication errors (Arundina & Widyaningrum, 2020)

3. Drug Management

One of the concerns in preventing medication errors is Look Alike Sound Alike (LASA) and high alert drug storage (ASHP, 2003). In-depth interviews with several informants found that the obstacle in drug management is the storage of LASA drugs which is still placed side by side and not separated due to limited storage space. This can increase the potential for incorrect drug preparation and cause medication errors (Arundina & Widyaningrum, 2020). Regarding this, expanding drug storage areas or using drug racks that have few partitions can be done so that drug storage is more efficient. Prevention strategies regarding LASA can also be implemented, which include using Tall Man Lettering or using letters, colors, or fonts to differentiate the LASA drugs (ASHP, 2003).

4. Facilities and Infrastructure

Proper drug storage in Pharmacy Installations, as well as the separation of LASA drugs can reduce the occurrence of medication errors (ASHP, 2003)Observations and in-depth interviews with several informants found that there were still medicines that are piled up and disorganized, including LASA, due to limited storage space. This can increase the potential for incorrect drug preparation and cause medication errors (Arundina & Widyaningrum, 2020) Company X is expected to expand the drug storage area or change the drug rack with fewer partitions so that drug storage is more efficient and LASA drugs can be seperated.

Using computerized information systems has been proven to reduce medication errors (Donaldson et al., 2021) In-depth interviews with several informants found that the Pharmacy Installation

are supported by an integrated Health Information System at the Clinic. However, there are some obstacles, such as long loading times and errors, unsynchronized drug stock in system and storage, and complicated operations, which is one of the factors causing ME events, where a system related to drug stocks that is not optimal can cause errors in prescribing (Aurelia, 2021)Improvement, development, and periodic reviews are needed to improve the quality of existing information systems.

Medication Error Staff Risk Factors

1. Staff Knowledge

Providing high quality health services, health workers are required to have a good level of knowledge, including knowledge about medication error prevention and management (Budihardjo, 2017). In-depth interviews with several informants found that all staff already know how to prevent medication errors, but don't know how to deal with medication errors when they occur, because they don't know how to report when medication errors occur. This shows that staff still have poor knowledge about the management of medication error incidents, which will increase the risk of medication error (Budihardjo, 2017). Reporting is one way to detect and study the incidence of medication errors, so pharmacists must be exposed and know how to report medication error (ASHP, 2003). More effective policies and SOPs socialization is needed regarding reporting of medication error events to increase the knowledge of pharmacy staff in dealing with medication error incidents.

2. Staff Performance

In-depth interviews with several informants found that the services provided were sometimes only based on habit and were rushed, so it didn't follow the existing SOPs. Secondary data review and in-depth interviews with several informants found that the handling of medication errors was also not in accordance with the existing SOPs. Health workers who don't comply with the policies and procedures that apply in the organization can cause medication error incidents (Brigitta & Dhamanti, 2020). To overcome this, Company X is carrying out supervision, which can find out if there are things that are not appropriate and can take immediate action to fix them (Ulfa & Chalidyanto, 2021)However, more awareness is needed for workers to internalize existing SOPs and be more active in providing input on updating existing SOPs.

In-depth interviews with several informants also found that all staff already had medication error prevention, but sometimes independent double checks could not be done. This can lead to poor performance and increase medication errors (Budihardjo, 2017). A verification process is needed to ensure accuracy in drug preparation and dispensing, which can be done with checklist that includes 5 correct; correct drug, correct dose, correct patient, correct time, and correct route.

3. Staff Communication

Health workers need to understand that good communication is one thing to prevent errors (Purwaningsih et al., 2022). In-depth interviews with several informants found that there were several obstacles in communication between staff, such as forgot to send reports between shifts and staff expected to be more active in coordination. This shows that staff communication is still not optimal, and can lead to misinterpretation of information and information is not conveyed, which then causes ME (Purwaningsih et al., 2022) Staff are expected to be more active in coordinating among staff to maintain the quality of the communications. Obstacles were also found in communicating with patients, where some patients refused to be educated on drug information because they were in a hurry. This can cause patients did not exposed to drug information and cause ME (Alawiyah, 2022). To overcome this, staff can ensure that the instructions written on the label are accurate by electronic labels, where the information has been automated and linked to electronic prescriptions. This is included in the use of Computerized Provider Order Entry (CPOE), which has been shown to reduce medication errors (Donaldson et al., 2021) It was also found that drug education was assisted by a checklist, but it was found that the checklist was sometimes not used, even though the checklist is a good way to standardize the stages in treatment, and increase treatment safety (Donaldson et al., 2021). Efforts that can be made to overcome this are held inspections to check the completion of the checklist to ensure the implementation of checklist controls.

4. Staff Behavior

There are several staff behaviors that contribute to medication errors, which include attention problems, fatigue, non-compliance, risky actions, acts of sabotage or crime, carelessness, routine violations, and overconfidence (World Health Organization, 2009) In-depth interviews with several informants found that the behavior that often appears at the Pharmacy Installation is fatigue and forgetfulness, which causes a lack of focus and inaccuracy. This can contribute to medication errors because it can lead to not optimal

performance of health workers (Alawiyah, 2022; Brigitta & Dhamanti, 2020)Related to this, every pharmacist has a personal strategy to deal with forgetfulness and fatigue.

HFMEA Design

1. Step 1: Define the topic

This step was done with the initial data collection of the study through unstructured interviews with Pharmacy Installation staff, and the topic obtained is prevention of medication errors in prescription services at the Company X Clinical Pharmacy Installation from organizational factors and staff factors.

2. Step 2: Assemble the team

The HFMEA team is defined based on the selected process scope, which includes Researchers, Pharmacists, Pharmacist Assistant, and QHSE Officers.

3. Step 3: Define the process

The process, or the Pharmacy Installation prescription service flow, is constructed based on the results of document review, observation, and in-depth interviews with several informants and have been verbally verified by the Pharmacist. The process flow will be illustrated with Swimlane Diagram, then the sub-processes will be directly written in the HFMEA worksheet. The diagram regarding the flow of prescription services in the Pharmacy Installation can be seen in Figure 1.

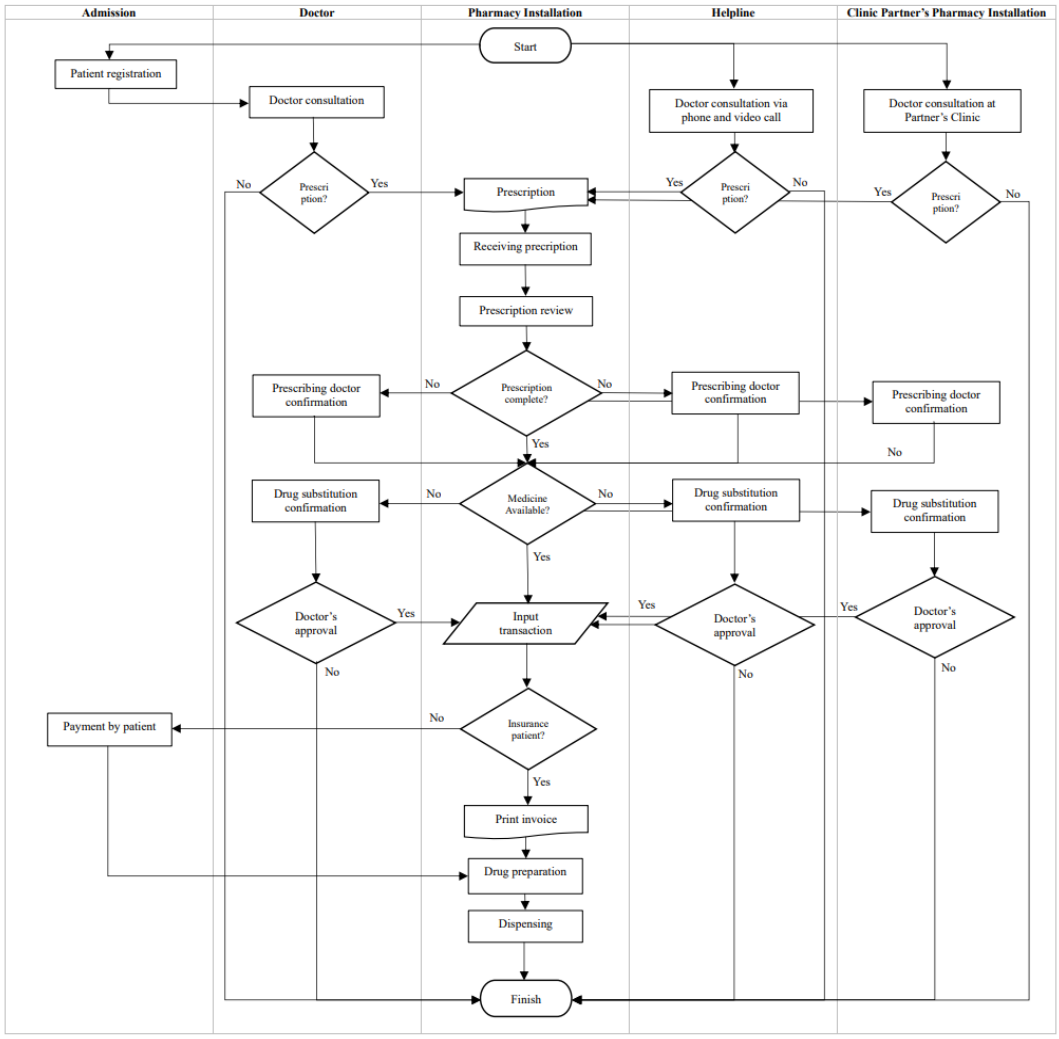

Figure 1. *Pharmacy installation medication process with swimlane diagram*

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4. Step 4: Hazard Analysis

Hazard analysis was done by focus group discussion with HFMEA Team. The failure mode was first obtained through the in-depth interviews with several informants which then discussed again during the FGD. The results of this step are entered into the HFMEA worksheet.

5. Step 5: Action and outcome measure

The HFMEA analysis concludes with the HFMEA Team designing an action and outcome measure. The results of this step are written into the HFMEA worksheet at Table 1.

Table 1. HFMEA Design as Medication Error Prevention at Company X Clinical Pharmacy Installation in 2023

HFMEA Step 3		HFMEA Step 4									HFMEA Step 5				
Process and Subprocess		**Failure Mode**	**Potential Causes**	**Severity**	**Probability**	**Hazard Score**	**Single Point Weakness?**	**Existing Control Measure?**	**Detectability?**	**Proceed?**	**Action Type**	**Actions or Rationale for Stopping**	**Outcome Measure**	**Person Responsible**	**Management Concurrence**
Receiving Prescription															
1A	Receive prescription or print out e-prescription	1 Doctor's handwriting is hard to read		3	3	9	→	N	N	Y					
			Doctor's handwriting is not clear and unrecognizable	3	3	9	→	N	N	Y	Control	E-prescription in all medication services	All prescription received is e-prescription	- Prescribing Doctor - Pharmacist - IT Team	
		2 The e-prescription has not been registered in the system so the patient is late to receive the drug		1	4	4	N	→	→	**STOP**					
			Prescribing doctor hasn't finished inputting the prescription into the system because occupied	1	4	4	N	→	→	**STOP**	→	Prescription will be input eventually and prescribing doctor confirmation as control was declared effective because there's no communication problems			

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HFMEA Step 3		HFMEA Step 4									HFMEA Step 5				
Process and Subprocess		**Failure Mode**		**Potential Causes**	**Severity**	**Probability**	**Hazard Score**	**Single Point Weakness?**	**Existing Control Measure?**	**Detectability?**	**Proceed?**	**Action Type**	**Actions or Rationale for Stopping**	**Outcome Measure**	**Person Responsible**	**Management Concurrence**
Prescription Review																
2A	Administrative, pharmaceutical, and clinical drug review	1	Patient's data incomplete		2	2	4	Y	Y	→	**STOP**					
				Doctor is in a hurry and missed to fill out some data	2	3	6	Y	Y	→	**STOP**	→	Prescribing doctor confirmation as control was declared effective because there's no communication problems			
		2	Doctor's identity incomplete		1	3	3	N	→	→	**STOP**					
				Doctor is in a hurry and missed to fill out some data	1	3	3	N	→	→	**STOP**	→	Prescribing doctor confirmation as control was declared effective because there's no communication problems			
		3	Drug dosage incomplete		3	4	12	→	N	N	Y					
				Prescription written manually so drug dosage not automatically complete	3	4	12	→	N	N	Y	Control	E-prescription in all medication services	All prescription received is e-prescription	- Prescribing Doctor - Pharmacist - IT Team	
2B	Checking drug's availability in the	1	Drug not available		1	4	4	Y	N	N	Y					
				Prescription written manually	1	4	4	Y	N	N	Y	Contr	E-prescription in all medication services	All prescription received is e-	- Prescribing Doctor	

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HFMEA Step 3		HFMEA Step 4									HFMEA Step 5				
Process and Subprocess		**Failure Mode**	**Potential Causes**	**Severity**	**Probability**	**Hazard Score**	**Single Point Weakness?**	**Existing Control Measure?**	**Detectability?**	**Proceed?**	**Action Type**	**Actions or Rationale for Stopping**	**Outcome Measure**	**Person Responsible**	**Management Concurrence**
	system and storage		so drug availability not automatically detected								ol		prescription	- Pharmacist - IT Team	
			Drug availability in the system and storage do not synchronized	1	4	4	N	→	→	**STOP**	→	Stock will be checked manually and will done a confirmation to prescribing doctor if problem were found. Prescribing doctor confirmation as control was declared effective because there's no communication problems			
		2 Drug availability in the system and storage do not synchronized		1	4	4	N	→	→	**STOP**					
			Pharmacy information system not working properly	1	4	4	N	→	→	**STOP**	→	Stock will be checked manually and will done a confirmation to prescribing doctor if problem were found. Prescribing doctor confirmation as control was declared effective because there's no			

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HFMEA Step 3		HFMEA Step 4									HFMEA Step 5				
Process and Subprocess		Failure Mode		Potential Causes	Severity	Probability	Hazard Score	Single Point Weakness?	Existing Control Measure?	Detectability?	Proceed?	Action Type	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
													communication problems			
		3	Drug availability in the card stock and storage do not synchronized		1	4	4	N	→	→	**STOP**					
				Non-compliance with stock card completion SOP	1	4	4	N	→	→	**STOP**	→	Random stock checking and daily drug stock list are done effectively as a control			
Input Medication Transaction																
3A	Input patient's identity and medicine to the system	1	Incorrect patient identity input to the system		1	2	2	Y	N	N	Y					
				Pharmacists are less thorough when inputting patient data	1	2	2	Y	N	N	Y	Control	For MC patients, the patient's identity data is transferred to the information system used, including the date of birth and the patient's photo so that the patient's identity can be verified	Patient's date of birth and photo is included at patient's data information system menu	IT Team	
				Patient's identity is not fully integrated in the information system so identity re-input must be done	1	4	4	Y	N	N	Y	Control				
		2	Incorrect patient drug input into the		3	3	9	→	N	N	Y					

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HFMEA Step 3		HFMEA Step 4									HFMEA Step 5				
Process and Subprocess		**Failure Mode**	**Potential Causes**	**Severity**	**Probability**	**Hazard Score**	**Single Point Weakness?**	**Existing Control Measure?**	**Detectability?**	**Proceed?**	**Action Type**	**Actions or Rationale for Stopping**	**Outcome Measure**	**Person Responsible**	**Management Concurrence**
		system													
			Doctor and Pharmacists are less thorough when inputting patient medication data	1	2	2	Y	N	N	Y	Control	E-prescription in all medication services	All prescription received is e-prescription	- Prescribing Doctor - Pharmacist - IT Team	
3B	Patient make payment to the admission	No failure mode found that impact medication error and patient safety													
Drug preparation															
4A	Drug preparation according to the type, amount, and dosage in the prescription	1 Incorrect drug taking		3	3	9	→	N	N	Y					
			Pharmacist not thorough enough with LASA drugs	3	3	9	→	N	N	Y	Control	Tall Man Lettering	All LASA drug list are written with Tall Man Lettering	- Pharmacist	
			LASA drug is placed side by side	3	3	9	→	N	N	Y	Control	Drug storage expansion and change in the type of drug shelf	Space between each LASA drugs is at least 1 box	- Head Clinic - Pharmacist	
			Limited drug storage space so that drugs pile up and disorganized	3	3	9	→	N	N	Y					
			Pharmacists not thorough and in a hurry to catch up service time	3	3	9	→	Y	→	**STOP**	→	Double check independent is done effectively as control			
		2 Incorrect drug amount		2	3	6	Y	Y	→	**STOP**					
			Pharmacists not	2	3	6	Y	Y	→	**STO**	→	Double check			

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HFMEA Step 3		HFMEA Step 4									HFMEA Step 5				
Process and Subprocess		**Failure Mode**		**Potential Causes**	**Severity**	**Probability**	**Hazard Score**	**Single Point Weakness?**	**Existing Control Measure?**	**Detectability?**	**Proceed?**	**Action Type**	**Actions or Rationale for Stopping**	**Outcome Measure**	**Person Responsible**	**Management Concurrence**
				thorough and in a hurry to catch up service time							**P**		independent is done effectively as control			
		3	Incorrect drug dosage		3	3	9	→	N	N	Y					
				LASA drug is placed side by side	3	3	9	→	N	N	Y	Control	Drug storage expansion Change in the type of drug shelf	Space between each LASA drugs is at least 1 box	- Head Clinic - Pharmacist	
				Pharmacists not thorough and in a hurry to catch up service time	3	3	9	→	Y	→	**STOP**	→	Double check independent is done effectively as control			
		4	Reduced quality of drugs given to patients		4	2	8	→	N	N	Y					
				Drug placement negligence with the FIFO/FEFO system	3	4	12	→	N	N	Y	Control	Replace first expired sticker with the bigger size and sticking it to each side of the first expired drug	All of the first expired drug are marked with bigger size sticker on every side.	- Pharmacist	
4B	Writing drug labels and pack the drug into the labels	1	Incorrect in writing drug instructions		3	3	9	→	N	N	Y					
				Pharmacists don't understand specific drug guidelines	3	2	6	Y	N	N	Y	Control	Internal training to improve pharmacy officer's competence	Internal training is held at least once every year	- Head Clinic - QHSE	
				Pharmacists not thorough and in a hurry to catch	3	3	9	→	N	N	Y	Control	Using electronic labelling on drugs	Using electronic labelling on drugs on every	- Prescribing Doctor - Pharmacist	

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HFMEA Step 3		HFMEA Step 4									HFMEA Step 5				
Process and Subprocess		**Failure Mode**		**Potential Causes**	**Severity**	**Probability**	**Hazard Score**	**Single Point Weakness?**	**Existing Control Measure?**	**Detectability?**	**Proceed?**	**Action Type**	**Actions or Rationale for Stopping**	**Outcome Measure**	**Person Responsible**	**Management Concurrence**
			up service time											type of pharmacy installation services	- IT Team	
		2	Pack the drugs into the wrong labels		3	2	6	Y	N	N	Y					
				Place for preparing the medicine is limited so that it mixes with other medicines that are being prepared	3	2	6	Y	N	N	Y	Control	Make a checklist to verify double check process, which include correct drug, correct time, correct route, correct dose, and correct patient identity.	There's a 5 correct checklist to verify double check in every pharmacy installation services.	- Pharmacist	
													Checklist completion inspection	Checklist completion inspection as a part of the audit	- QHSE - Head Clinic - Pharmacist	
				Pharmacists not thorough and in a hurry to catch up service time	3	2	6	Y	Y	→	**STOP**	→	Double check independent is done effectively as control			
Dispensing																
5A	Double check	1	The pharmacist wasn't thorough in double checking		3	3	9	→	N	N	Y					
				Pharmacists in a hurry to catch up service time	3	2	6	Y	N	N	Y	Control	Make a checklist to verify double check process, which include correct drug, correct time, correct route, correct dose,	There's a 5 correct checklist to verify double check in every pharmacy installation	- Pharmacist	

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HFMEA Step 3		HFMEA Step 4									HFMEA Step 5				
Process and Subprocess		Failure Mode		Potential Causes	Severity	Probability	Hazard Score	Single Point Weakness?	Existing Control Measure?	Detectability?	Proceed?	Action Type	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
													and correct patient identity.	services.		
													Checklist completion inspection	Checklist completion inspection as a part of the audit	- QHSE - Head Clinic - Pharmacist	
		2	Double check independent can't be done		3	3	9	→	N	N	Y					
				There's only one Pharmacist in a certain shift	3	3	9	→	N	N	Y	Control	Make a checklist to verify double check process, which include correct drug, correct time, correct route, correct dose, and correct patient identity.	There's a 5 correct checklist to verify double check in every pharmacy installation services.	- Pharmacist	
													Checklist completion inspection	Checklist completion inspection as a part of the audit	- QHSE - Head Clinic - Pharmacist	
5B	Call the patient and check the patient's identity	1	Re-checking patient's identity is not done		3	2	6	Y	N	N	Y					
				Pharmacists overwhelmed because patients are piling up at certain time	3	3	9	→	N	N	Y	Control	Make a checklist to verify double check process, which include correct drug, correct time, correct route, correct dose, and correct patient identity.	There's a 5 correct checklist to verify double check in every pharmacy installation services.	- Pharmacist	
													Checklist completion	Checklist	- QHSE	

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HFMEA Step 3		HFMEA Step 4									HFMEA Step 5				
Process and Subprocess		Failure Mode		Potential Causes	Severity	Probability	Hazard Score	Single Point Weakness?	Existing Control Measure?	Detectability?	Proceed?	Action Type	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
													inspection	completion inspection as a part of the audit	- Head Clinic - Pharmacist	
5C	Dispensing drug and explaining the drugs to patient	1	Dispensing medication to the wrong patient		3	3	9	Y	N	N	Y					
				Re-checking patient's identity is not done	3	3	9	→	N	N	Y	Control	Make a checklist to verify double check process, which include correct drug, correct time, correct route, correct dose, and correct patient identity.	There's a 5 correct checklist to verify double check in every pharmacy installation services.	- Pharmacist	
													Checklist completion inspection	Checklist completion inspection as a part of the audit	- QHSE - Head Clinic - Pharmacist	
				Patient's identity is not fully integrated in the information system so identity verification can't be done	3	3	9	→	N	N	Y	Control	For MC patients, the patient's identity data is transferred to the information system used, including the date of birth and the patient's photo so that the patient's identity can be verified	Patient's date of birth and photo is included at patient's data information system menu	- IT Team	
		2	The patient received the wrong drug and		3	3	9	→	N	N	Y					

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HFMEA Step 3		HFMEA Step 4									HFMEA Step 5				
Process and Subprocess		**Failure Mode**		**Potential Causes**	**Severity**	**Probability**	**Hazard Score**	**Single Point Weakness?**	**Existing Control Measure?**	**Detectability?**	**Proceed?**	**Action Type**	**Actions or Rationale for Stopping**	**Outcome Measure**	**Person Responsible**	**Management Concurrence**
			dose													
				There's no checklist control to verify drug preparation process and double check	3	3	9	→	N	N	Y	Control	Make a checklist to verify double check process, which include correct drug, correct time, correct route, correct dose, and correct patient identity.	There's a 5 correct checklist to verify double check in every pharmacy installation services.	- Pharmacist	
													Checklist completion inspection	Checklist completion inspection as a part of the audit	- QHSE - Head Clinic - Pharmacist	
		3	Drug information is not understood and well received by patients		3	3	9	→	N	N	Y					
				There is no process to verify drug information understanding from patients	3	3	9	→	N	N	Y	Control	Verify patient's understanding of drug information by recalling drug information from patients	Recalling drug information from patients on every pharmacy installation services	- Pharmacist	
				Patient refuses to do drug education	3	2	6	N	→	→	**STOP**	→	Writing labels correctly is done effectively as a control			
				The drug information delivery area is not conducive	3	2	6	N	→	→	**STOP**	→	Writing labels correctly is done effectively as a control			
5B	Confirm patient's address	1	Dispensing medicatio		3	2	6	Y	N	N	Y					

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HFMEA Step 3		HFMEA Step 4								HFMEA Step 5				
Process and Subprocess		Failure Mode	Potential Causes	Severity	Probability	Hazard Score	Single Point Weakness?	Existing Control Measure?	Detectability?	Proceed?	Action Type	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
	and explaining the drugs to patient	n to the wrong patient													
			The drug delivery courier could not confirm the patient's identity	3	2	6	Y	N	N	Y	Control	Confirm the recipient of the drug to the patient via wa			
			Incorrect patient address input	1	2	2	Y	Y	→	**STOP**	→	Address confirmation is done effectively as control because there's no communication problem			
		2 The patient received the wrong drug and dose		3	3	9	→	N	N	Y					
			There's no checklist control to verify drug preparation process and double check	3	3	9	→	N	N	Y	Control	Make a checklist to verify double check process, which include correct drug, correct time, correct route, correct dose, and correct patient identity.	There's a 5 correct checklist to verify double check in every pharmacy installation services.	- Pharmacist	
												Checklist completion inspection	Checklist completion inspection as a part of the audit	- QHSE - Head Clinic - Pharmacist	
		3 Drug information is not understood and well		3	2	6	N	→	→	**STOP**					

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HFMEA Step 3		HFMEA Step 4									HFMEA Step 5				
Process and Subprocess		**Failure Mode**		**Potential Causes**	**Severity**	**Probability**	**Hazard Score**	**Single Point Weakness?**	**Existing Control Measure?**	**Detectability?**	**Proceed?**	**Action Type**	**Actions or Rationale for Stopping**	**Outcome Measure**	**Person Responsible**	**Management Concurrence**
			received by patients													
				Signal problems when contacting patients and explaining drug information	3	2	6	N	→	→	**STOP**	→	Prescribing doctor also explain the drug's information			
		4	Drug information explanation is not done to the patients		3	2	6	N	→	→	**STOP**					
				Patient cannot be contacted	3	2	6	N	→	→	**STOP**	→	Prescribing doctor also explain the drug's information			
5CC	Drug delivery	1	Medicines received by patients are incomplete		2	2	4	Y	N	N	Y					
				The medicine fell during the drug delivery process because the packaging was not sealed	2	2	4	Y	N	N	Y	Control	Use plastic seal on drug delivery	All drugs delivered using plastic seal	- Pharmacist	
													Use polymailer plastic to pack the drugs	All drugs are packed using polymailer plastic	- Pharmacist	
5D	Prescription documentation	No failure mode found that impact medication error and patient safety														

Based on the HFMEA design analysis, 11 risks that required attention and 14 action plans were found. Action plans that have been sorted by improvement priority according to the results of the analysis, are written as follows. Using electronic prescriptions in all types of Pharmacy Installation services can overcome all the risks caused by manual prescription writing. Replacing first expired drug sticker with the size of 8mm can overcome negligence at organizing FIFO/FEFO. Making a verification 5 correct checklist and inspecting the completion of the checklist can verify drug preparation and dispensing. Expanding drug storage areas and changing drug racks with few partitions so that drug storage is more efficient can overcome the limitations of drug storage areas. Writing LASA drugs with Tall Man Lettering was done to overcome risks about LASA drugs. Using electronic labels is done to overcome inaccuracies when writing drug instructions on labels. Recall of drug information from patients is done to verify patient understanding. Organizing internal training can improve the staff's competence. Confirm the drug recipient to the patient via wa can be done to ensure the patient's identity in drug delivery. Adding photos and date of birth to the information system can be done to verify patient identity at the clinic. Lastly, using plastic seals and polymailer plastic packaging can maintain the safety of drug delivery to patients.

4. Conclusion and Suggestion

In conclusion, the research identifies key organizational and staff factors contributing to medication errors in Company X Clinical Pharmacy Installation. These include issues with policy socialization, training, drug handling, staff knowledge and performance, also communication among staff. The HFMEA design analysis offers valuable insights and recommends specific action plans for improvement.

Company X should consider implementing the HFMEA design and the proposed action plans to enhance patient safety. Additionally, future research could focus on further analyzing the HFMEA design in the context of telemedicine patients and collaborating with management decision-makers for streamlined approval processes.

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