Application of Failure Mode Effect Analysis (FMEA) to Improve Medication Safety in the Dispensing Process – A Study at A Teaching Hospital, Sri Lanka

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Abstract

Background: Failure Mode Effect Analysis (FMEA) is a prospective, team based, structured process used to identify system failures of high risk processes before they occur. Medication dispensing is a risky process that should be analysed for its inherent risks using FMEA.

Objectives: The objective of this study was to identify possible failure modes, their effects and causes in the dispensing process of a selected tertiary care hospital using FMEA.

Methods: Two independent teams (Team A and Team B) of pharmacists conducted the FMEA for two months in the Department of Pharmacy of a selected teaching hospital, Colombo, Sri Lanka. Each team had five meetings of two hours each, where the dispensing process and sub processes were mapped, and possible failure modes, their effects, and causes, were identified. A score for potential severity (S), frequency (F) and detectability (D) was assigned for each failure mode. Risk Priority Numbers (RPNs) were calculated (RPN=SxFxD) to prioritise identified failure modes.

Results: Team A identified 48 failure modes while Team B identified 42. Among all 90 failure modes, 69 were common to both teams. Using the RPN, Team A prioritised one failure mode, while Team B prioritised three (having identical RPNs). Both teams identified overcrowded dispensing counters as a cause for 57 failure modes. Redesigning of, dispensing tables, dispensing labels, the dispensing and medication re-packing processes, and establishing a patient counseling unit were the major suggestions for correction.

Conclusion: FMEA was successfully used to identify and prioritise possible failure modes of the dispensing process through active involvement of pharmacists.

Background

Medication safety is a global concern and a matter of interest for healthcare professionals and researchers worldwide. As a result, in 2017, the World Health Organization (WHO) initiated the “Third Global Patient Safety Challenge with a theme on medication safety” along with the challenge to “reduce the frequency and impact of medication errors”(1). Jain et al., (2) defines medication errors as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer”. Medication errors are further classified as prescribing, dispensing, medication administration, and patient compliance errors (2) caused mainly due to faulty systems and rarely due human neglect (1).

The focus of the present study was on dispensing errors. Dispensing is an important element of pharmaceutical care, which in turn is an indispensable aspect of total patient care. As the American Pharmaceutical Association describes, the pharmacist must be “responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes” (3) and must be responsible for ensuring patient safety. Especially in ambulatory care, a pharmacist dispensing medication is the last

healthcare professional who can capture any errors that occur at this stage (4). It is reported that 37% of dispensing errors are organisational or system problems while 30% are related to the individual professional, 17% to prescription, 10% to medication, and 4% to the patient (5). Thus, a proactive effort to error-proof the dispensing process would clearly benefit in improving patient safety.

The Institute of Medicine recommends conducting prospective risk analysis studies on medication safety in pharmacy rather than basic epidemiological studies (6). The Failure Mode Effect Analysis (FMEA) is an ideal tool for this purpose as it is able to identify potential failures before harmful events occur (7). FMEA offers a proactive approach to detecting failures in contrast to incident analysis and Root Cause Analysis which are performed retrospectively. As FMEA is able to identify errors before it happens, industries such as aviation, aerospace, nuclear power and automobiles (8) use it widely. Lately, FMEA has been adopted to assess risks in healthcare and to identify areas that need improvement in the healthcare system so much that the United Kingdom National Patient Safety Agency recommends to apply FMEA to assess new policies and procedures before implementing them (9) and the Joint Commission on Accreditation of Healthcare Organizations, USA has asked its accredited institutes to carry out an annual proactive risk assessment study such as FMEA (9, 10).

FMEA is used in many healthcare specialties including chemotherapy (11-14), paediatrics (12, 15-17), and pharmacy, and in different settings such as inpatient settings (10-12, 18), intensive care units (17, 19), community clinics (20) and community pharmacies (6, 21). FMEA has even been successfully used to analyse new policies before implementing them (22). However, there were no reports on using FMEA to assess the safety of the dispensing process of out-patients and clinic patients in hospitals.

Therefore, the objective of this study was to identify possible failures in the dispensing processes serving out-patients and clinic patients of a tertiary care hospital, their effects, and causes, using Failure Mode Effect Analysis and to recommend corrective actions for selected failure modes.

Methodology

The present cross sectional descriptive study was conducted from August 2018 to October 2018 in the Pharmacy Department of a selected teaching hospital, Colombo, Sri Lanka. The Pharmacy Department consists of four dispensing units for out-patients and clinic patients, one in-patient pharmacy, one surgical store and a main medication store. The FMEA process was carried out to assess the safety of the medication dispensing process for out-patients and clinic patients of the study setting.

Approximately 2,000 out-patients and 2,500 clinic patients attend the Pharmacy Department a day and were manned by 15 pharmacists at the time of the study. The hospital uses hand-written prescriptions for both out-patients and clinic patients, while medication stock management, dispensing and documentation are also manual. During the dispensing process, a single prescription is handled by one pharmacist only. Selected fast moving medications are pre-packed as monthly supplies for the ease of dispensing, labeled with the name and strength of the medication and are stored in separate drawers. One medication is packed into packets of different quantities according to the requirement (E.g.

Metformin tablet packets with 56 tablets and 84 tablets). Some selected medications are considered as “Accountable medications” which require strict documentation and are determined according to national and institutional guidelines.

FMEA was conducted according to guidelines specified in the FMEA framework of the Institute of Safe Medication Practices (ISMP), Canada (7) as illustrated in Figure 1.

Step 1 – Assembling a team to conduct FMEA

Thirteen pharmacists participated in two teams for the FMEA discussions. Pharmacists involved in dispensing medications as their daily routine of work and pharmacists’ in-charge of dispensing units were included in the study. Participants, after consenting to participate in the study, were divided in to two teams (Team A and Team B) to avoid any disruptions to the daily dispensing process of the study hospital. This process is consistent with past studies where FMEA discussions were conducted in two or more teams to avoid practical issues (9, 10, 23, 24). Both teams followed the same set of steps and had a similar composition of team members. We ensured that each team had one pharmacist in-charge to represent the managerial level, at least one senior pharmacist with more than ten years of working experience, and at least one graduate pharmacist. Each team had five meetings of two hours each. The researcher participated as the facilitator for all the FMEA discussions conducted by both teams and all discussions were audio recorded.

At the first meeting the researcher introduced the FMEA process to team members with illustrations (7, 25). To ensure that all were knowledgeable about the concept of a safety culture in the hospital, all the team members previously (Five months prior to this FMEA) attended a workshop on medication safety organised by the research team where various aspects of medication safety were emphasised. Safety culture was measured before and after the workshop using a safety culture assessment questionnaire developed in-house. Although there was no significant difference ($p=0.285$) in the level of safety culture among participants before and after the workshop, it is noteworthy that the number of “Don’t know” answers had decreased significantly ($n=25$ to 11, $p=0.019$)(26). Further, this effort indicated that members of both teams were knowledgeable on medication safety and safety culture before engaging in FMEA.

At the first meeting, all team members agreed that dispensing medications is a high-risk process highly likely to cause patient harm if any error occurred.

Step 2 – Mapping the process and sub processes of dispensing

Initially, each team member individually and independently sketched the main steps of the dispensing process as perceived by them. Then team members collated individual inputs to map one final dispensing process, agreed by all team members, to be used in subsequent steps of the FMEA process. The team then identified and mapped sub processes of each dispensing step identified by them.

Step 3 – Brainstorming to identify potential failure modes in each sub process of dispensing, their effects and causes

In the next step, team members brainstormed and identified possible failure modes in each sub process of dispensing, and documented them as recommended by ISMP, Canada (7). Each failure mode was given an identification number. Next, team members brainstormed to identify possible effects and causes of each failure mode. Disagreements were discussed until a final agreement was reached by team members.

Step 4 – Giving a numerical value (scoring) for the severity, frequency and detectability of each failure mode and calculating the Risk Priority Number (RPN)

Thereafter each failure mode was scored separately for severity, frequency and detectability. Numerical scores were assigned by team members based on their perception using guidelines specified by ISMP, Canada FMEA framework (7) (Table 1).

Table 1: Scoring scale given by ISMP, Canada for severity, frequency and detectability of failure modes (Source – FMEA framework, ISMP, Canada (7))

	Definition	Score
Severity (S)	No effect *(Failure is not noticeable and does not affect the patient or process)*	1
	Slight effect *(Failure causes minor effects or is a trouble to the patient or process, without injury or increase in level of care required)*	2
	Moderate effect *(Failure causes some performance loss and may increase the level of care (e.g., requiring hospitalisation or increasing the length of hospital stay))*	3
	Major effect *(Failure causes a high degree of performance loss, with permanent impact on the patient)*	4
	Severe or catastrophic effect *(Failure causes death or major, permanent loss of function)*	5
Frequency (F)	Yearly	1
	Monthly	2
	Weekly	3
	Daily	4
	Hourly	5
Detectability* (D)	Always	1
	Likely	2
	Unlikely	3
	Never	4

*Detectability was defined as 'Detectability of the error before it reaches to the patient'

Team members discussed to come to a final consensus on scores given for each failure mode. Disagreements were resolved through discussion until 100% agreement was reached. The three individual scores (score for severity, score for frequency, score for detectability for each failure mode) were multiplied to calculate the risk priority number (RPN = S x F x D) for each failure mode. According to the scale, the RPN ranged from 1-100. Failure modes that were not common to the two teams were exchanged for assigning scores.

Step 5 – Suggesting corrective actions for selected failure modes

Team members then recommended possible corrective action for prioritised failure modes. Failure modes with high RPN numbers and those with low RPN but high scores for severity and detectability (i.e. difficult to detect) were discussed for corrective measures. Failure modes with low RPN values and low severity

scores were not discussed further. Team members then discussed on feasibility of suggested corrective actions and highlighted the most important and feasible ones.

Results

Step 1 – Assembling a team to conduct FMEA

Team A had six female pharmacists including one in-charge pharmacist, one graduate pharmacist, two senior pharmacists with more than ten years of experience, and two junior pharmacists. Team B had four male and three female pharmacists including one in-charge pharmacist, two graduate pharmacists, two senior pharmacists with more than ten years of experience, and one junior pharmacist.

Step 2 – Mapping the process and sub processes of dispensing

Team A identified eight main process steps and 24 sub processes while Team B identified five main process steps and 21 sub processes. Process and sub process maps of both teams are shown in Figures 2 and 3 respectively.

Step 3 – Brainstorming to identify potential failures of each sub process, their effects and causes

During the brain storming process, Team A identified 48 failure modes and Team B identified 42 failure modes. Among all 90 failure modes, 69 were common to both teams. Failure modes identified by both teams, and failure modes identified only by one specific team are shown in Table 2.

Table 2: Failure modes identified by Failure Mode Effect Analysis and their Risk Priority Numbers

Common failure modes identified by both Team A and Team B		
Failure mode	**RPN A**	**RPN B**
Patient erroneously brings a wrong prescription issued to another patient at the clinic	20	6
Pharmacist dispenses medications to a prescription not relevant to that dispensing counter/section	8	8
Pharmacist does not check the clinic registration number of the patient	20	6
Pharmacist does not check the date of the prescription and age of patient	16	24
Pharmacist misreads the medication name, dose or strength	15	16
Pharmacist unintentionally misses dispensation of some medications in long prescriptions	24	4
Pharmacist fails to identify prescribing errors on prescriptions	12	24
Pharmacist misreads the duration of the prescription	8	12
Pharmacist does not notify patient on out of stock medications	8	16
Pharmacist picks up the wrong medication packet (pre-packed) without checking the label	30	12
Pharmacist picks up the medication packet (pre-packed) with the wrong quantity	20	12
Pharmacist incompletely labels the medication packet	27	24
Pharmacist accidentally writes an incorrect dose or frequency on medication label	36	6
Pharmacist writes directions (dose, frequency, before/after meals) in unclear handwriting	12	18
Pharmacist picks the wrong medication container from the dispensing shelf	8	8
Pharmacist does not check the physical appearance of medications in the container before preparation	18	8
Pharmacist counts the wrong quantity of medications	40	16
Pharmacist fills the medications to a wrong envelope which was labelled for another medication	6	12
Patient does not understand the language of written instructions and/or verbal instructions given by the pharmacist	4	4
Pharmacist fails to tell some important information when giving verbal instructions briefly	12	12
Pharmacist gives incomplete instructions for external preparations and/or only give verbal instructions without written instructions (E.g. Dermatological preparations)	18	12
Pharmacist fails to give verbal instructions	18	8

Leaflets may be unavailable and/or pharmacist may forget to give it to the patient	4	3
Pharmacist fails to document accountable medications	24	4
Failure modes identified by Team A only (but scored by both teams)		
Pharmacist incorrectly guesses information on unclear prescriptions	8	18
Pharmacist uses an envelope with incomplete or unclear label stamp to pack medications	12	8
Pharmacist fails to check the quality of the medication packing envelope	15	2
Pharmacist fills the medications into an unlabeled medication packing envelope	12	8
Pharmacist fails to fill a labeled medication packing envelope	18	4
Leaflets may be unavailable in different languages (E.g. Tamil)	4	2
Pharmacist fails to dispense some filled medication packets to the patient	8	18
Pharmacist dispenses unfilled medication packets to the patient	8	4
Pharmacist dispenses or patient takes wrong medication packets which are left on the dispensing table	18	8
Pharmacist fails to update the accountable medication books daily	5	2
Failure modes identified by Team B only (but scored by both teams)		
Pharmacist accidentally mixes-up prescriptions of two paediatric patients	6	12
Pharmacist marks available medications as out of stock medications	1	12
Support staff (non-pharmacist) accidentally packs a wrong medication into pre-packed medication packets	12	12
Pre-packed medication packs may contain expired medications	9	9
Pre-packed medication packets may be left for longer duration after packing	6	8
Pharmacist gives written directions to illiterate patients	3	12
Pharmacist fails to check the expiry date of the medication	9	6
Pharmacist accidentally fills a wrong prescription given by another patient	3	6

RPN A – Risk Priority Number assigned by Team A; RPN B – Risk Priority Number assigned by Team B

Numbers of failure modes identified by each team at each process step are shown in Table 3.

Table 3: Number of failure modes identified at each main process step

Main process of dispensing	Number of failure modes identified	
	Team A (N=48)	Team B (N=42)
Pharmacist receives the prescription	1	2
Pharmacist checks the prescription	9	10
Pharmacist selects pre-packed medication packets with attached labels and writes instructions on them	5	12
Pharmacist labels medication packing envelopes and fills medications to them	13	9
Pharmacist dispenses medications with verbal instructions	14	6
Pharmacist documents details of accountable medications dispensed	6	3

Among sub processes, Team A identified the highest number of failure modes in checking the accuracy of prescriptions (N=4), and in counting and filling medications into envelopes by pharmacists (N=4). Team B identified the highest number of failure modes in sub processes, selecting the medication pack to be dispensed from the pre-packed medication tray (N=05), and writing directions on label (N=5).

Among the effects and causes of identified failure modes, the ones common to both teams are indicated in Table 4.

Table 4: Effects and causes of identified failure modes common to both teams

Causes of failure modes identified by both teams	
1	Overcrowded medication counters
2	Pharmacists working long hours without a break due to inadequate staff
3	Unclear prescriptions
4	Improper arrangement of dispensing tables
5	Not rechecking the dispensed medications
6	Negligence/poor attention by pharmacist
7	Environmental distractions
8	Improper/ unclear labels attached to the pre-packed medication packs
9	Poor communication with patients
Effects of failure modes identified by both teams	
1	Patient receiving wrong medication
2	Patient receiving wrong dose of medication
3	Patient receiving wrong quantity of medication
4	Patient taking medications incorrectly due to unclear instructions (verbal and/or written)
5	Patient does not achieve the intended therapeutic outcome which will lead to loss of medication adherence
6	Patient does not receive all required medications
7	Patient receives unnecessary medications
8	Another healthcare professional will not able to identify the medications taken by the patient if allergy develops or treat other health condition when medication name is not indicated on the label
9	Patient loses the medication history if medications were issued from an irrelevant pharmacy counter and by misplacing the hospital copy of the medication list of the patient

Having overcrowded medication counters was stated as a cause for 57 failure modes by both teams. In addition to causes commonly identified by both teams, Team B identified, pharmacists not adhering to a uniform method of medication labeling as a cause for unclear instructions; Poor communication among pharmacists as a reason to miss notifying about stock medications to patients; Inadequate supervision of the medication repacking process carried out by support staff (non-pharmacists) leading to medication errors.

Step 4 – Giving a numerical value (scoring) for severity, frequency and detectability of each failure mode and calculating the Risk Priority Number (RPN)

The highest RPN given by Team A was 40 which was for the failure mode, “Counting the wrong amount of medication” when filling medications in the dispensing process. The lowest RPN value by Team A was 2 which was for “Use of unclear printed information material (patient information leaflets)” when dispensing medications with verbal instructions and “Failing to document dispensing accountable medications”.

The highest RPN given by Team B was 24 which was scored for three failure modes; 1) Mixing up two prescriptions given by one person when checking the prescription (If one person comes to collect the medications for own self and to another), 2) Failing to identify overdoses and interactions when checking the prescription, and 3) Incomplete labeling when labeling and assembling medications. The lowest RPN value for Team B was also 2. The two failure modes with a RPN of 2 were for 1) Unavailability of printed information material (patient information leaflets) when dispensing medications with verbal instructions and 2) Adding the hospital copy of the prescriptions into the wrong storage box after documentation. RPN values assigned by both teams for each failure mode are shown in Table 2.

Step 5 – Suggesting corrective actions for prioritised failure modes

Team A prioritised 36 failure modes and Team B prioritised 30 failure modes to discuss for corrective action. Some of the major suggestions were applicable for more than one failure mode. Team A suggested that failure modes such as misidentification of clinics and unclear prescriptions could be resolved with the introduction of a computerised prescribing system and bar code identification of patients. Other suggestions by Team A for 22 failure modes were to redesign the dispensing area with patient waiting facilities, and to limit one patient per counter at a time.

The major suggestion by Team B for seven failure modes was to reorganise the dispensing process where dispensed medications could be rechecked by at least two pharmacists (having more than one pharmacist involved in dispensing to one patient). Other solutions suggested by them were to increase communication with patients, establish a separate patient counseling unit with a pharmacist, display maximum doses and serious interactions of commonly used medications to be easily viewed by the dispensing pharmacists, display the list of out of stock medications and regularly updating the list, hang an alert label on containers with short expiry medications three months prior to the expiry date, and to redesign the medication repacking process to be carried out under the supervision of a pharmacist.

Commonly suggested corrective measures were increasing the awareness of pharmacists, redesigning the labels of pre-packed medication packs with a colour code for identification, rearranging all dispensing shelves in a uniform manner and separating look-alike containers. Increasing the number of pharmacists was suggested as a corrective action by Team A for 28 of 48 failure modes, and by Team B for four failure modes.

Discussion

This study aimed at using FMEA to prospectively identify failure modes, possible causes, and related corrective action, to improve the safety of the dispensing process at a selected tertiary care hospital in Sri Lanka. A total of 90 failure modes were identified by the two FMEA teams. They identified overcrowded medication counters, unclear prescriptions, distractive working environment, and communication issues as common causes for failures which could result in patients receiving wrong medications and/or medication doses, and in turn lead to poor medication adherence. Teams proposed the need for redesigning dispensing counters, dispensing shelves and medication labels to improve medication safety in the dispensing process, while supervision of the medication repacking process by a pharmacist, including two or more pharmacists in the medication dispensing process, and establishing a separate patient counseling unit with a dedicated pharmacist were prioritised as process improvements.

With the intention of having a comprehensive understanding on FMEA prior to starting the present study, authors conducted a systematic review on application of FMEA on different medication use processes. PubMed, JSTOR, Emerald, SAGE, Wiley online, Oxford journals, Web of science, Scopus and Cochrane library databases were searched for relevant studies from January 2006 to December 2017(27). During this review, we found a number of studies using FMEA in areas such as chemotherapy (11-14), parenteral nutrition (28), medication management (2, 29, 30), medication administration (31, 32), medication use process (one or more steps from prescribing to dispensing) among in-patients (18, 33, 34) and paediatrics (12, 15-17, 23). We found only two studies (6, 21) on using FMEA to analyse the dispensing process of out-patients where both studies were carried out in the community. No studies had carried out FMEA on the dispensing process for ambulatory patients in hospitals. Therefore, to the best of our knowledge, this study is the first model for using FMEA in an out-patient hospital pharmacy to analyse the safety of the dispensing process.

This study was carried out to assess the safety of the dispensing process in the study setting which is a university based teaching hospital in Colombo, Sri Lanka. FMEA was conducted in two teams to minimise the disruption to routine dispensing services at the study hospital and was successfully completed by both teams. Although, most FMEA studies found in the literature proceeded with one team (2, 6, 13-15, 18, 21, 28, 31, 33), Shebl et al.,(9) reported the reliability of a FMEA study conducted using two teams in two settings and thus justifying the method we used. Some other researchers also used more than one group for scoring of failure modes (10) and to represent multiple units of a single setting (23).

Both teams mapped the dispensing process in a similar manner except when Team A identified two pathways of medication assembling while Team B identified this division at the sub process level. However, the dispensing process map identified by our team is similar to those mapped by others (6, 21) except where the step on rechecking medications before dispensing is missing in ours. Nevertheless, pharmacists in both teams identified this missing step as a cause of error, and Team B even suggested redesigning the dispensing process to include a rechecking step by a second pharmacist.

Among all 90 failure modes, 69 failure-modes were independently identified by both teams indicating the suitability and reliability of the FMEA process in diagnosing critical issues in a system. Failure modes identified by both teams such as, failure to identify prescription errors, incomplete and/or incorrect medication labeling, and insufficient verbal information given to patients were also identified by other researchers (6, 21). Similar to our findings, a study conducted in a community pharmacy in Serbia (6) stated that dispensing wrong medication/dose/quantity are also possible failure modes.

Causes of failure modes documented in this study were also consistent with studies done worldwide. FMEA studies conducted on areas such as chemotherapy (12, 35), medication prescribing, prescription validation and dispensing for in-patients (33) and on medication administration (9) in countries such as Netherland, China, Spain and the United Kingdom reported work overload due to inadequate staff as a major cause of medication errors which is similar to our findings. Like in this study, communication issues between healthcare professionals and patient was also reported as a cause of error by many others (2, 6, 14, 16, 21, 31). Environmental distractions, illegible handwriting of prescriptions and/or labels, knowledge deficit of healthcare professionals and lack of awareness of healthcare professionals acknowledged as causes in this study were also shared by many other researchers (6, 9, 11, 14, 16, 21, 30, 31).

Interestingly, corrective action suggested by team members in this study were also similar to those reported by other FMEA studies. Incorporating modern technology such as computerised prescription order systems, and bar code identification of patients (6, 9, 11, 18, 21, 23, 30), improving communication strategies, and double checking of any healthcare process (6, 9, 12, 14, 15, 18, 21, 23, 24, 30, 35, 36) were the most commonly highlighted solutions by many.

Although the inability to generalise results is an inherent limitation of FMEA, there were marked similarities of failure modes, causes, and solutions, of medication errors identified among different studies using this proactive tool across a variety of healthcare settings. Thus, we believe that the findings of this study too will be applicable to similar healthcare settings. However, we must acknowledge the subjective nature of FMEA studies which was apparent when assigning RPN values to failure modes by Teams, A and B. The mathematical accuracy of calculating RPN values has been a concern for other researchers as well (37) and is a known limitation of FMEA.

Failing to conduct a second FMEA after implementing corrective action is a limitation of this study but this model provides evidence that FMEA can be successfully used to identify possible failure modes of the dispensing process in out-patient care of hospitals. Conducting an FMEA makes pharmacists more aware of possible failure modes as they are personally involved in this activity. Feedback obtained from team members also revealed that this process helped them to think seriously on possible failure modes possible in day today practice and provided a good platform to share experiences among fellow colleagues.

Conclusions And Practical Implications

This study depicts a model of successfully using FMEA to identify and prioritise possible failure-modes, causes and possible corrective action, of the dispensing process through active involvement of pharmacists. Two FMEA teams identified 90 possible failure modes in the dispensing process, their causes and effects.

Conducting a proactive assessment such as FMEA helps pharmacists to be more vigilant and be actively involved in minimising medication errors. As a result of this FMEA study, corrective action which could be implemented easily such as improving dispensing labels with colour codes, incorporating the quantity of medications on the dispensing label, and reorganising of all dispensing tables were initiated immediately. General suggestions to improve medication safety of the dispensing process (highlighted during the study) were brought to a discussion table with the management of the Department of Pharmacy including the establishment of a separate medication re-packing unit and redesigning of dispensing counters serving one patient at a time. Further, a study was initiated to assess the medication safety of the medication re-packing process.

Finally we urge that this effort could be used as a guide by other similar institutes in order to achieve a safer healthcare system and to offer better pharmaceutical care with minimum hazards.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from Ethics Review Committees of University of Sri Jayewardenepura (Ref no. 64/17) and Colombo South Teaching Hospital (Application no. 621).

All methods were performed in accordance with the relevant guidelines and regulations (FMEA guidelines of ISMP, Canada; ref - The Systems Approach to Quality Assurance for Pharmacy Practice: A Framework for Mitigating Risk. Institute for Safe Medication Practices, Canada 2012) and informed consent was taken from all participants.

Consent for publication

Not applicable

Availability of data and materials

All data generated or analysed during this study are included in this published article

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

The research concept was by N.R. The research was carried out by J.A.L. with supervision of N.R. and V.

J.A.L. was the facilitator to conduct the FMEA discussions while N.R. was the advisor. J.A.L. wrote the manuscript in consultation with N.R. and V. All three authors iteratively read the manuscript, revised and agreed with the final version of the manuscript. V. did the language editing of the manuscript.

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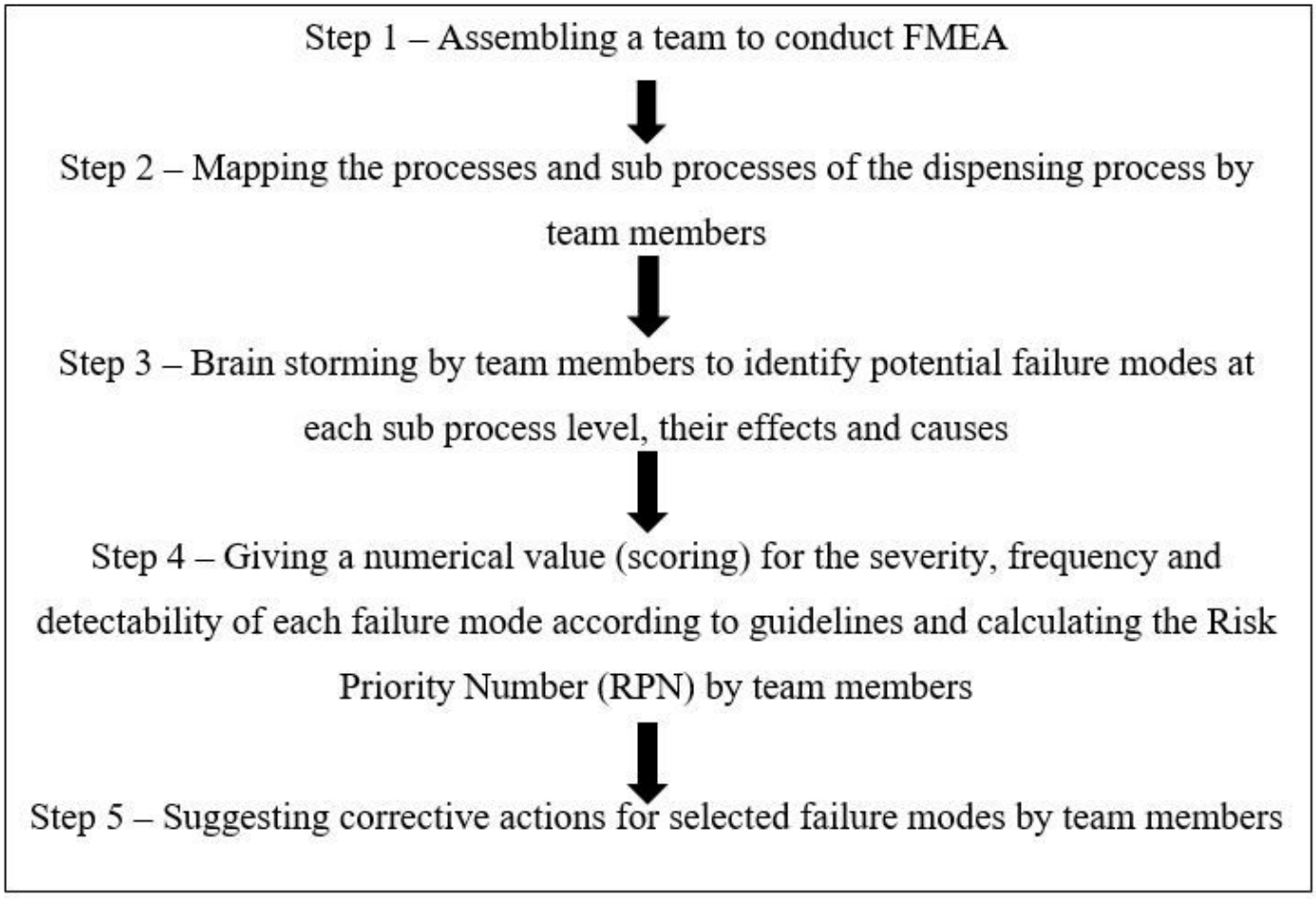
Figures



Source – ISMP guidelines, Canada

Figure 1

Steps of the Failure Mode Effect Analysis (FMEA) according to ISMP, Canada guidelines (7)

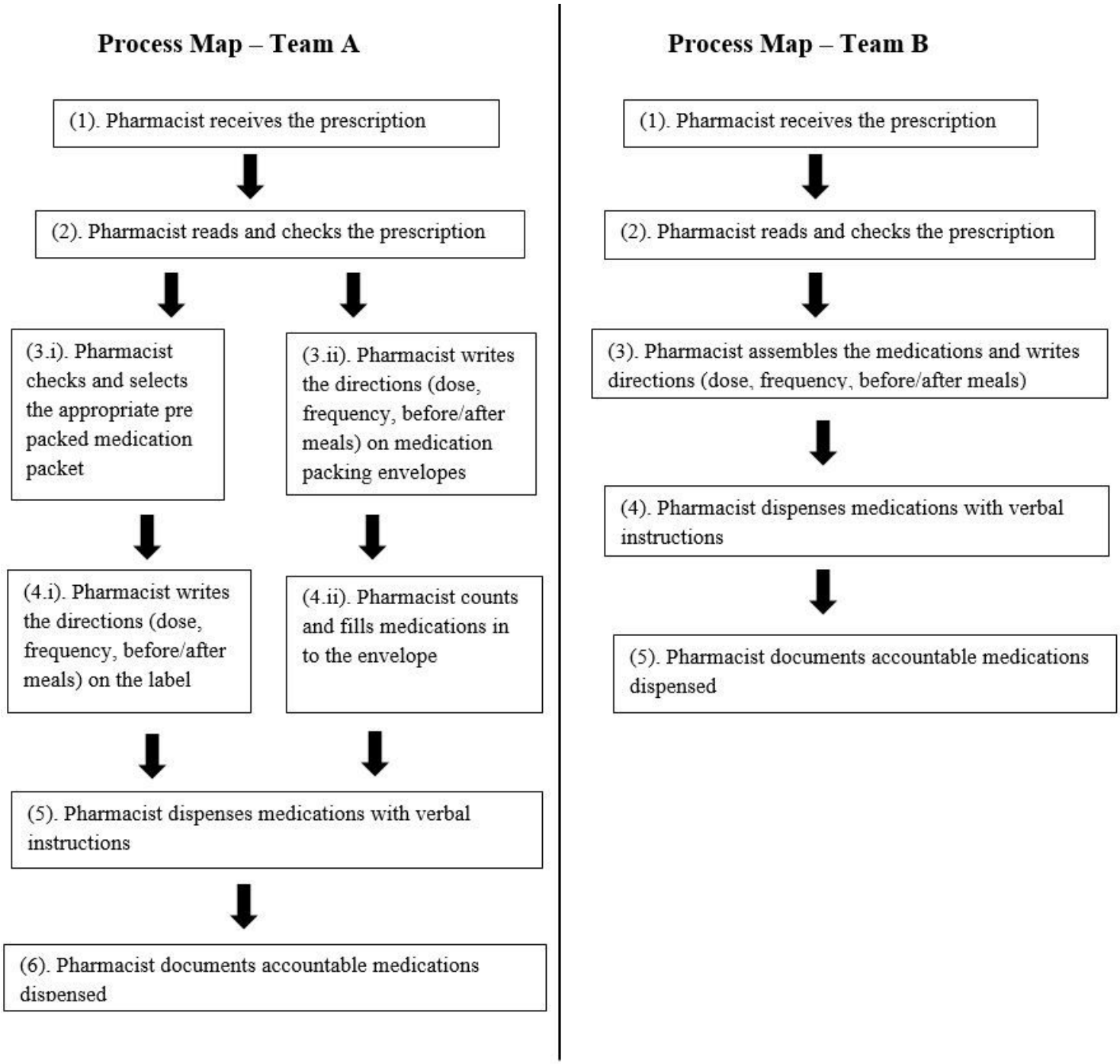
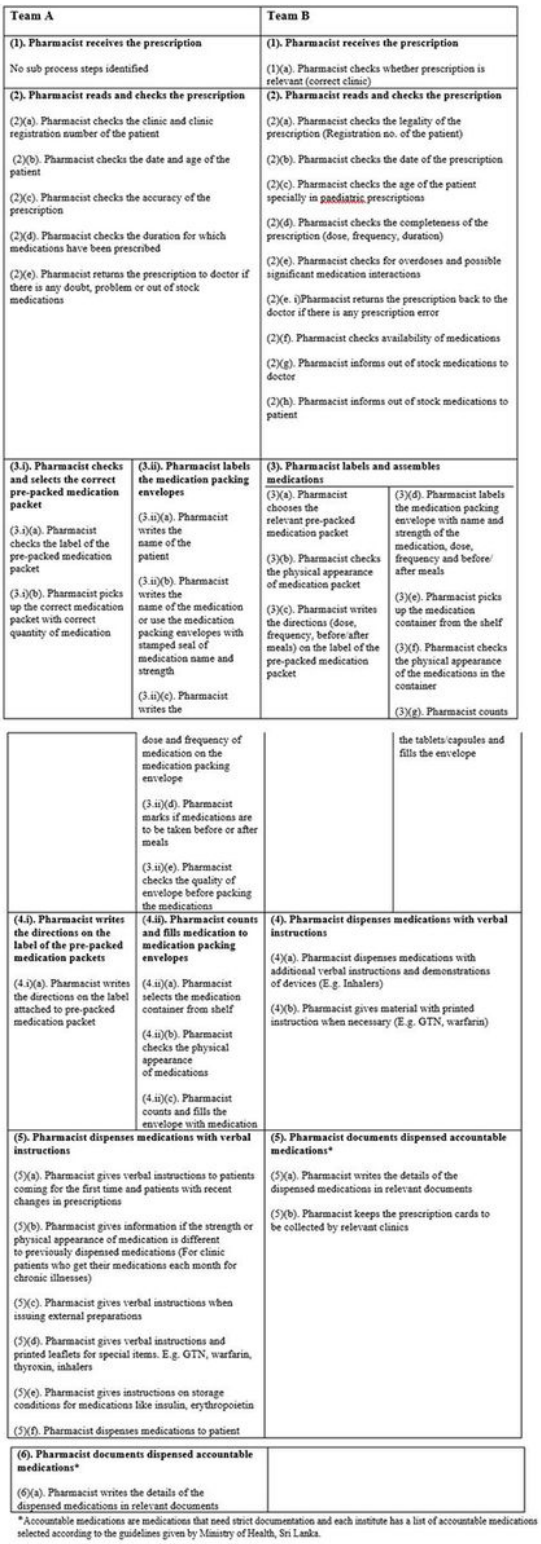


Figure 2

Dispensing process maps of Team A and Team B



Team A		Team B	
(1). Pharmacist receives the prescription No sub process steps identified		**(1). Pharmacist receives the prescription** (1)(a). Pharmacist checks whether prescription is relevant (correct clinic)	
(2). Pharmacist reads and checks the prescription (2)(a). Pharmacist checks the clinic and clinic registration number of the patient (2)(b). Pharmacist checks the date and age of the patient (2)(c). Pharmacist checks the accuracy of the prescription (2)(d). Pharmacist checks the duration for which medications have been prescribed (2)(e). Pharmacist returns the prescription to doctor if there is any doubt, problem or out of stock medications		**(2). Pharmacist reads and checks the prescription** (2)(a). Pharmacist checks the legality of the prescription (Registration no. of the patient) (2)(b). Pharmacist checks the date of the prescription (2)(c). Pharmacist checks the age of the patient specially in paediatric prescriptions (2)(d). Pharmacist checks the completeness of the prescription (dose, frequency, duration) (2)(e). Pharmacist checks for overdoses and possible significant medication interactions (2(e. i)Pharmacist returns the prescription back to the doctor if there is any prescription error (2)(f). Pharmacist checks availability of medications (2)(g). Pharmacist informs out of stock medications to doctor (2)(h). Pharmacist informs out of stock medications to patient	
(3.i). Pharmacist checks and selects the correct pre-packed medication packet (3.i)(a). Pharmacist checks the label of the pre-packed medication packet (3.i)(b). Pharmacist picks up the correct medication packet with correct quantity of medication	**(3.ii). Pharmacist labels the medication packing envelopes** (3.ii)(a). Pharmacist writes the name of the patient (3.ii)(b). Pharmacist writes the name of the medication or use the medication packing envelopes with stamped seal of medication name and strength (3.ii)(c). Pharmacist writes the	**(3). Pharmacist labels and assembles medications** (3)(a). Pharmacist chooses the relevant pre-packed medication packet (3)(b). Pharmacist checks the physical appearance of medication packet (3)(c). Pharmacist writes the directions (dose, frequency, before/after meals) on the label of the pre-packed medication packet	(3)(d). Pharmacist labels the medication packing envelope with name and strength of the medication, dose, frequency and before/ after meals (3)(e). Pharmacist picks up the medication container from the shelf (3)(f). Pharmacist checks the physical appearance of the medications in the container (3)(g). Pharmacist counts
	dose and frequency of medication on the medication packing envelope (3.ii)(d). Pharmacist marks if medications are to be taken before or after meals (3.ii)(e). Pharmacist checks the quality of envelope before packing the medications		the tablets/capsules and fills the envelope
(4.i). Pharmacist writes the directions on the label of the pre-packed medication packets (4.i)(a). Pharmacist writes the directions on the label attached to pre-packed medication packet	**(4.ii). Pharmacist counts and fills medication to medication packing envelopes** (4.ii)(a). Pharmacist selects the medication container from shelf (4.ii)(b). Pharmacist checks the physical appearance of medications (4.ii)(c). Pharmacist counts and fills the envelope with medication	**(4). Pharmacist dispenses medications with verbal instructions** (4)(a). Pharmacist dispenses medications with additional verbal instructions and demonstrations of devices (E.g. Inhalers) (4)(b). Pharmacist gives material with printed instruction when necessary (E.g. GTN, warfarin)	
(5). Pharmacist dispenses medications with verbal instructions (5)(a). Pharmacist gives verbal instructions to patients coming for the first time and patients with recent changes in prescriptions (5)(b). Pharmacist gives information if the strength or physical appearance of medication is different to previously dispensed medications (For clinic patients who get their medications each month for chronic illnesses) (5)(c). Pharmacist gives verbal instructions when issuing external preparations (5)(d). Pharmacist gives verbal instructions and printed leaflets for special items. E.g. GTN, warfarin, thyroxin, inhalers (5)(e). Pharmacist gives instructions on storage conditions for medications like insulin, erythropoietin (5)(f). Pharmacist dispenses medications to patient		**(5). Pharmacist documents dispensed accountable medications*** (5)(a). Pharmacist writes the details of the dispensed medications in relevant documents (5)(b). Pharmacist keeps the prescription cards to be collected by relevant clinics	
(6). Pharmacist documents dispensed accountable medications* (6)(a). Pharmacist writes the details of the dispensed medications in relevant documents			

*Accountable medications are medications that need strict documentation and each institute has a list of accountable medications selected according to the guidelines given by Ministry of Health, Sri Lanka.

Figure 3

Sub processes of dispensing identified by Team A and Team B