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Original article

Challenges experienced during pharmacy automation and robotics implementation in JCI accredited hospital in the Arabian Gulf area: FMEA analysis-qualitative approach

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ABSTRACT

Background: Pharmacy automation and robotics implementation are essential aspects of healthcare facilities. It streamlines the medication dispensing process and significantly reduces medication errors. However, implementing automation and robotics in pharmacies comes with its challenges. We aim to detect and rectify potential dangers in the pharmacy workflow by utilizing the Failure Mode and Effects Analysis (FMEA) methodology; this is expected to augment performance and increase profitability.

Materials and methods: In this study, we conducted an FMEA analysis using a qualitative approach to identify the challenges experienced during pharmacy automation and robotics implementation in a Joint Commission International (JCI) accredited hospital in the Arabian Gulf area. The pharmacy processes and procedures were mapped in a Flow chart to visualize the pharmacy workflow, including highlighting the risks that were found. Then these risks were arranged as Potential failure modes and added to the table as 9 main points for each RPNs were calculated, and then the 9 points were prioritized for the action plans.

Results: Via applying traditional Risk Priority Number (RPN) FMEA, the Pharmacy board identified the process stages marked risky failure modes through several FMEAs, calculating the total RPNs at the implementation phase. It revealed several challenges, including staff training, technical issues, and inadequate communication. Furthermore, the study resulted in corrective and intervention steps.

Conclusion: Pharmacy automation and robotics implementation is a complex process that requires proper planning, preparation, and execution. The FMEA approach effectively identifies potential problems and evaluates their impact on the pharmacy system. Nine major failure modes appeared to be risky stages with high RPN scores. Therefore, multiple interventions were done during the implementation to enhance the knowledge of challenges faced during the implementation of the automation process and solve it. Future studies should address the identified challenges and develop strategies to mitigate them.

Abbreviations: JCI, Joint Commission International; FMEA, Failure Mode and Effects Analysis; RPN, Risk priority number; ADS, automated dispensing system; NHS, National Health Service; IRB, Institutional Review Board; O, occurrence probability; S, severity; D, detectability; HIS, Health Information System; FMECA, Failure Mode Effects and Criticality Analysis.

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1. Background/ Introduction

Medication errors significantly burden healthcare systems, providers, and patients. The most severe outcome of medication errors is death, with an estimated 7,000 to 9,000 deaths occurring annually in the United States; other outcomes include permanent disabilities, extended hospital stays, and increased healthcare costs estimated at $21 billion per year (Borgès Da Silva et al., 2018; Giannetta et al., 2022; Jaam et al., 2021; Tariq et al., 2018; Whittaker et al., 2018).

The National Coordinating Council for Medication Error Reporting and Prevention defines a medication error as any avoidable occurrence that may lead to inappropriate medication use or harm to the patient while the medication is controlled by healthcare professionals or the patient. (NCCMERP, 2022). Medication errors hit three categories: system, healthcare provider, and patient. The first category (system) includes but is not limited to prescribing, communicating orders, labeling the products, packaging, terminology, compounding, supplying, delivering, administration, tutoring, monitoring, and usage (Trakulsunti et al., 2020; World Health Organization, 2016). The second category involves healthcare personnel, such as less experienced staff, stressed staff, and many others(Ambwani et al., 2019). The last category (the patient's condition) includes but is not limited to impaired cognition, polypharmacy, and adherence (Ganio and Jerry, 2022; Iredell et al., 2022).

As a result of the previous, the automated dispensing system (ADS) was approved by the American Society of Health-System Pharmacists in 2010 as a step towards reducing medication errors and stress and saving time and effort (Ganio and Jerry, 2022; Iredell et al., 2022). ADS has been observed to reduce workload and work-related stress by around 21.8% in outpatient pharmacies (Coombs et al., 2020) and decrease drug errors while increasing patient safety by 37% in pharmacies (Hohmeier and Desselle, 2019; Kechagias et al., 2021; Sng et al., 2019). The use of robotics in healthcare facilities was proposed as a must. The Audit Commission for Local Authorities and the National Health Service (NHS) in England and Wales recommended it in 2001.

In addition, in "A Spoonful of Sugar," the Audit Commission's paper examined the status of pharmaceutical services and their operations. It highlighted that innovation could tackle staff shortages, especially in pharmacies using information technology and automation (Audit Commission for Local Authorities and the National Health Service in England and Wales, 2001). Nevertheless, another study comparing workforce requirements between manual, and ADS found that ADS only reduced the burden of pharmacy technicians while increasing the workload of pharmacists (Ahtiainen et al., 2020). The increased involvement of pharmacists in the work process, in conjunction with computerized ADS, can directly improve the efficiency of the drug distribution system while indirectly improving the quality of patient care in the hospital (Ahtiainen et al., 2020; Audit Commission for Local Authorities and the National Health Service in England and Wales, 2001).

According to the 'A Spoonful of Sugar' report, it is important to redesign workflows or services to enable pharmacists to provide better care to patients and showcase their value (Audit Commission for Local Authorities and the National Health Service in England and Wales, 2001); this may involve reviewing the tasks of pharmacists and automating simple tasks like dispensing (Ahtiainen et al., 2020; Audit Commission for Local Authorities and the National Health Service in England and Wales, 2001). Automating such tasks can free up time for staff to provide patient-centered services and reduce the chances of dispensing errors (Ahtiainen et al., 2020; Audit Commission for Local Authorities and the National Health Service in England and Wales, 2001). Additionally, if appropriate competency assessments are created and followed, pharmacy technician and assistant roles can be expanded in the ADS strategy (Kiran, 2017). As a result, ADS offers several benefits, including reducing patients' waiting time and the time needed for prescription filling (Rodriguez-Gonzalez et al., 2019; Sng et al., 2019).

FMEA, or Failure Mode and Effects Analysis, is a systematic approach used to identify potential weak points in the design, manufacturing, or delivery of a product or service; it outlines possible breakdown modes and highlights potential flaws, especially those that could harm the consumer (Huang et al., 2020; Liu et al., 2020; Ouyang et al., 2022a; Simsekler et al., 2019; Strauch, 2021). FMEA is also beneficial in determining the impact of these breakdowns and prioritizing which failures require the most attention. Business analysts often use FMEA templates to complete their evaluations, and healthcare facilities also utilize this method for the same purpose (Huang et al., 2020; Liu et al., 2020; Ouyang et al., 2022a; Simsekler et al., 2019; Strauch, 2021). FMEA scoring ranges from 1 to 10 and is a risk assessment tool. A score of one indicates low risk, while a score of ten represents high risk (Huang et al., 2020; Liu et al., 2020; Ouyang et al., 2022a; Simsekler et al., 2019; Strauch, 2021).

Despite its advantages, FMEA has limitations and risks. It relies on the team's expertise, and failure modes may be missed if not identified properly(Ouyang et al., 2022b). It can be time-consuming, labor-intensive, difficult to estimate the probability of failure, or even difficult to develop effective preventive actions. Prioritization helps focus on critical issues but is only a partial solution. FMEA requires balancing scope and detail(Ouyang et al., 2022b). Finally, organizations must commit to implementing recommended actions for FMEA to be effective(Ouyang et al., 2022b).

When conducting an FMEA, it is important to prioritize failure modes to identify the most critical ones that require attention (Cho et al., 2022). However, it is not enough to simply prioritize them – action must be taken and evaluated for effectiveness to eliminate the failure mode. In some cases, additional action beyond the scope of the FMEA may be necessary (Cho et al., 2022). Identifying failure modes is a team effort that requires attention to detail and time to analyze the process or design thoroughly; if the team does not conduct a thorough analysis, important failure modes could be overlooked, potentially resulting in future issues (Cho et al., 2022). Rushing the process is not recommended as it takes time to get into the details and ensure team members have adequate time to contribute (Cho et al., 2022). It is also possible that a failure mode or effect outside the team's experiences could be missed (Cho et al., 2022). Meaningful rating scales should be utilized and clarified for everyone in the organization to improve the rating process. Generic rating scales can be confusing and prevent management from effectively comparing risks and prioritizing activities between teams (Cho et al., 2022). Overall, it is critical to conduct FMEAs early in the design process and to ensure that the team properly investigates probable failure modes (Cho et al., 2022).

Our study aims to evaluate the risks associated with the current manual workflow of the pharmacy, identify the root causes of reported difficulties, and implement remedial measures for long-term profitability and high-quality execution using traditional Risk Priority Number (RPN) FMEA.

2. Materials and methods

2.1. Setting and study timeline

The Institutional Review Board (Ref # 21–389) approved the study on January 5th, 2021. The project commenced in 2020 and

extended to 2021–2022, introducing pharmacy workstations at the Department of Pharmaceutical Services in a tertiary hospital located in one of the Gulf Cooperation Council countries upon receiving ethical approval from the Institutional Review Board (IRB), an expert panel comprised of both pharmacy and medical personnel.

We used the traditional RPN FMEA techniques to investigate each aspect of the process and obtain risk priority numbers (RPNs) (Webster et al., 2020). These RPNs will be used to develop action plans based on the severity, probability of occurrence, and detectability scores for each failure mode (Webster et al., 2020). Additionally, we will focus on reducing the RPNs associated with implementing ADS. Previous studies by (Huang et al., 2020; Liu et al., 2020; Ouyang et al., 2022a; Simsekler et al., 2019; Strauch, 2021; Webster et al., 2020) have also utilized the FMEA process to achieve similar objectives.

As mentioned earlier, a medication error can be found as an outcome of three categories: system issues or human faults (either failure of healthcare personnel or the patient's condition). Our target in these 3 categories was mainly the first and the second concerning our study, which is the system and the healthcare personnel; both were the focus of the flow.

2.2. Study type

A descriptive mixed observational study.

Although the FMEA data will end up being quantitative, it impacts a qualitative outcome. The data collection method to build up the FMEA and the outpatient flowchart was group interviews, online surveys, observation, and recording of the flow in addition to policy and procedures set in the hospital and the related document review. All the data were collected from the outpatient pharmacists, physicians, nurses, and the information technology department. Data were collected, the information was used to build the flowchart of the outpatient pharmacy process, and the gaps were visualized within the flow. The collected gaps were considered potential failure mode and added to the FMEA skeleton and RPN calculations were done before and after analysis.

2.3. Phase one

The panel of experts thoroughly analyzed the pharmacy workflow in the outpatient setting based on all gathered data. The workflow was segmented into two main parts: 1. receiving, storing, and organizing medication stock; and 2. validating, preparing, and dispensing medication, plus addressing scattered problems related to automation. These potential risks must be addressed and mitigated to ensure the safety and well-being of patients. The Flow chart has created a visualization of the pharmacy workflow, including the gaps and risks found. Potential risks were identified at every stage of the process as per Fig. 1, highlighted in red boxes, and FMEA points were assembled for Phase Two to evaluate the level of risk.

2.4. Phase two

The expert panel and the end users were involved in several brainstorming sessions to identify the root cause. As a result, the necessary remedial measures were taken to ensure long-term profitability and high-quality execution.

The gaps/risks at the flowchart were considered the Potential failure modes; they were added to the FMEA table as 9 main points per the expert panel involved. In addition, the FMEA process was initiated to investigate reported difficulties, including obtaining RPN for each difficulty and potential risks found in Phase One. The approach employed by FMEA provided a systematic, proactive method to identify and evaluate the process failure modes and assessed the probable failure of the process and its consequences and the potential failure causes; in addition to the measures that could remove or lessen the likelihood of a prospective failure occurring, and it logs the process.

Failure Modes Priority System for contemplating preventative/-corrective action and calculated the occurrence probability (O), severity (S), and detectability (D) for every failure identified. Additionally, the RPN enabled a plan for the appropriate proactive steps to limit the possibility of failure (Table 1). The calculation of the RPN numbers uses the following:

- Occurrence (O) - the likelihood or frequency of the failure occurring.
- Severity (S) - the consequence of the failure should it occur.
- Detectability (D): The likelihood of detecting a failure or the effect of a failure BEFORE it is felt by the patient. The maximum RPN was 1,000 (Anjalee et al., 2021; Sharma et al., 2019).

$$RPN = Occurrence \times Severity \times Detection$$

The expert panel relied on the RPN value to determine the appropriate course of action for each challenge. They also took steps to identify the issue's root cause(s), confirm that it had been resolved, and update checklists to prevent future occurrences. It is crucial to enhance the claims evaluation process by leveraging recent experience. The FMEA documentation, applications, evaluation, and grading process were all overseen by highly skilled professionals. Metrics such as the number, timeliness, and authenticity of reported issues and the time taken to resolve them are crucial in measuring performance. The team promptly addressed any concerns regarding critical pharmaceutical services. Early and timely resolution of quality issues led to lower costs and improved overall service performance. Additionally, ensuring homogeneity and consistency in the evaluation process was essential to achieving reliable RPN results consistently.

2.5. Phase three

The scoring process used by RPN followed the normal flow and sequence of the process, and interventions were implemented accordingly. These interventions included the ADS and corrective actions. Prioritization was given to interventions with high RPN numbers, and they were tackled first, following the sequence from highest to lowest value. From Phase Two, RPNs were calculated for the 9 points prioritized in Table 3 for the action plans in Phase Three.

The first phase revealed potential hazards in the pharmacy's manual workflow, as shown in Fig. 1. The second phase, shown in Table 2, outlined the process in 9 main segments and identified high-risk failure modes noted by the panel per segment, with corresponding RPN scores during implementation phases outlined in the flowcharts. Phase Three, displayed in Table 3, prioritized the calculated RPNs for implementing action plans.

3. Results

(See).

4. Discussion

Pharmacy automation and robotics implementation are improvements in the pharmaceutical sector. Automating the major processes of pharmaceutical dispensing, such as counting and labeling, reduces human error, speeds up the process, and reduces costs. However, installing pharmacy automation and robotics in hospitals is not without challenges. These challenges include the

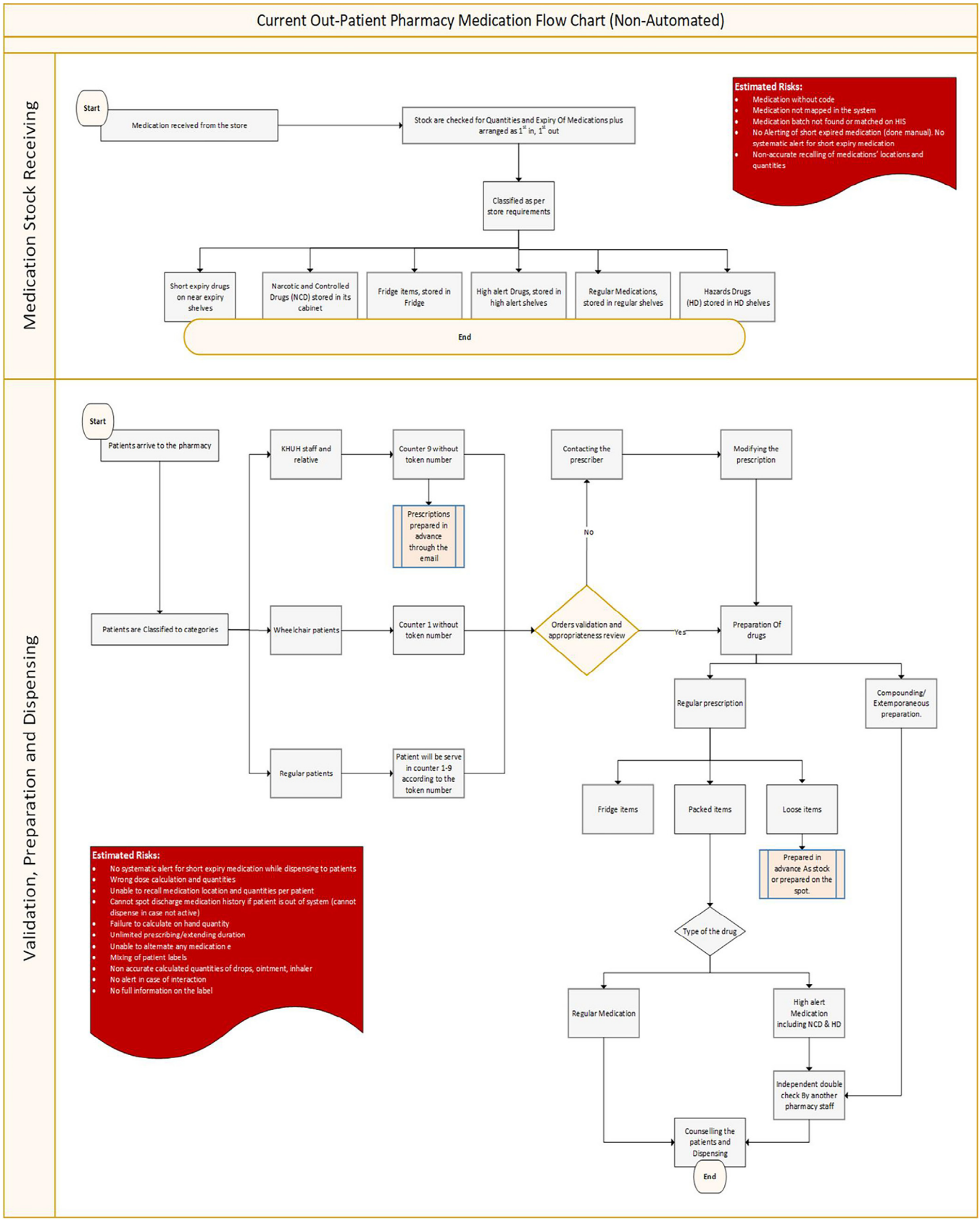

Fig. 1. Flowchart of Areas of Failures in Outpatient Pharmacy.

Table 1
Scales of rating and for the values of the occurrence, severity, and detection (O), (S), and (D) respectively scores in FMEA.

Occurrence (O)		Severity (S)		Detection (D)	
Score	**Probability of Occurrence**	**Score**	**Severity of Effect**	**Score**	**Ease of Detection**
10	Very high > 1 in 2	**10**	Hazardous without warning	**10**	Absolutely impossible to detect
9	Very high 1 in 3	**9**	Hazardous with warning	**9**	Very remote: detected 1/10 times
8	High 1 in 8	**8**	Very high	**8**	Remote: detected 2/10 times
7	High 1 in 20	**7**	High	**7**	Very low: detected 3/10 times
6	Moderate 1 in 80	**6**	Moderate	**6**	Low: detected 4/10 times
5	Moderate 1 in 400	**5**	Low	**5**	Moderate: detected 6/10 times
4	Moderate 1 in 2000	**4**	Very low	**4**	Moderately high: detected 7/10 times
3	Low 1 in 15,000	**3**	Minor	**3**	High: detected 8/10 times
2	Very low 1 in 150,000	**2**	Very minor	**2**	Very high: detected 9/10 times
1	Remote < 1in1,500,00	**1**	None	**1**	Almost certain

Table 2
Failure Mode Effect Analysis (FMEA).

Stage	Potential Failure Modes	Potential Effect(s)	Causes	O	S	D	RPN 0	Recommendations/Actions taken	New O	New S	New D	RPN 1
1	Medication receipt from the main Drug store	Medication without tracking barcode. is not mapped in the system. The medication batch is not found in the system.	-Manual process. –No database.	9	6	7	378	-Full Mapping of the Health Information System (HIS). System shall not allow expired medication dispensing.	3	3	5	45
2	Medication filling and arranged on shelves	Manual process, no inventory or expiry track that is linked to Health Information System (HIS)	–No database.	8	9	9	648	-Full Mapping on the HIS.	5	3	5	75
3	Prescriptions, including outsourced drugs, are unavailable.	Service delay leads and inadequate time management.	-Physical check by pharmaceutical professionals by going to the drug rack and checking it, then returning to the call to clarify with the prescriber. -Manual method.	7	6	9	378	-Full HIS Mapping. -Notify the clinician that substitutes are available -Allow adding non-formulary medications into the system.	3	3	6	54
4	Multiple modifications on the same day of the patient's regimen	A medication order is not dispensed. Manual process.	-Wrong order that requires					clarification/modification. -Missed order that needs to be processed. –No alert of duplication or interaction.	10	10	10	1000
-	Introduce the clinical decision support that will follow the proper drug that is mapped	4	5	4	80							
5	The patient's medical history shall be checked and reconciled at admission and discharge.	If not done, the drug is not ordered or dispensed and could be missing. This causes a delay in service; the wrong medicine or dose maybe not be given. -Hand-driven operation. -The quantity available cannot be estimated	-Faulty order requiring explanation due to mismatch of diagnosis or improper reconciliation. -Risk of missed order that needs to be processed. -Prescribing the wrong medication based on the patient or relatives' feedback.	8	10	10	800	-Making a master list of all active and inactive medicines given to the patients throughout all visits. -Computerize the reconciliation process much more than possible when it comes to – Mandatory reconciliation upon admission and discharge. -For nonformulary drugs: manual entries; are to be filled in the very same screen from a data set that allows additions on the HIS	5	9	5	225

(*continued on next page*)

Table 2 (*continued*)

Stage	Potential Failure Modes	Potential Effect(s)	Causes	O	S	D	RPN 0	Recommendations/Actions taken	New O	New S	New D	RPN 1
6	Order Review	-Medication mishaps -There is no documentation of the prescriptions' appropriateness review or the procedure of checking order clarity and suitability.	-The system does not highlight interactions, duplications, and cross allergies (it depends on the pharmacist's manual review). -When dispensing medications to patients, there is no routine alert for medications that always seem to be expired or near expiry. -Dose calculations and numbers need to be corrected. -Drops, ointment, and inhaler quantities are miscalculated. -Clarification, if done, will be over the phone audibly with no records.	7	9	10	630	-Prescriptions must be filled out using drop-list options and minimizing free texts as much as possible. –On the order entry stage, pharmacy clarification shall be documented HIS-wise. -The order's status and progress are to be displayed. -The system is designed to prevent off-readings and restrictions specified by the pharmacy and the assistance of the clinical decision-support system.	4	6	3	72
7	Order validation	-The possibility of orders that are not processed or dispensed because they were missed -If processing is delayed, the wrong medicine or dose may be given.	-The patient's medication may not be appropriate.	6	9	9	486	-The orders' status of processing is displayed. -The system is designed to prevent off-readings and restrictions specified by the pharmacy and the assistance of the clinical decision-support system.	3	7	5	105
8	Preparation and dispensing	- Adverse drug events may occur if there is a shortage of pharmacy stock, increased workload, and poor time management. -Dispensing the incorrect drug that is not appropriate for the patient due to mode of administration, cross allergy, or even duplication of therapy errors on printed labels -Inadequate double-checking by staff who alter labels manually -Inconsistencies in stock on HIS displays -Dispensing expired medications -There needs to be detailed information on the label. -Except for high-alert medications, there is no double-checking, and it is up to the employees involved. -There needs to be traceable documentation of the medicine receipt.	-There is no retroactive verification and validation. -There are no appropriateness review checkpoints. -Printable labels cannot be edited. -A shortage of Personnel. –On the HIS, the label needs to be correctly mapped. -Labels only include some of the information required by the labeling policy. –No modification options for the label shall be printed on HIS.	7	7	10	490	-Ready batches/quantities for fast-moving pharmaceuticals. -Allow label editing. -Medicines identified by date and time and linked to a patient for tracking -Actions are recorded and tracked electronically.	3	6	5	90

Table 2 (*continued*)

Stage	Potential Failure Modes	Potential Effect(s)	Causes	O	S	D	RPN 0	Recommendations/Actions taken	New O	New S	New D	RPN 1
9	Health Information System (HIS)	Medication incidents of the wrong patient or dose	HIS screens have no fixed headers, causing mix-ups between patients' medications upon printing labels, especially in the manual issue.	10	10	10	1000	Standardize the screens to follow the standard pharmacy requirements per national and international elements. mapping the drugs with templates and linking them to the clinical decision support system	8	7	7	392
Total RPN (RPN 0)				**5810**				**Total New RPN (RPN 1)**	**1138**			

Table 3
The areas of interventions in sequences of priorities.

Priority	Potential Failure Modes	O	S	D	RPN 0
1st	Multiple modifications on the same day of the patient's regimen	10	10	10	1000
	Health information system (HIS)	10	10	10	1000
2nd	Patient History and reconciliation upon admission and discharge	8	10	10	800
3rd	Medication filling and arranged on shelves	8	9	9	648
4th	Order Review	7	9	10	630
5th	Preparation and dispensing	7	7	10	490
6th	order validation	6	9	9	486
7th	Medication receipt from the Drug store	9	6	7	378
	Prescribing out-of-stock, non-available, or patient-own drugs	7	6	9	378

high cost of implementation, staff resistance, system compatibility, and software integration challenges. The complexity of pharmacy automation and robotics requires that hospitals implement strategies to manage the risks associated with the implementation process.

FMEA analysis is a method used to identify and assess potential failures when implementing complex systems like pharmacy automation and robotics. It is a robust process for identifying and prioritizing the risks based on severity, occurrence probability, and detection capability. The output of FMEA analysis is the RPN. However, to ensure the effectiveness of FMEA analysis in healthcare, it is recommended that a qualitative approach is used.

The qualitative approach of FMEA analysis enables healthcare professionals to understand the risks posed by implementing pharmacy automation and robotics. It is considered the best approach because it allows healthcare professionals to assess the potential impact of each failure mode on patients' health and well-being. This approach also enables healthcare professionals to understand the root cause of each potential failure mode, the likelihood of its occurrence, and the effectiveness of the current control measures to avoid it.

When using FMEA analysis, the RPN is calculated based on three factors: severity (S), occurrence (O), and detection (D). The severity of a failure mode is based on the potential harm it could cause. The occurrence of a failure mode is the likelihood that it will occur. The detection of a failure mode is the likelihood that it will be detected before it causes harm.

A review of 153 articles published between 1998 and 2018 showed that FMEA is effective in hospitals for quality improvement and error reduction (Liu, 2019). The classical RPN technique is commonly used for healthcare risk evaluation, and there is a trend toward streamlined versions of FMEA (Liu, 2019). This review guides academics and practitioners in the healthcare industry, providing 11 improved FMEA approaches (Liu, 2019). Nevertheless, the traditional RPN FMEA was sufficient for our study after reviewing the 11 approaches.

As mentioned, FMEA is a method for detecting and reducing potential failure modes and risks in real-world systems (Carlson, 2012; Liu, 2019; McDermott et al., 2009; Ouyang et al., 2022a; Parretti et al., 2022; Stamatis, 2003). It involves considering cost, timeframe, efficacy, and feasibility when prioritizing corrective actions (Carlson, 2012; Stamatis, 2003). However, its implementation can be challenging due to insufficient resources, lack of buy-in, difficulty in identifying failure modes, difficulty in prioritizing corrective measures, uncertainty, and lack of follow-up; henceforth, organizations shall commit to continuous monitoring and follow-up to ensure proper implementation and minimize the risk associated with failure modes (Asan and Soyer, 2016; Li et al., 2023; Liu and Tang, 2022; Stamatis, 2003; Wu et al., 2023; Yazdi, 2019). Misconceptions concerning FMEAs, such as their one-time nature, flexibility with organizational goals and resources, and difficulties for small enterprises, must be addressed for successful implementation. (Carlson, 2012). Furthermore, FMEA faces challenges in practice, including data availability, expertise, time and resource constraints, inadequate risk assessment and uncertainties, difficulty in prioritizing risks, and implementation challenges (Cai, 1996; Huang et al., 2020; Liu et al., 2020; Liu, 2019; Saxena et al., 2021).

Uncertainty can arise in FMEA when the severity or occurrence of a failure mode is difficult to predict or when the effects of a failure mode are unknown (Asan and Soyer, 2016; Liu and Tang, 2022). In such cases, the FMEA team may need to engage subject-matter experts, conduct additional tests or experiments, consult relevant literature to reduce uncertainty, gather additional data, perform expert reviews, use data-driven approaches, perform sensitivity analysis, apply statistical methods, and execute pilot studies (Asan and Soyer, 2016; Li et al., 2023; Liu and Tang, 2022; Wu et al., 2023; Yazdi, 2019; Yuan and Tang, 2022). Consequently, to minimize bias in FMEA data collection, organizations must define clear criteria, train data collectors objectively, use multiple data sources, use blind data collection, use standardized measurement tools, monitor data quality, and conduct peer reviews (Asan and Soyer, 2016; Huang et al., 2020; Liu et al.,

2019, 2020, 2022; Liu, 2019; McDermott et al., 2009; Stamatis, 2003; Wu et al., 2023).

To mitigate uncertainty, techniques like sensitivity analysis, probabilistic risk assessment, and Monte Carlo simulation can be utilized to minimize uncertainty in FMEA (Harrison et al., 2010; Liu and Tang, 2022; Sharma and Luthra, 2023; TİMLİOĞLU İPER et al., 2022; Wu et al., 2023). Also, fuzzy FMEA is a structured approach that incorporates fuzzy logic to address uncertainty and imprecision in real-world systems (Cai, 1996; Li et al., 2023; Saxena et al., 2021; Zolfaghari and Mousavi, 2021). Likewise, the Li J & Pan Q study offered a method for uncertainty modeling and measurement using the Dempster-Shafer theory and Belief & Focal element entropy (Cai, 1996; Harrison et al., 2010; Li and Pan, 2020; Liu et al., 2019; Smets, 1990; Song and Deng, 2019; Yuan and Tang, 2022). However, in some situations, such as a lack of evidence, a high degree of uncertainty, or strong dependencies between variables, other methods may be more appropriate (Li and Pan, 2020). Similarly, FMECA (Failure Mode, Effects, and Criticality Analysis) includes additional techniques such as fault tree analysis, hazard analysis, and risk assessment in addition to Monte Carlo simulation (Bhirich et al., 2023; Giardina et al., 2022; Iadanza et al., 2021). Additionally, FMECA places a greater emphasis on the criticality of each failure mode, decreasing the uncertainties to nil levels (Bhirich et al., 2023; Giardina et al., 2022; Iadanza et al., 2021).

These techniques can help quantify the uncertainty associated with various parameters and assumptions used in the analysis and provide a more realistic estimate of the potential risks and their impacts. Uncertainty can be addressed and rolled out through a thorough analysis of potential failure modes, their effects, and the likelihood of their occurrence (Asan and Soyer, 2016; Li et al., 2023; Liu and Tang, 2022; Wu et al., 2023; Yazdi, 2019; Yuan and Tang, 2022). The FMEA process involves identifying potential failure modes, determining the severity of their effects, and assessing the likelihood of their occurrence.

Adding to FMEA limitations, it was found to have a modest accuracy level as per studies; however, it has limitations that can be modified when its reliability is assessed and validated by taking an average numerical value and starting with high priority (Rezaei et al., 2018). Reporting near misses and associated drug events is crucial for safety since such comprehensive quality techniques may economically evaluate all potential and erroneous conditions (Ahtiainen et al., 2020). Such techniques are also being used at our facility, which was reflected in the total decrease in RPN of 80.4%.

The ADS does not eradicate errors or medication-related incidents as it still has limitations (Zolfaghari and Mousavi, 2021); however, it has proved significantly less risky for FMEA carried out and deployed in our hospital. It is a tool for learning.

Traditional FMEA aims to reduce uncertainty by gathering and analyzing accurate data, identifying input variables, using validated models, conducting sensitivity analyses, and involving subject-matter experts (Yazdi, 2019). However, it's essential to acknowledge that some level of uncertainty is inherent in risk assessment processes and may not be eliminated (Yazdi, 2019). The goal is to identify and mitigate potential failure modes as much as possible, given available data and resources (Yazdi, 2019).

One significant challenge experienced during the implementation of pharmacy automation and robotics in hospitals is the cost of implementation. The implementation cost of pharmacy automation and robotics is capital-intensive, requiring significant investment in technology, training, and infrastructure. However, through FMEA analysis, hospitals can identify potential failure modes that could cause equipment downtime or inefficiencies. By identifying these failure modes, hospitals can take steps to mitigate the risks and ensure that the equipment operates efficiently.

Another challenge experienced during implementation is staff resistance. Some healthcare professionals may hesitate to adopt the new technology due to fear of losing their jobs or inadequacy in operating the new system. However, through FMEA analysis, healthcare professionals can identify potential failure modes that could lead to human error and cause harm to patients. This analysis will help healthcare professionals understand the importance of pharmacy automation and robotics in reducing human error and improving patient safety.

A third challenge is system compatibility and software integration challenges. Installing new pharmacy automation and robotics systems may cause incompatibility issues with other existing systems or may not integrate well with the hospital's infrastructure. Through FMEA analysis, hospitals can identify potential failure modes that could cause software integration issues, equipment downtime, and inefficiencies. Hospitals can take steps to eliminate or reduce the risks by identifying these potential failure modes.

As FMEA is a qualitative approach used to identify potential risks in a product, process, or service. It helps to identify all the possible failure modes, their causes, and the effects of those failures on customers or other stakeholders. It also helps to prioritize actions that can be taken to reduce or eliminate those risks.

FMEA Analysis-Qualitative Approach has many advantages, such as providing an organized approach for analyzing risks and identifying potential problems that might arise during the development or production process. It also helps improve quality control by identifying potential sources of errors before they occur. On the other hand, it may not be suitable for all types of projects due to its complexity and time-consuming nature. Furthermore, it requires experienced professionals to interpret the results correctly and recommend corrective actions accordingly.

FMEA was used in a descriptive qualitative research method, using observation, interviews, and documentation as data collection techniques to measure Quality Risk Management (Ratnamurni et al., 2022). Another qualitative study was conducted during intrahospital patient transfers, which included direct observation and interviews with porters where the patient transfer procedure was documented and compared to institutional policies and procedures, and the FMEA was used to identify potential system fault (Suclupe et al., 2023). Likewise, using the FMEA technique, an institution did descriptive research examining the failure modes and their impacts qualitatively and quantitatively; they created an FMEA team, and the targeted processes were outlined in a flowchart (Yazdanian et al., 2022). Following that, probable failures in each stage were discovered, and each failure mode was graded; the RPN was calculated, and for high-risk failure modes (RPN250), corrective actions and preventative tactics were proposed (Yazdanian et al., 2022). FMEA was also utilized in an exploratory study, where it was found that it was an efficient approach for resolving major challenges associated with Remote Patient Telemonitoring process implementation and resulted in successful adoption (Parretti et al., 2022). Another phenomenology case study was used to enhance pharmacy operations as well as boost patient care (Hohmeier et al., 2022).

The expert panel chose the FMEA method in this study due to its proven track record worldwide in the military and healthcare industries. The panel went through different designs of improved FMEAs and settled with the traditional style as it fits our findings. Through FMEA, potential failures that may harm or injure patients and healthcare providers using the medication management system were identified. This method effectively allowed the panel to comprehensively understand the process's multiple operations and evaluate the risks involved (Liu et al., 2020). Compared to traditional quality improvement schemes, FMEA provided unique information that helped prioritize procedures that needed improvement and minimized gaps in medication-use processes (Anjalee et al., 2021; Liu et al., 2020; Rhodes and McCarthy,

2019). Our hospital found FMEA to be the most suitable framework for conducting risk assessments on medication management aspects due to its ability to analyze incidents in detail. In addition, it allowed for rigorous, detailed analysis of medication incidents recognized through reporting issues voluntarily.

5. Conclusion

The Pharmacy and an expert panel proactively evaluated the deployment of ADS by conducting a traditional RPN FMEA. This analysis was the best approach to address the challenges often encountered while implementing hospital pharmacy automation and robotics. Through the qualitative FMEA analysis approach, healthcare professionals could identify potential failure modes and prioritize them based on their RPN. This analysis can help hospitals take steps to ensure the effective implementation of pharmacy automation and robotics technology, ultimately improving patient safety. The study recommends applying systems theory at every level of implementing an automated system, which involves understanding that modifying one subsystem can affect another. Staff must be trained in automation approaches and problem-solving techniques and be aware of changes during the invalidation, preparation, and dispensing stages. Additionally, physicians and nurses must be trained on using the system and informed of any changes during the process.

6. Authors' contributions

All authors have contributed to preparing, writing, and reviewing the manuscript.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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