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Reducing Drug Wastage at Ward Level: Using Failure Mode Effects Analysis (Fmea) Tool

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Abstract: *For year 2010, total value of drugs disposed was RM 8,575.50 due to expired or spoiled items returned from wards. The main reason was due to the failure of nurses to check the stock regularly. They only do the checking upon ordering of new stock from Pharmacy department. FMEA tool was selected by the Management to solve this problem. A special committee was set up to implement the FMEA in January 2011.The committee thru brainstorming session had developed seven steps in implementing the FMEA. At step three , Risk Priority Number (RPN) was determined. At step four with the highest RPN of 36, it was found that the failure mode of the system were due to failure of checking stock at ward level, not double checking of the drug received and wrong storage of drug at ward level. A new supply system was implemented at step five and monitoring of drug disposed started in July 2011. In this system ,pharmacy staff will go to the wards once a month to check stock of drugs kept at ward level. After the implementation of the new process, RPN was calculated again and it was found that the value was between 3 to 8 which was considered as low. Monitoring of compliance was done using ward check form based on storage condition, par level, labeling and packaging and non- conformances for spoilt and expired items. Compliance in term of drug storage was 100% and labeling compliance was 97.2% . However the compliance on par level was only 81.9% and in term of expiry date validity, the compliance was 96.5%. Based on FMEA , it was found that the main reason for expired/spoiled drugs is because of insufficient checking of ward stocks. Corrective actions are ongoing to improve further the process of supply by re-designing a new form of ward checking, re-modifying indenting process of ward stocks via the HITS system and conducting training and awareness. After implementing the new system, the value of drug disposed was RM 3,060.78 which was 94% lower. Therefore the study has shown remarkable results in reducing the amount of drug disposal which will help the organization to reduce the risk to patients and avoid wastage.*

Key words: *Drug wastage, Failure Mode Effect Analysis(FMEA) , Risk Priority Number (RPN)*

I. Introduction

KPJ Seremban Specialist Hospital is the subsidiary of KPJ Healthcare Berhad, the biggest chain of private hospital in Malaysia .Pharmacy department received high return of short expiry, expired or spoiled drugs. For year 2010, total value of drug disposed was RM 8,575.50 due to expired or spoiled items returned from wards. Therefore patients are at risk of getting expired or spoiled drugs during their admission in the hospital. Based on the analysis it was found that that checking of drugs was only done by the nurses when they plan to indent new stock from Pharmacy. Some drugs are slow moving and remain in stock until used. As a result those drugs may have expired without anyone noticing. In order to overcome the problem, FMEA was implemented to look at the ward stock indent processes to identify the failure mode , its effects and causes and subsequently designing a new plan to minimize the risk and losses. The ultimate goal of FMEA is to prevent bad outcomes and prevent harm. The greatest strength of FMEA lies in its ability to focus users on the process of redesigning potential problematic processes to prevent the occurrence of failures (JCI,FMEA)

II. Objectives

1.To find out the value of drugs disposed from ward's level
2.To identify the failure mode of the system of supply
3.To implement a new system to reduce the failure rate
4.To monitor the performance of the new system

III. Methodology

In January 2011,the management decided to implement FMEA in pharmacy department based on the value of drugs disposal from January to December 2010. The implementation of FMEA will follow the following steps

STEP ONE:

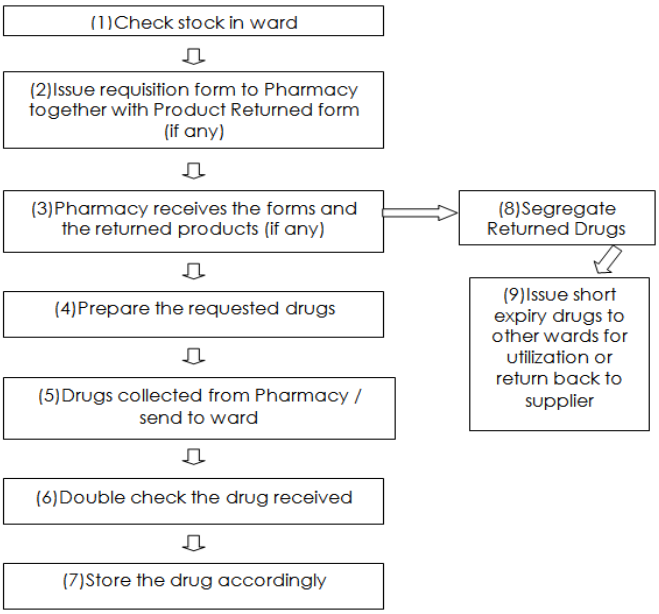
To form a committee of the FMEA at the hospital level. The committee was headed by the Chief Pharmacist assisted by three nursing personals , three pharmacy staff and Quality Executive .

FMEA is a commonly used prospective risk assessment approach in health care. It is time consuming and resource intensive and team performance
is crucial for FMEA success (Wetterneck, 2009)

STEP TWO:

To assess the current ward stock indenting process. The assessment was done using FMEA worksheet (McDermott, 2009)

WARD STOCK INDENTING PROCESS



Nurses checked their stock when they plan to indent drugs from Pharmacy. During checking, nurses are required to check par level, storage, expiry date and physical condition of drugs.

STEP THREE:

To brainstorming.

The process of brainstorming follows the techniques of Tischler, 2010. During brainstorming activity, potential failure modes, its effects and causes within each process are tabulated. Scoring the FMEA is done according to the Guidelines below.

SCORING GUIDELINES:

Key for Severity Rating: Determine the severity of the effect on the patient / organization

Severity Score	Description
1	Minor patient / company outcome: No injury, increased LOS or level of care; no incur loss
2	Moderate patient / company outcome: Injury, Increased LOS or level of care; incurred loss
3	Major patient / company outcome: Major medical intervention required, increased LOS and/or level of care for >3patients; major incurred losses
4	Catastrophic patient / company outcome: Death or major permanent loss of function, wrong procedure on wrong patient, medication error / ADR incidents; lawsuits

Key for Occurence Rating: Determine the frequency of causes occurence

Occurence Score	Description
1	*Remote*: unlikely to occur (sometime in 3-10 years)
2	*Uncommon*: Possible to occur (few times in a year)
3	*Occasional*: Probably will occur (eg several times in a month)
4	*Frequent*: Likely to occur immediately or within a short period

Key for Detectability Score: Determine the detectability of problem before affecting patient / organization

Detectability Score	Description
1	Easily detectable
2	Often detectable
3	Unlikely detected
4	Rarely detected

*Scoring method adapted from: National Centre for Patient Safety, Healthcare Failure Mode and Effect Analysis (HFMEA) Institute for Safe Medication Practices (ISMP) 2005

Risk Priority Number (RPN): Determines where the greatest hazard lies. It is a measure for comparison within one process only; it is not a measure for comparing risk between processes or organizations (Institute of Health Improvement)

RPN = Severity x Occurrence x Detectability

IV. Failure Modes And Effects Analysis

No	Process	Failure Modes	Effects	Sev e-rity	Causes of Failure	Occ ur-renc es	Dete ct-abili ty	RPN	Rank	Action to Reduce Failure Mode
1	Check stock level in ward	SN did not check ward stock level.	No replenishment, stock not sufficient	2	Inadequat e staffing,	3	3	18	3	Reschedule **staffing pattern**
				2	Lack of making the check a priority	3	3	18	3	Engaging staff in culture of safety – importance of daily checking
			Patient may not get medication on time during emergency	4	Replenish ment failure	3	3	**36**	**1**	Integrate check process into daily task
				4	Staff unaware of stock level	2	3	**24**	**2**	Daily monitoring of stock level – bin card
		Check inadequate	Replenishment not according to usage	1	Inefficient workflow	4	4	16	4	Daily monitoring of stock level – bin card to check on usage
		Staff not sure how to check and indent	Wrongly indent item	2	New staff	2	3	12	5	Training
				2	Staff competenc y	2	3	12	5	Training and supervision
			Over stock / Understock	2	Not aware on drug usage	3	3	18	3	Drug par level
No	**Process**	**Failure Modes**	**Effects**	**Sev e-rity**	**Causes of Failure**	**Occ ur-renc es**	**Dete ct-abili ty**	**RPN**	**Rank**	**Action to Reduce Failure Mode**
2	Issue requisitio n form to Pharmacy together with Product Returned form (if	Wrong item entered – Order not complete	Supply wrong medication	4	Illegible hand writing – staff misread drug indent	3	2	**24**	**2**	Printed order / computerised
				4	LASA	3	2	**2**	**2**	Write in

	any)				drug			**4**		CAPITAL letter
		Forms not received by Pharmacy	No supply made or returned drugs received	2	Forms misplace / missing	2	2	8	6	Form should be accompanied with trolley/ medication box
		Staff not sure how to check and indent	Wrongly indent item	4	New staff	2	3	**24**	**2**	Training
				4	Staff competency	2	3	**24**	**2**	Training and supervision
			Over stock / Understock	2	Not aware on drug usage	3	3	18	3	Drug par level
			Short expiry / expired drugs not returned to Pharmacy	4	No regular checking	2	3	**24**	**2**	Short expiry drugs to be tag with reminder label
No	**Process**	**Failure Modes**	**Effects**	**Sev e-rity**	**Causes of Failure**	**Occ ur-rences**	**Dete ct-ability**	**RPN**	**Rank**	**Action to Reduce Failure Mode**
3	Pharmacy receives the forms and the returned products (if any)	Delay in receiving form or not received at all	No supply – insufficient stock	2	Misplace request form	2	1	4	8	System for top up to be designed – include scheduling for topping up. Indent form should be accompanied with trolley/ medication box
				2	Inefficient process for sending orders	2	1	4	8	Work on workflow for top up system Training to all staff involved
			Short expiry / expired drugs not returned	4	Misplace request form	2	1	4	8	Returned drug should be accompanied with trolley / medication box
4	Prepare the requested drugs	No stock issue	No supply to ward / inadequate	2	Supplier out of stock	2	1	4	8	Find alternative drug to cover usage Sms drop/ memo circulation to all involved on substitution available
		Inaccurate labeling i.e unclear printing, label lost	Wrong drug / strength supplied	2	Human errors, ambiguous information	1	1	2	9	Double checking procedure Separation and alert label for LASA drug
			Ineffective drug – expiry date unclear	4	Equipment malfunction	1	1	4	8	Routine equipment maintenance check
No	**Process**	**Failure Modes**	**Effects**	**Sev e-rity**	**Causes of Failure**	**Occ ur-rences**	**Dete ct-ability**	**RPN**	**Rank**	**Action to Reduce Failure Mode**

4	Prepare the requested drugs (con't)	Wrong quantity supplied	Stock not sufficient to usage / over supplied	2	Counting error	2	3	12	5	Double checking on receiving drug
		Supplied short expiry / expired drug	ADR, allergic reaction or ineffective treatment if administered to patient	4	Not practice FIFO Lack of monitoring of stock expiry	2	3	**24**	**2**	Double checking on receiving drug Routine check on expiry and separate drugs on immediate use area FIFO arrangement
		Preparation of drug delay due to various reasons i.e. insufficient bottles, staff in-charge on sick leave	Supply to ward inadequate and delayed.	2	Failure of dry stock monitoring	3	1	6	7	Bin card use to monitor stock availability of preparation supplies. Appoint staff in-charge on monitoring dry stock consistently
				2	Inadequate staffing	3	1	6	7	Replacement staff to cover duty
No	**Process**	**Failure Modes**	**Effects**	**Severity**	**Causes of Failure**	**Occurrences**	**Detectability**	**RPN**	**Rank**	**Action to Reduce Failure Mode**
5	Drug collected from Pharmacy / send to ward	Delay in delivery / collection	Shortage of stock in ward	2	Human errors i.e. Staff forgot to collect / send	2	2	8	6	Establish top up system time frame for collection / delivery Assign staff for delivery / collection
				2	Heavy workload – staff occupied with other task	2	2	8	6	Assign staff for delivery / collection
				2	Inadequate staffing – staff on leave	2	2	8	6	Replacement staff to cover duty
		Delivered to wrong unit	Overstock / under stock	2	Many trolleys in pharmacy – staff may get confused	2	1	4	8	Accurately label each unit's trolley Dedicated space for indent trolley to avoid congestion in Pharmacy
		Drug dropped – broken / missing during transit	Cost to company – to replace loss of drug	2	Trolleys not stable	1	2	4	8	Proper arrangement of drug on trolley Routine check on trolleys
				2	Security of drugs during transit	2	2	8	6	Medication box use to transfer drugs
No	**Process**	**Failure Modes**	**Effects**	**Severe-**	**Causes of Failure**	**Occur-**	**Detect-**	**RP**	**Rank**	**Action to Reduce Failure**

				rity		rences	ability	N		Mode
5	Drug collected from Pharmacy / send to ward (con't)	Drug dropped – broken / missing during transit (con't)	Staff injury – medical cost	3	Human factors i.e. carelessness	2	2	12	5	Increase mental focus
				3	Environmental factors i.e. distractions, space, lighting, hindrance, noise)	2	2	12	5	Environmental and workflow improvement, avoid hindrances
6	Double check the drug received.	Staff did not double check	Discrepancies in stock level	2	In adequate staffing	3	3	18	3	Reschedule staffing pattern
				2	Lack of making the check a priority	2	3	12	5	Engaging staff in culture of safety – importance of double checking
		Inadequate checking	Potential error on patient's safety not detected (eg expiry date, correct drug / strength, storage requirement)	4	Check process not integrated in workflow	3	3	**36**	**1**	Staff to document signature upon counterchecking Training on correct checking
				4	Heavy workload	2	3	**24**	**2**	Task assignment to in-charge
No	**Process**	**Failure Modes**	**Effects**	**Severity**	**Causes of Failure**	**Occurrences**	**Detectability**	**RPN**	**Rank**	**Action to Reduce Failure Mode**
7	Store drug accordingly in ward	Drug not stored correctly (according to storage requirement)	Damaged drug – loss to company	3	Staff unaware of storage condition	2	3	18	3	Storage condition requirements for drugs to be displayed clearly Training to staff
				3	Staff mistakenly placed drug	2	2	12	5	Bin card update 5s arrangement Regular check on stock level
		Not practicing FIFO	Increased expired drug – loss to company	4	No regular check	3	3	**36**	**1**	Regular checking should be done Highlight short expiry drugs or separate at immediate use area
		Storage space inadequate	Potential error on patient's safety not detected (eg mixing of multiple drug, LASA)	4	Environmental factors eg space constraint	2	3	**24**	**2**	To allocate space for drug storage 5S arrangement Alert tag displayed, LASA drug not placed next to each other
				4	Human factors eg staff misplace drug	2	3	**24**	**2**	Drugs segregated in proper container and clearly labelled
			Delay patient's treatment	2	Lack of ease on finding correct drug	2	3	12	5	5S arrangement Drugs segregated in proper container and clearly labeled

			Risk on drug dropped / broken	2	Cramped storage area	2	3	12	5	Allocated space for drug storage Avoid overstocking by establishing par level for ward stock
No	**Process**	**Failure Modes**	**Effects**	**Sev e-rity**	**Causes of Failure**	**Occ ur-renc es**	**Dete ct-abili ty**	**R P N**	**Ra nk**	**Action to Reduce Failure Mode**
8	Segregate Returned Drugs	Drug mixed up - Disposed short expiry drugs which can be utilized	Loss to company	3	Human factors eg staff error	2	3	18	3	Double checking with another staff
9	Issue short expiry drugs to other wards for utilization or return back to supplier	Short expiry drugs not monitored - expired	ADR, allergic reaction or ineffective treatment if administered to patient	4	Not practice FIFO Lack of monitoring of stock expiry	2	3	**24**	**2**	Separate drugs on immediate use area FIFO arrangement Regular monitoring
		Drugs not returnable	Loss to company – drugs to be disposed off	3	Drugs has expired or very short expiry not accepted for return	2	3	18	3	Control of drug ordering for non-returnable drugs
10	Expired / spoilt item disposed	Procedures of drug disposal not properly conducted	Environmental hazards	4	Staff competency	2	2	16	4	Training & awareness SOP available in work area

STEP FOUR:

Identify the highest Risk Priority Number (RPN) based on step three.

The Risk Priority Number (RPN) determines which processes' failure modes affects the most and used to determine the rank for us to address the failure modes with the highest RPN. From table below, it showed that failure modes that are most severe, occur often and hard to detect are ranked # 1 as greatest hazard to our patients.

No	**Process**	**Failure Modes**	**Effects**	**Sev e-rity**	**Causes of Failure**	**Occu r-renc es**	**Dete ct-abilit y**	**RPN**	**Rank**	**Action to Reduce Failure Mode**
1	Check stock level in ward	SN did not check ward stock level.	Patient may not get medication on time during emergency	4	Replenishment failure	3	3	**36**	**1**	Integrate check process into daily task
2	Double check the drug received.	Inadequate checking	Potential error on patient's safety not detected (eg expiry date, correct drug / strength, storage requirement)	4	Check process not integrated in workflow	3	3	**36**	**1**	Staff to document signature upon counterchecking Training on correct checking
3	Store drug accordingly in ward	Not practicing FIFO	Increased expired drug – loss to company	4	No regular check	3	3	**36**	**1**	Regular checking should be done Highlight short expiry drugs or separate at immediate use area

In step four, it was found that check stock level in ward, double checking the drug received and store drug accordingly in ward received the highest RPN of 36.

STEP FIVE:

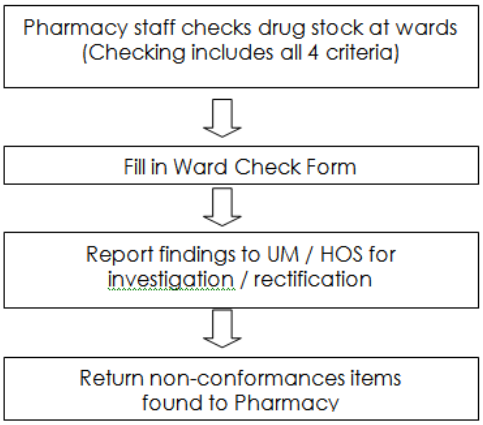
One of the most important factors for the success of FMEA in any organization is an effective FMEA Process. It takes a focused strategy to bring about the infrastructure that is necessary to support effective FMEAs, but it is well worth the time and effort (Carlson, 2012). Therefore the team decided to redesign the supply process .In the new system , pharmacy staff will go to each ward to check the stock of drugs kept at the ward level. They are required to check drugs stored at ward level once a month using the following criteria:

i. Storage condition
ii. Par level (excess / shortage)
iii. Labeling & Packaging
iv. Non-conformances (Spoilt / Expired)

The findings and corrective actions shall be documented in Ward Check Form and duly reported to the relevant personnel (Chief Pharmacist and Unit Managers). Findings for each ward are scored accordingly and tabulated.

In June 2011 , a new process of indenting of drugs for ward stock was implemented.

New Process Of Monthly Ward Stock Check By Pharmacy Staff



STEP SIXTH:

After implementing the new process, another FMEA was done.

V. Fmea On New Process Of Monthly Ward Check By Pharmacy Staff:

No	Process	Failure Modes	Effects	Sev e-rity	Causes of Failure	Occ ur-renc es	Dete ct-abili ty	RPN	Rank	Action to Reduce Failure Mode
1	Pharmacy staff checks drug stock at wards (Checkin g includes all 4 criteria)	Staff did not carry out ward check	Ward stock is not properly stored and overstock	3	Human factors e.g staff forgot	2	1	6	2	Monitoring of activity by Pharmacist Impose as staff KPI
				3	Lack of making the check a priority	2	1	6	2	Engaging staff in culture of safety Training & awareness
		Inadequate checking	Potential error on patient's safety not detected (eg expiry date, correct drug / strength, storage requirement)	4	Staff do not understand how to check	2	1	8	1	Training & Briefing Reinforce in services meeting Monitoring by the Pharmacist
				4	Staff competenc y – new staff	2	1	8	1	Training
1	(con't..) Pharmacy staff checks	Inadequate checking	Potential error on patient's safety not detected (eg	4	Not using ward check form as	2	1	8	1	Make sure form is available all the times

	drug stock at wards (Checking includes all 4 criteria)		expiry date, correct drug / strength, storage requirement)		references					
2	Fill in Ward Check Form	Form incomplete	Pharmacist / UM is not informed on any non-conformances	3	Staff do not understand how to fill in the form	2	1	6	2	Training & Briefing Reinforce in services meeting Form to be verified by Pharmacist
		Form is not filled in	No documentation	3	Form not available	2	1	6	2	Make sure form is available all the times , routine monitoring by Pharmacy Clerk
3	Report findings to UM / HOS for investigation /rectification	Findings was not reported	Discrepancies was not rectified – risk of potential error to patient safety is not minimize	4	Human factors e.g staff forgot, staff competency	2	1	8	1	Reinforce verification by UM & Pharmacist
4	Return non-conformances items found to Pharmacy	Drug dropped – broken during transit	Cost to company – to replace loss of drug	3	Security of drugs during transit	1	1	3	3	Medication box use to transfer drugs
			Staff injury – medical cost	3	Human factors i.e. carelessness	1	1	3	3	Increase mental focus
				3	Environmental factors i.e. distractions, space, lighting, hindrance, noise)	1	1	3	3	Environmental and workflow improvement, avoid hindrances

Based on the new FMEA it was found that although the severity score is high, the occurrences level and detectability score is low as the activity is conducted monthly under the Pharmacist's supervision and reported to unit managers. Therefore, RPN is also low which indicates improvement in terms of minimizing the risk of hazardous effects .

STEP SEVEN:

To monitor the new process using ward check form based on the following criteria:

i) Storage condition
ii) Par level (excess / shortage)
iii) Labelling & Packaging
iv) Non-conformances (Spoilt / Expired)

Scoring mechanism is as follows:

1 – No discrepancies observed

0 – Discrepancies observed such as very short expiry /expired drugs, exceeded par level, no label, incorrect storage condition.

VI. Results

1. Data of drug disposed

	January-December 2010 (old system for drug ordering)	July 2011 –June 2012 (new system for drug ordering)	Variance
Value of drugs disposed	RM 8,575.50	RM 3,060.78	94%

2. Checking compliance for drug storage

Checking of compliance at ward level was implemented in July 2011.

Percentage (%) of Compliance on Overall Drug Storage in Wards

CRITERIA	JULY 2011	AUG 2011	SEPT 2011	OCT 2011	NOV 2011	DEC 2011	JAN 2012	FEB 2012	MAC 2012	APR 2012	MAY 2012	JUNE 2012	TOTAL
STORAGE CONDITION	100	100	100	100	100	100	100	100	100	100	100	100	100
PAR LEVEL	91.7	91.7	83.3	50	66.7	66.7	91.7	75	91.7	91.7	92.0	91.7	81.9
LABELLING	91.7	100	100	100	100	100	100	91.7	91.7	91.7	100	100	97.2
EXPIRY DATE STILL VALID	98.7	100	98.7	96.7	93.3	96.7	93.3	95.6	95.9	94.5	97.3	97.2	96.5

VII. Discussion

Before implementing the FMEA, the value of drugs disposed was RM 8,775.50 due to expired or spoiled items returned from wards. After implementing the new system based on the FMEA ,the value of drugs disposed reduced to RM 3,060.78 . Therefore there was 94% reduction in term of drug wastage. The main reason is because in the old system, checking of drugs at ward level was done by nurses when they plan to indent the new stock. In the new system, checking are done by pharmacy staff regularly once a month. Monthly report will be given to all unit managers . Compliance in term of drug storage was 100% and labeling compliance was 97.2% .However the compliance on par level was only 81.9%. Therefore drugs exceeding par level will be taken back to pharmacy department. In term of expiry date validity, the compliance was 96.5%. Based on the FMEA tool, it was found that the main reason for expired /spoiled drugs is because of insufficient checking of ward stocks. Corrective actions are ongoing to improve further the process of supply by taking the following actions:

- Re-designing a new form of ward checking to ensure all drugs storage areas at wards are checked
- Re-modifying indenting process of ward stocks via the HITS system, where wards will be ordering drugs through HITS and Pharmacy can monitor ward stock level before replenishment to the respective wards.
- Conducting training & awareness on the importance of drug safety and its risk for new staff

VIII. Conclusion

FMEA was found to be an effective tool for identifying potential problems and the same tool can be applied to other process in the hospital. The study has shown remarkable results in reducing amount of drug disposal in KPJ Seremban which will help the organization to reduce the risk to patients and avoid wastage.

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