

# Healthcare Failure Mode and Effect Analysis: Dispensing Errors in the Pharmacy of an Outpatient Department of a Public Sector Tertiary-care Teaching Hospital

Rajat Prakash<sup>1</sup>, Shashikant Sharma<sup>2</sup>, Ashutosh Sharma<sup>3</sup>

## ABSTRACT

**Background:** Dispensing failures mean that a breach has occurred in one of the last safety links in the use of drugs. Although most failures do not harm patients, their existence suggests fragility in the process and indicates an increased risk of severe accidents.

**Materials and methods:** To address these gaps in our understanding of dispensing errors, we conducted a direct observational study to determine the various failure modes, categorize the types of errors, and evaluate their potential to cause patient harm using healthcare failure mode and effect analysis (HFMEA).

**Results:** The high-risk failure modes identified were as follows: patient unable to understand the prescription, illegible prescription, medication dispensed to wrong patient, counseling about new dose does not occur or ineffective, and patient taking incorrect dose.

**Conclusion:** None of the steps in the drug-dispensing process were free of potential failure modes, but six failure modes emerged as the most vulnerable steps [with risk priority numbers (RPNs) over 168]. The most critical elements in the dispensing of drugs in the present setting were where patient does not understand proper use of prescription of potentially dangerous drug interaction (RPN 432) followed by illegible prescription. There is a dire need of application of systems theory with actions needed at every level of drug dispensing mechanism. Quality tools such as HFMEA and root cause analysis are warranted to forecast various failure modes and to find out root causes of adverse events that happen.

**Keywords:** Failure mode and effect analysis, Medication errors, Patient safety, Quality.

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## INTRODUCTION

Patient safety became an important issue in health care, particularly after the publication of the report "To Err is Human: Building a Safer Health System" by the Institute of Medicine in the United States in 1999. This report made the general public, healthcare policy makers, and healthcare providers aware that targeted actions are needed to increase patient safety. The report placed patient safety high on the healthcare agenda. In October 2004, the World Health Organization (WHO) launched the World Alliance for Patient Safety. Several interventions were started to improve the safety of patients. For instance, the WHO Collaboration Centre for Patient Safety invested with several countries in projects on managing concentrated injectable medicines, assuring medication accuracy at transitions in care and performance of the correct procedure at the correct body site. Range of other strategies and policies have been developed with the intention to enhance patient safety.

Risk associated with medical drugs, one of the main tools used today to protect, maintain, and restore health, has increased. The onset of adverse effects, with its damaging consequences for patients, healthcare professionals, and healthcare institutions, is a reason for concern in most health-related sectors. This concern, in fact, is linked to the origin itself of therapeutics. The archaic Greek word "pharmakon" means a sacrifice made to the gods to seek a cure and bears a double meaning: remedy and poison.

Drug safety is not a static concept. The perception of what is acceptable as risk or benefit together with safety evidence requirements has radically changed during the 20th century. This is in tune with therapeutic developments and the resulting disasters related to such developments.

<sup>1</sup>Department of Hospital Administration, Army Hospital Research and Referral, New Delhi, India

<sup>2,3</sup>Department of Hospital Administration, Armed Forces Medical College, Pune, Maharashtra, India

**Corresponding Author:** Shashikant Sharma, Department of Hospital Administration, Armed Forces Medical College, Pune, Maharashtra, India, Phone: +91 8412821773, e-mail: shashi0681@gmail.com

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## MEDICATION ERRORS

Medication errors are common and often preventable. The hospital pharmacy's medication dispensing process is a source of many medication errors and potential adverse drug events (ADEs). Hospital pharmacies dispense hundreds of thousands to millions of medication doses annually, and therefore, even low dispensing error rates can generate many errors. Research indicates that nurses only intercept 33% of serious medication dispensing errors before medication administration, so many of these errors could reach patients.<sup>1</sup>

## DISPENSING MEDICATION

Dispensing medication is the core function of pharmaceutical care and millions of medicines are dispensed each year by

community and hospital pharmacies. Dispensing is a complex process unequivocally under the supervision of the pharmacist. Traditionally, dispensing has involved pharmacy staff manually selecting medications from shelves, transferring the correct number of medication dose units to a container, and/or labeling the assembled product. However, in recent years the use of automated dispensing systems has been widely advocated to improve efficiency, maximize storage capacity, and minimize dispensing errors. Consequently, automated dispensing systems are becoming increasingly commonplace in hospital and community pharmacies across the world.<sup>1</sup>

Errors can arise at any stage during the dispensing process. It is estimated that each year 1,34,341 dispensing errors occur in community pharmacies in England and Wales. The majority (85%) of these errors are detected by pharmacists before the medication is supplied to the patient. However, some errors are undetected and may cause serious harm to patient and result in death occasionally. Thus, it is imperative that pharmacists review data on dispensing errors so that risk-reduction strategies are developed to safeguard the quality and safety of patient care.<sup>1</sup>

**DEFINITION OF A DISPENSING ERROR**

A dispensing error is a discrepancy between a prescription and the medicine that the pharmacy delivers to the patient or distributes to the ward on the basis of this prescription. It includes dispensing of a medicine with inferior pharmaceutical or informational quality.<sup>2-7</sup>

**CATEGORIES OF DISPENSING ERRORS**

If dispensing errors are considered from the perspective that the quality of all pharmacy-related activities should be assured by the pharmacist, this list can be extended by the addition of three other categories:

- Failure to detect and correct a prescribing error before dispensing;
- Failure to detect a manufacturing error before dispensing; and
- Failure to provide adequate patient counseling in order to prevent administration errors.

These categories arise in other segments of the pharmaceutical patient care chain, but they are nevertheless important when one strives for a full assessment of the pharmacy's performance.<sup>8,9</sup> Table 1 identifies different categories of dispensing errors.

**UNDERLYING CAUSES OF DISPENSING ERRORS**

Causes of dispensing errors can be traced by root cause analysis or by eliciting explanations from practicing pharmacists by means of a survey. Root cause analysis comes closer to reality, because a survey measures only the perceptions and opinions of pharmacists.

An example of the former or latter type was a study in a UK hospital in which the researchers used semi-structured interviews of pharmacy staff about self-reported dispensing errors.<sup>2</sup> In all, 106 error-producing conditions were mentioned in the interviews. The most common causes mentioned were as follows: being busy (21%), being short-staffed (12%), being subject to time constraints (11%), fatigue of healthcare providers (11%), interruptions during dispensing (9.4%), and look-alike/sound-alike (LASA) medicines (8.5%).

In a Danish study, a research team analyzed self-reports of community pharmacies to identify the causes of dispensing errors.<sup>10</sup>

**Table 1: Categories of dispensing errors**

|   |
|---|
| Dispensing medicine to the wrong patient (or to the wrong ward)               |
| Dispensing the wrong medicine   |
| Dispensing the wrong drug strength  |
| Dispensing at the wrong time  |
| Dispensing the wrong quantity   |
| Dispensing the wrong dosage form  |
| Dispensing an expired or almost expired medicine                              |
| Omission (e.g., failure to dispense)  |
| Dispensing a medicine of inferior quality (pharmaceutical companies)          |
| Dispensing with the wrong information on the label                            |
| Incorrect instruction (including incorrect dosage)                            |
| Incorrect drug quantity   |
| Incorrect dosage form   |
| Omission of additional warning(s)   |
| Dispensing with the wrong verbal information to the patient or representative |

The research team identified four causes: poor, often unreadable, handwriting; "traps" (LASA medications); lack of effective controls; and lack of concentration caused by interruptions.

In a Finnish study, a survey questionnaire was used to elicit pharmacists' perceptions and opinions.<sup>11</sup> There were five main categories of potential causes. The first was related to organization (37% of all potential causes given). The other categories were as follows: individual professionals (30%), prescriptions (17%), drugs (10%), and problems with customers (4%). Examples of the last were talkative customers, conversations with customers, customers with many prescriptions, and customers in a hurry.

Two studies have investigated the potential causes of failure to detect and prevent drug–drug interaction problems during dispensing. In the first study, the researchers calculated the dispensing ratios for 11 undesirable drug–drug interactions in 256 Dutch community pharmacies; only one of these was significantly related to determinants—the type of medication surveillance system and whether the pharmacy was part of a healthcare center.<sup>12</sup> The second study was performed in the USA and evaluated the relations between handling 25 potential drug–drug interactions and the operational characteristics of community pharmacies; the risk of dispensing drugs with potential drug–drug interactions was significantly related to pharmacist workload, overall pharmacy workload, and automated telephone systems for prescription orders.<sup>13</sup>

**FAILURE MODE AND EFFECT ANALYSIS**

Failure mode and effect analysis (FMEA) is a method used in industry to assess complex processes according to a standardized approach with a view of identifying the elements that carry a risk of causing harm and, consequently, prioritizing remedial measures. It is based on the concept that a risk is related not only to the likelihood of a failure occurring, but also to the severity of the failure's consequences and the feasibility of detecting and intercepting a failure before it occurs.

The FMEA approach also enables each of the elements comprising process under investigation to be attributed accumulative numerical value, the RPN, which can be used to



prioritize the action to be taken because it is a numerical rating of the severity, probability, and detectability of each failure mode.<sup>14</sup>

## FMEA TERMS

### Failure Mode

A failure mode is the way in which the component, subassembly, product, input, or process could fail to perform its intended function. Failure modes may be the result of upstream operations or may cause downstream operations to fail, that is, things that could go wrong.

- Effect: the impact on the process or customer requirements as a result of the failure;
- Severity: the impact of the effect on the customer or process;
- Root cause: the initiating source of the failure mode;
- Occurrence (or frequency): how often the failure is likely to occur; and
- Detection: the likelihood that the failure will be discovered in a timely manner, or before it can reach the customer.

### FMEA in Health Care

Failure mode and effects analysis was developed outside of health care and is now being used in health care to assess the risk of failure and harm in processes and to identify the most important areas for process improvements. Failure mode and effects analysis has been used by hundreds of hospitals in a variety of institutes for healthcare improvement programs, including idealized design of medication systems, patient safety collaborative, and patient safety summits.

### Steps for Conducting FMEA

#### Step 1

Select a process to evaluate with FMEA. Evaluation using FMEA works best on the processes that do not have too many sub-processes. Instead of doing an FMEA on a large and complex process, such as medication management in a hospital, try doing an FMEA on sub-processes or variants. Conducting an FMEA of the entire medication management process would be an overwhelming task. Instead, consider individual FMEA analyses of the medication ordering, dispensing, and administration processes.

#### Step 2

Recruit a multidisciplinary team. Be sure to include everyone who is involved at any point in the process. Some people may not need to be part of the team throughout the entire analysis, but they should certainly be included in discussions of those steps in the process in which they are involved. For example, hospital may utilize couriers to transport medications from the pharmacy to nursing units. It would be important to include the couriers in the FMEA of the steps that occur during the transport itself, which may not be known to personnel in the pharmacy or on the nursing unit.

#### Step 3

Have the team meet together to list all of the steps in the process. Number every step of the process and be as specific as possible. It may take several meetings for the team to complete this part of the FMEA, depending on the number of steps and the complexity of the process. Flowcharting can be a helpful tool for outlining the steps. When you are finished, be sure to obtain consensus from the group. The team should agree that the steps enumerated in the FMEA accurately describe the process.

#### Step 4

Have the team list failure modes and causes for each step in the process, and list all possible “failure modes”—that is, anything that could go wrong, including minor and rare problems. Then, for each failure mode listed, identify all possible causes.

#### Step 5

For each failure mode, have the team assign a numeric value (known as the RPN) for likelihood of occurrence, likelihood of detection, and severity. Assigning RPNs helps the team prioritize the areas to focus on and can also help in assessing opportunities for improvement. For every failure mode identified, the team should answer the following questions and assign the appropriate score (the team should do this as a group and have consensus on all values assigned):

- Likelihood of occurrence: How likely is it that this failure mode will occur? Assign a score between 1 and 10, with 1 meaning “very unlikely to occur” and 10 meaning “very likely to occur.”
- Likelihood of detection: If this failure mode occurs, how likely is it that the failure will be detected? Assign a score between 1 and 10, with 1 meaning “very likely to be detected” and 10 meaning “very unlikely to be detected.”
- Severity: If this failure mode occurs, how likely is it that harm will occur? Assign a score between 1 and 10, with 1 meaning “very unlikely that harm will occur” and 10 meaning “very likely that severe harm will occur.” In patient care examples, a score of 10 for harm often denotes death.

#### Step 6: Evaluate the Results

To calculate the RPN for each failure mode, multiply the three scores obtained (the 1–10 score for each of likelihood of occurrence, detection, and severity). For example, the failure mode “Wrong medication selected” has a 3 for likelihood of occurrence, a 5 for likelihood of detection, and a 5 for severity, for an overall RPN of 75. The lowest possible score will be 1 and the highest 1,000. Identify the failure modes with the top 10 highest RPNs.

These are the ones the team should consider first as improvement opportunities. To calculate the RPN for the entire process, simply add up all of the individual RPNs for each failure mode. Use RPNs to plan improvement efforts. Failure modes with high RPNs are probably the most important parts of the process on which to focus improvement efforts. Failure modes with very low RPNs are not likely to affect the overall process very much, even if eliminated completely, and they should therefore be at the bottom of the list of priorities.

## AIM OF THE STUDY

To use FMEA to identify potential failure modes of dispensing errors in the pharmacy of a outpatient department (OPD) of a public sector tertiary care teaching hospital.

## OBJECTIVES

The objectives of the study are as follows:

- To study and map the complete process of dispensing of medications in the pharmacy.
- To identify various failure modes and effects in dispensing of medications to the patients.

- To each failure mode assign a numeric value (known as the RPN for likelihood of occurrence, likelihood of detection, and severity).
- To prioritize various types of failure modes using risk priority matrix and use RPNs to plan improvement efforts and purpose strategies and recommendations to avoid such errors.

## MATERIALS AND METHODS

To address these gaps in our understanding of dispensing errors, we conducted a direct observational study to determine the various failure modes, categorize the types of errors, and evaluate their potential to cause patient harm.

### Setting

The project was conducted at the pharmacy of an OPD in a tertiary care teaching hospital providing super-specialty care. It is also an academic institution providing undergraduate training and post-graduate training to medical students.

Outpatient area has its own therapy order form, where physicians write their prescriptions. All prescriptions are, still, calculated manually by physicians and are handwritten on the therapy order form. Finally, the actual dispensing of medicines is done by the pharmacist. The pharmacy staff are also responsible for the drug inventory within the unit. Although with different levels of responsibility, and always under supervision, trainee residents and trainee pharmacist are also involved in prescribing and dispensing.

### Composition of the Team and Analysis of the Drug-delivery Process

The team consisted of eight members between the frontline staff who were familiar with the process, including doctors, residents, nurses, and patients' safety experts, risk management experts, and/or a quality improvement specialist. A pharmacist, a representative of service for health professions, and an administrative officer were involved when specific identified risks were analyzed. As FMEA is performed by process mapping and then identifying failure modes for each step, their responsibilities were as follows:

- To identify and describe the steps involved in the process of prescribing, and dispensing drugs at the OPD and pharmacy (producing flow diagrams).
- To highlight possible sources of errors at each step.
- To clarify the reason why a failure might occur in completing each step.
- To quantify the severity of the effects of such potential failures.

The team was then asked to estimate (score) the likelihood of a specific error occurring, its severity, and the chances of the error being detected and intercepted before it could occur, calculating the specific RPN. This permitted the prioritization of the multiple failure modes, identifying those at greater risk of harm. Each member identified from this analysis the higher risk failure modes as those with the highest severity and frequency scores and lowest likelihood of detection, plotted in the red or yellow area of the priority matrix (Fig. 1) and developed corrective actions assigning them an appropriate priority.

A value in the range of 1–10 was attributed to each step in the drug-delivery process to quantify the potential occurrence of a failure (O); the severity of its potential negative impact on the overall process (S); and the chances of the failure being detected and

intercepted before it occurs (D), according to the joint commission classification.<sup>14</sup>

All the numerical scores were directly proportional to the estimated frequency of the failure, the severity of its impact, and the difficulty of intercepting it. Values of 10 thus reflected a near-certain likelihood of failure, the effects of which would be fatal, and there was practically no chance of the failure being detected before it caused harm.

The agreement on the final score to attribute each critical step in the complex process of ordering and dispensing drugs was reached by asking each member of the team to quantify their personal estimation of the related risk according to the previously defined, precise, and strict criteria, followed by a shared discussion in the case of overt discordance (Table 2). The numerical value obtained by multiplying these three factors is the RPN ( $O \times S \times D$ ), which was used to grade the relevance of each step, in terms of its overall influence on the process. The RPN therefore enabled the elements most likely to contribute to serious drug dispensing failures to be pinpointed. The maximum RPN was 1,000. The RPN was also used to establish the priority of remedial measures.

The hazard analysis was completed by plotting the RPNs of higher risk failure modes in a priority matrix (Fig. 1), which is a graph divided into three colored areas reflecting different levels of priority for action:

- Area 1 (red) urgent action required;
- Area 2 (yellow) prompt actions required; and
- Area 3 (green) scheduled actions or monitoring required.

The priority matrix gave graphical evidence of which steps, in the complex process of administering drugs, more urgently needed corrective action to reduce the risk of failures.

## RESULTS

The team developed a detailed process map for the process of medication prescribing and dispensing, identifying failure modes for each step. As process steps may be susceptible to multiple failure modes, the calculation of RPNs is acceptable to identify the failure modes that pose the greatest risk of harm. Table 3 displays the number of process steps and the high-risk failure modes that team identified in multiple FMEAs with the RPNs count.

### Failure Modes

A total of 15 high-risk failures were identified, plotted in areas 1 (red), 2 (yellow), and 3 (green) of the priority matrix, with associated causes and effects mentioned in Table 4.

## DISCUSSION

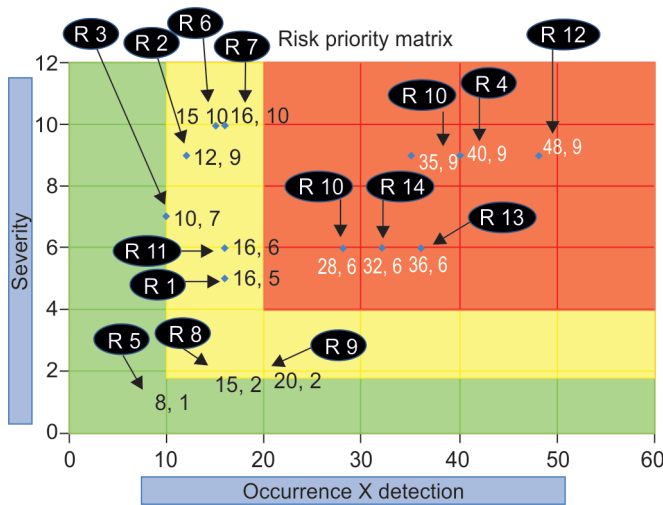
The hospital utilizes an individualized direct drug-dispensing system, where the prescription is written over carbon paper and the prescription is taken by hand to the pharmacy for collection of medications by individual patients.

None of the steps in the drug-dispensing process were free of potential failure modes, but six failure modes emerged as the most vulnerable steps (with RPNs over 168) Table 4 shows the various failure modes along with cause and effect and suggested remedial actions. The most critical elements in the dispensing of drugs in the present setting were where patient does not understand proper use

**Table 2:** Rating scales to assign values to occurrence (O), severity (S), and detection (D) scores in FMEA of the drug administration process

| Occurrence (O) |   | Severity (S) |   | Detection (D) |                                |
|----------------|---|--------------|---|---------------|--------------------------------|
| Score          | Failure mode probability  | Score        | Descriptive of injury   | Score         | Likelihood of detection        |
| 1              | Remote: failure unlikely to occur (happening in 1 in 10000 episodes observed) | 1            | No injury or patient monitoring alone                                 | 1             | Very high: detected 9/10 times |
| 2              | Low: relatively rare failure (happening in 1 in 1000 episodes observed)       | 2            | Temporary injury needing additional intervention or treatment         | 2             | High: detected 7/10 times      |
| 3              | Moderate: occasional failure (happening in 200 episodes observed)             | 3            | Temporary injury with longer hospital stay or increased level of care | 3             | Medium: detected 5/10 times    |
| 4              | High: recurrent failure (happening in 1 in 100 episodes observed)             | 4            | Permanent effects on body functions                                   | 4             | Low: detected 2/10 times       |
| 5              | Very high: common failure (happening in 1 in 20 episodes observed)            | 5            | Death of permanent loss of major body functions                       | 5             | Remote: detected 0/10 times    |

The risk priority number (RPN) is calculated by multiplying the O, S and D scores.



**Fig. 1:** Hazard analysis

of prescription of potentially dangerous drug interactions (RPN 432) followed by illegible prescription, ineffective patient counseling, and wrong drug delivery to the patient. All of the above failure modes were identified as high risk requiring immediate attention.

**LIMITATIONS OF THE STUDY**

This study has some limitations. As a single-institution study, the findings reflect the care delivery model in a particular setting, although many features are common to other healthcare organizations. For these reasons, the results might not be completely generalized to all the other organizations. Notwithstanding that, FMEA permits identification of higher risk of failure modes through a meticulous, time-intensive, and resource-intensive methodology. Its successful completion is highly dependent on the team member’s aptitude and commitment to introduce corrective measures in clinical practice. For these reasons, it is important to create a multidisciplinary team of front-line people who know perfectly the process guided by an experienced facilitator. This can improve the consistency of an FMEA program and also minimize the number of hours it takes to complete an FMEA.

**RECOMMENDATIONS**

There is a dire need of application of systems theory with actions needed at every level of drug-dispensing mechanism. According to systems theory, a change in one sub-system is bound to affect other subsystem.

Actions required at organizational level for the pharmacy in question:

- Use of bar coding technology in pharmacy;
- implementation of computerized physician order entry (CPOE);
- clean and organized work area to avoid human factors errors;
- effective and efficient inventory control techniques;
- having a qualified pharmacist staff in pharmacy or available on telephone to consult patient questions; and
- Training and awareness of staff on effective communication techniques.

**Actions Required at Physician Level**

- Training and awareness of doctors on benefits of prescription writing;
- Doctors to mention allergies boldly on patient treatment books;
- Formulation change should be clearly communicated to the patient and formulation change stickers can be used; and
- Adequate patient counseling. Repeat check-back procedure.

**Actions Required at Staff Level**

- Training and education of staff on benefits of safe drug dispensing.
- Double check of patient name and identification.
- Double-check of medicines before dispensing.
- Checking on patient treatment book before dispensing medications.
- Qualified pharmacist available on board or on call to provide explicit instructions on prescription use and possible negative interactions with other drugs.

**CONCLUSION**

In today’s healthcare world, patient-safety issues are of major concern. Over the years, pharmacists have implemented various

Table 3: No of process steps with RPN scores

| Description           | Failure mode | Causes   | Effects   | RPN = O × D × S |     |           |     |       | Actions   |
|-----------------------|--------------|--|---|-----------------|-----|-----------|-----|-------|---|
|                       |              |  |   | OCC             | DET | P = O × D | SEV | D × S |   |
| Doctor diagnosis      | R1           | Doctor uses incorrect abbreviation symbols indicating a solid strength versus a liquid strength or erroneously mentioning wrong dose | The pharmacist or doctor in civil OPD would ultimately catch this error, but if the medicine was dispensed as written, with strength for liquid applied to strength for solid, it could be harmful or even dangerous to the patient | 2               | 8   | 16        | 5   | 80    | IMDT: pharmacists review and questions any prescriptions that do not make sense.<br>Long-term: implementation of CPOE system  |
|                       | R2           | Allergies not updated  | Delay, dispense something patient allergic to   | 4               | 3   | 12        | 9   | 108   |   |
| Prescription input    | R3           | Prescription has incorrect name on it  | Medicine to the wrong patient, insurance may not be paid for the patient, or the patient will not be able to receive their medication   | 2               | 8   | 10        | 7   | 112   | Doctors to be advised to mention allergies boldly on the patient treatment books<br>Double-check patient name, have ID number to match name, ask patient name when receiving prescription<br>Use computer system not paper to manage prescriptions in database that allows doctor to directly enter |
|                       | R4           | Prescription unable to be read   | May give the patient the wrong medication, wrong strength, wrong frequency, and for the wrong length of time  | 5               | 8   | 40        | 9   | 360   |   |
| Dispensing medication | R5           | Older prescription pads, or prescription pads used in the interim of new pads be in ordered  | May cause physician authentication problems   | 1               | 8   | 8         | 1   | 8     | Double-check prescription on entry to ensure that all pertinent information is on prescription<br>Keep work area clean so that medications are not mixed up due to human error  |
|                       | R6           | Careless errors Messy work area (may pick up the wrong drug)   | Patient gets wrong medication and/or wrong dosage. Could lead to hospitalization or possibly death  | 3               | 5   | 15        | 10  | 150   |   |
|                       | R7           | Patient picks up the incorrect set, may take the wrong medication  | Could be severe if a patient receives and is administered incorrect medication  | 2               | 8   | 16        | 10  | 160   | At the pharmacy, all medications are double-checked as they are placed into the bags<br>Effective inventory control techniques to be utilized   |
|                       | R8           | Forgot to order, backorder, manufacturer cannot supply   | Delay   | 5               | 3   | 15        | 2   | 30    |   |
|                       | R9           | Interruptions  | Inadequate medication supplied to patient   | 4               | 5   | 20        | 2   | 40    | Training and education of pharmacy staff  |
|                       | R10          | Count wrong amount Medication picked up given to wrong patient   | Medication error  | 5               | 7   | 35        | 9   | 315   | Training and education of pharmacy staff  |

Contd..



Contd..

| Description  | Failure mode   | Causes   | Effects | OCC | DET | P = O × D | SEV | D × S | RPN = O × D × S  | Actions |
|--|--|--|---------|-----|-----|-----------|-----|-------|--|---------|
|  |  |  |         |     |     |           |     |       |  |         |
| R11<br>Change of formulation not indicated on the prescription   | Prescriber error   | Reduced chance of detection of change by pharmacy, patient given new strength and not counseled about it   | 8       | 2   | 16  | 6         | 96  |       | Checking of patient treatment book to confirm  |         |
| Informing patient<br>R12<br>Patient does not understand proper use of prescription of potentially dangerous drug interaction | No pharmacist/nurse present to counsel customers, pharmacy does not provide sufficient literature or explicit warnings about drugs effects                                       | Prescription may be used incorrectly and potentially dangerously or in effectively. Patient may mix with another drug with negative effects leading to medical complications or injury | 6       | 8   | 48  | 9         | 432 |       | Have pharmacist on staff in pharmacy or available by telephone to consult patient questions. Provide explicit instructions on prescription use and possible negative interactions with other drugs |         |
| Counseling patient about change<br>R13<br>Counseling about new dose does not occur   | Person handing out medication unaware first time receiving new formulation strength so counseling about the new formulation does not occur                                       | Patient unaware of the change so takes the incorrect dose  | 4       | 9   | 36  | 6         | 216 |       | Formulation change sticker will clearly indicate whether patient needs counseling  |         |
| R14<br>Counseling ineffective  | Patient does not listen or has trouble with English Ineffective communication by HCP   | Patient unaware of formulation change and takes the incorrect dose   | 4       | 8   | 32  | 6         | 192 |       | Training and awareness amongst staff on effective communication techniques   |         |
| Patient takes medication<br>R15<br>Patient takes incorrect dose  | Confusion over change, no info given, and patient did not read/listen to information. Patient has supply of both strengths at home and becomes confused and takes wrong strength | Patient takes wrong dose (higher dose potential risk of side effects)  | 4       | 7   | 28  | 6         | 168 |       | Adequate patient counseling, repeat back and check back procedure  |         |

**Table 4:** Classification of failure modes

| Risk no   | Failure Mode  | RPN no |
|---|---|--------|
| <i>Area 1: Urgent action required</i>                   |   |        |
| R12   | Patient does not understand proper use of prescription of potentially dangerous drug interaction. | 432    |
| R4  | Prescription unable to be read  | 360    |
| R10   | Medication picked up given to wrong patient   | 315    |
| R13   | Counseling about new dose doesn't occur   | 216    |
| R14   | Counseling ineffective  | 192    |
| R15   | Patient takes incorrect dose  | 168    |
| <i>Area 2: Prompt actions required</i>                  |   |        |
| R7  | Incorrect medication delivered to patient   | 160    |
| R6  | Incorrect medication sorted for patient   | 150    |
| R3  | Prescription has incorrect name on it   | 112    |
| R2  | Allergies not updated   | 108    |
| R11   | Change of formulation not indicated on the prescription   | 96     |
| R1  | Doctor indicates an incorrect strength or form of medication                                      | 80     |
| R9  | Count wrong amount  | 40     |
| R8  | Drug out of stock   | 30     |
| <i>Area 3: Scheduled actions or monitoring required</i> |   |        |
| R5  | Prescription does not contain relevant information  | 8      |

methods to reduce the rates of dispensing errors. With a view to reduce the risk of medication errors and to improve patient safety, the data presented here entitles to say that tools such as FMEA enable a prospective analysis of the process of drug delivery. This helps to decrease potential failure modes and their associated causes and assess which risks have the greatest concern. It also stimulates the most urgent improvement efforts in clinical practice to prevent errors before they occur and to identify opportunities to improve medication safety in healthcare delivery.

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