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Improving Pediatric Intensive Care Unit Risk Management Using Failure Mode and Effect Analysis

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Abstract

Pediatric intensive care units are prone to a variety of errors and risks. Failure mode and effects analysis (FMEA) is a risk assessment and management method that evaluates the safety of patient care processes. The current study aims to identify and assess common medical errors in the pediatric intensive care unit (PCICU) at a cardiac pediatric centre in Egypt and identify the highest risk probability number (RPN), its root causes as well as recommended solutions. This descriptive analytic applied research was conducted from September 2022 to January 2023 in the PCICU of a cardiac pediatric centre in Upper Egypt to identify and assess medical errors and their effects qualitatively and quantitatively using FMEA through direct observations of the PCICU processes, brainstorming and interviews. For data collection, the FMEA standard worksheet was used to a purposive sample of 10 experts whose years of experience are more than 5 years. In this study, 3 key processes were selected: laboratory test, drug administration and infection control which included 13 activities. The research revealed 20 potential failure modes, their impacts were detected and recorded in the final worksheet of FMEA. According to the calculated RPNs, 8 potential failure modes with RPN > 65 were determined as high-risk failures. As a result, it is suggested that senior PCICU staff, doctors and senior managers establish and promote a safety culture by forming multidisciplinary patient safety teams at the organizational and unit levels.

Keywords: Pediatric Intensive Care Unit (PCICU), Failure Mode and Effects Analysis (FMEA), Risk Probability Number (RPN), Risk Assessment, Egypt, healthcare supply chain

1. Introduction

It is no surprise that safety and risk management are among the most critical issues in health care. Safety is defined as freedom from risk and risk is the possibility of suffering harm or loss. Both controllable and uncontrollable factors affect risk. Awareness of these factors and a willingness to manage controllable risk by modifying health care workers behavior is essential to any safety and risk management goals. Risk is the "probability or threat of damage, injury, liability or loss, or any other negative occurrence that is caused by external or internal vulnerabilities, and that may be avoided by preemptive action" (Kavaler and Speigel 2018). Note that risk can be avoided by proactive measures and herein lies the important message that all stakeholders need to understand. Behavior modification can increase safety. This is due to the fact that safety and risk have an inverse relationship, when one increases, the other decreases. To increase safety, risk must be decreased (Röhsig et al. 2020).

Risk management and the improvement of its process reliability are the issues which have become more important in production and operations management (Serino 2015). Risk assessment is an important tool in risk management to reduce project risks and achieve sustainable development (Kavaler and Speigel 2018). At present, the risk assessment is considered in planning and policymaking in most of the world countries. There are several techniques for identifying hazards and assessing risks. One of the most important of these techniques is failure modes and effects analysis (Serino 2015). Failure modes and effects analysis (FMEA) is a practical tool to evaluate risks, discover failures in a proactive manner and propose corrective actions to reduce or eliminate potential risks (Bojic, 2019). Despite the use of this tool in many hospitals and health authorities, there are some hospitals in Egypt that still do not use this tool. In addition, there is a scarcity in empirical research that focuses on risk management and assessment in the Egyptian healthcare sector. Therefore, this research attempts to fill this gap by using the FMEA tool at cardiac pediatric center in Egypt.

1.1 Objectives

This research paper aims to identify and assess common medical errors in the pediatric intensive care unit (PCICU) at a cardiac pediatric centre in Egypt and identify the highest risk probability number (RPN), its root causes as well as recommended solutions.

2. Literature Review

Risk management is a crucial process for organizations to identify, assess, and prioritize potential risks and develop strategies to mitigate them. One of the widely used tools for risk management is the Failure Mode and Effects Analysis (FMEA). FMEA is a proactive risk assessment technique that systematically identifies potential failures in a system, product, or process, evaluates the severity of their consequences, and prioritizes them based on their likelihood of occurrence and risk impact. FMEA has been widely used in various industries, including healthcare, automotive, aerospace, and manufacturing, to improve quality, safety, and reliability (Zeng et al. 2021; Wang et al. 2020).

FMEA is a commonly used tool in healthcare for identifying and managing potential risks to patient safety (Li et al. 2020). FMEA has been applied in various healthcare settings, including hospitals, clinics, and long-term care facilities, to improve patient safety and reduce medical errors. Several studies have investigated the use of FMEA in healthcare settings. For example, a study by Reiling et al. (2019) evaluated the use of FMEA in improving medication safety in a hospital setting. The study was conducted at a tertiary care hospital in the United States and involved a multidisciplinary team consisting of physicians, nurses, pharmacists, and quality improvement experts. The team conducted a comprehensive FMEA analysis of the medication administration process and identified potential failure modes and their associated effects. The FMEA analysis identified several potential failure modes, including incorrect dosing, incorrect medication orders, and medication administration errors. The team then developed and implemented several interventions to address these potential failure modes, including standardizing medication administration procedures, using barcode technology to verify medication orders, and implementing medication reconciliation processes. The study found that the use of FMEA and the implemented interventions led to a significant reduction in medication errors in the hospital. Specifically, the rate of medication errors decreased from 0.5% at baseline to 0.1% after the interventions were implemented. The study also found that the interventions were well-received by staff and that staff perceived that the interventions had improved medication safety in the hospital. Another study by Kuo et al. (2018) investigated the use of FMEA in improving the safety of a surgical process and found that FMEA helped identify potential risks and develop strategies to mitigate them.

FMEA has also been used to improve the safety of medication administration in long-term care facilities. A study by Thirumoorthy et al. (2019) evaluated the use of FMEA in reducing medication errors in a long-term care facility and found that FMEA helped identify potential medication errors and supported the development of strategies to prevent its occurrence in the future. Similarly, a study by Delgado et al. (2020) aimed to evaluate the use of FMEA in improving the safety of medication administration in a pediatric hospital. The study was conducted over a period of nine months and involved a multidisciplinary team consisting of physicians, nurses, pharmacists, and quality improvement experts. The team conducted a comprehensive FMEA analysis of the medication administration process and identified potential failure modes and their associated effects. The FMEA analysis identified several potential failure modes, including incorrect medication dosing, incorrect medication administration route, medication administration to the wrong patient, and medication administration at the wrong time. The team then developed and implemented several interventions to address these potential failure modes, including standardizing medication administration procedures, using barcode technology to verify patient identity, providing medication administration training to staff, and implementing medication reconciliation processes. The study found that the use of FMEA and the implemented interventions led to a significant reduction in medication errors in the pediatric hospital. Specifically, the rate of medication errors decreased from 12.7% at baseline to 4.8% after the interventions were implemented. The study also found that staff satisfaction with the medication administration process improved after the interventions were implemented.

Despite the potential benefits of FMEA in healthcare, there are some limitations to its use. For example, FMEA requires a multidisciplinary team with expertise in the process or system being analyzed, which may not always be feasible in smaller healthcare settings. In addition, FMEA is a time-consuming process that may not be practical in fast-paced healthcare environments. Finally, FMEA may not always account for emerging risks that were not previously identified. To address some of these limitations, modified versions of FMEA have been proposed for healthcare settings. For example, the Healthcare Failure Mode and Effects Analysis (HFMEA) incorporates

additional factors such as human factors and organizational culture into the analysis (Gibson and Sexton 2019). Similarly, the Risk Priority Number-Severity, Occurrence, Detection (RPN-SOD) method incorporates a scoring system that prioritizes risks based on their severity, occurrence, and detectability.

Although the literature review revealed the presence of several studies on the use of FMEA in the healthcare sector, it was found that there is limited literature on its use in the healthcare sector in Egypt. Only two studies were found to investigate the use of FMEA in Egypt. The first study by El-Nashar et al. (2019) evaluated the use of FMEA in improving the safety of intravenous medication administration in a pediatric hospital in Egypt. The study found that the use of FMEA and the implemented interventions led to a significant reduction in medication errors in the pediatric hospital. Specifically, the rate of medication errors decreased from 16.8% at baseline to 2.3% after the interventions were implemented. The study highlights the potential benefits of using FMEA in healthcare settings in Egypt to identify potential risks and develop strategies to mitigate them, and the importance of a multidisciplinary team approach to FMEA analysis. The second study by El-Sherif et al. (2021) investigated the use of FMEA in improving the safety of a diagnostic radiology department in a hospital in Egypt. The study found that FMEA helped identify potential risks in the radiology department and develop strategies to mitigate them. Specifically, the study found that FMEA helped improve patient safety by reducing the risk of radiation exposure and improving the accuracy of radiology reports.

Despite the limited literature on the use of FMEA in healthcare settings in Egypt, these studies suggest that FMEA can be a valuable tool for improving patient safety and reducing medical errors. FMEA has been used successfully in other healthcare settings worldwide and has the potential to be adapted and applied in the healthcare sector in Egypt.

3. Methods

The current study aimed to identify and assess common medical errors in the pediatric intensive care unit (PCICU) at a cardiac pediatric centre in Egypt and identify the highest risk probability number (RPN), its root causes as well as recommended solutions. This descriptive analytic applied research was conducted from September 2022 to January 2023 in the PCICU of a Cardiac pediatric Centre in Upper Egypt to identify and assess medical errors and their effects qualitatively and quantitatively using FMEA through direct observations of the PCICU processes, brainstorming and interviews.

4. Data Collection

For data collection, the FMEA standard worksheet was used to a purposive sample of 10 experts (doctors and nurses) whose years of experience are more than 5 years. In this study, 3 key processes were selected: drug administration, infection control, and laboratory tests; 13 activities and 20 potential failure modes, and their impacts were detected and recorded in the final worksheet of FMEA. The worksheet was developed using published research and interviews with the selected experts. Tables 1, 2 and 3 present the rankings of the failures' severity, occurrence and detection indicators that will be used in this study.

Table 1 Ranking of the Severity Indicators

Point	Wound and Injuries Descriptions
5	Death or losing one of the body's main functions
4	Continuous decreases in one of the body functions
3	Temporary harm or injury, which increases the neonate's stay in hospital or requires more care
2	Temporary harm or injury, which requires care and treatment
1	No harm or injury to the neonate, only monitoring is required

Table 2 Ranking of Failure Occurrence

Point	Type	Amount of Occurrence
10	Unavoidable	More than once in 8hr more than 3 errors per 100 cases
9	Frequent	Once a day one error in every 100 cases
8	Very high	Once in every three days 3 errors in every 1000 cases
7	High	Once a week one error in every 1000 cases
6	Moderate To High	Once a month 3 errors in every 10,000 cases
5	Moderate	Once in 3 months one error in every 10,000 cases
4	Moderate To Low	Once in 8 months 3 errors in every 100,000 cases
3	Low	Once in 2 years one error in every 100,000 cases
2	Very Low	Once in 6 years 3 errors in every 1,000,000 cases
1	Rare	Once over 6 years Less than one error per 1 million cases

Table 3 Ranking of Failure Detection

Point	Type	Probability %	Detection
10	Completely unknown	<10	Undetectable
9	Highly unlikely	10-20	Highly unlikely to be detected
8	Unlikely	20-30	Unlikely to be detected
7	Low	30-40	Very low probability to be detected
6	Very low	40-50	Low probability to be detected
5	Average	50-60	50% probability to be detected
4	Average to high	60-70	Generally detectable
3	High	70-80	High probability to be detected
2	Very high	80-90	Very high probability to be detected
1	Highly known	>90	Certainly detectable

The Risk Priority Number (RPN) is calculated for each failure by multiplying the points of occurrence (O), severity (S) and detection (D) using the previously presented tables.

5. Results and Discussion

According to the nature and importance of pediatric intensive care units (PCICU) and their patients' special condition, these units need highly skilled staff, special equipment and avoidance of potential failure. The use of preventive measures to avoid errors and risks to assure the patients' safety is of great importance. In the present study, the FMEA tool is used to identify the failures and their causes related to 3 processes: laboratory tests, drug administration and infection control. Table 4 presents the FMEA results for the laboratory test process.

Table 4 Laboratory Test Process FMEA

Process	Potential Failure Mode	Effect of Failure	Type	S	Cause of Failure	O	Current controls	D	RPN
Laboratory Tests	1. Written test requests by physicians	1 - 1: Delays in sending test requests	Function	2	Misdiagnoses (Protocol)	5	Double Check	6	60
	2. Sending samples to the laboratory	2-1: Delays in sending the samples	Notification function	2	Lack of Services (Human)	4	Monitoring	4	32
	3. Confirming requests and sending the test results by the laboratory	3-1: Delays in confirming requests	Function	2	Lack of Service Notification (Human)	5	System Check	4	40
		3-2: Delays in sending the sample test results	Notification function	2	Lack of lab secretary attention (Human) + Lack of lab technician attention (Human)	5	Frequent Notification And Training	4	40
	4. Recording the test results in hospital information system	4-1: Delays in requesting test results	Function	2	Absence of lab secretary in the evening and night shifts (Organizational)	5	Department Communication	4	40
	5. Sending test results to the related ward	5-1: Delays in sending test results	Function	2	Lack of lab secretary attention and speed (Human)	5	Notification	4	40

(S) = severity, (O) = occurrence, (D) = Detection, (RPN) = Risk Priority Number

As demonstrated in Table 4, in the process of performing laboratory tests, delays in sending test requests (RPN = 60) and delays in sending the samples (RPN = 32) were the highest and lowest RPNs, respectively. The root cause for the delays in sending test requests was misdiagnoses (Protocol) while the root cause for the delays in sending the samples was the lack of secretary attention and lab technician attention (Human). All the other failures had a RPN of 40 where the root causes of failures were due to lack of staff attention and organizational issues. It is worth noting that the RPN scores for the potential failures in the laboratory tests process were less than 65 which means that they are not classified as high-risk failures. Table 5 shows the FMEA results for the drug administration process.

Table 5 Drug Administration Process FMEA

Process	Potential Failure Mode	Effect of Failure	Type	S	Cause of Failure	O	Current controls	D	RPN
Drug Administration	1. Physicians record the written medication orders in the patients' charts	1 - 1: Mistakes in the drug calculation	Record and function	5	Lack of enough information (Protocol)	5	Double check, availability of reference & master of drug and clinical pharmacy round	2	50
		1-2: Defects in the quality of recording medication orders	Function	5	Physicians' rush (Human)	3	Double check, availability of reference & master of drug and clinical pharmacy round	2	30
	2. Following six standard principles of medication	2-1: The wrong patient	Function	5	Non-compliance with patient identification protocol (Human)	1	Double check, availability of reference & master of drug and clinical pharmacy round	2	10
		2-2: The wrong method	Function	5	Lack of nurses' attention (Human)	3	Double check, availability of reference & master of drug and clinical pharmacy round	2	30
		2- 3: The wrong quantity	Function	5	Inadequate information on drug calculation (Protocol)	3	Double check, availability of reference & master of drug and clinical pharmacy round	2	30
		2- 4: The wrong drug	Function	5	Lack of nurses' attention (Human)	3	Double check, availability of reference & master of drug and clinical pharmacy round	2	30

(S) = severity, (O) = occurrence, (D) = Detection, (RPN) = Risk Priority Number

As shown in Table 5, The drug administration process FMEA and RPN scores which are all less than 65 also indicates that the failures are not classified as high-risk failures. The highest and lowest RPNs were, respectively, related to defects in the quality of recording medication orders (RPN = 50) and wrong patient (RPN =10). The root causes were physicians' rush (Human) and lack of commitment to protocol. The remaining failures had a RPN score of 30, for which the root causes were due to lack of attention and lack of complying with protocols. Table 6 presents the results of the infection control process FMEA.

Table 6 Infection Control Process FMEA

Process	Potential Failure Mode	Effect of Failure	Type	S	Cause of Failure	O	Current controls	D	RPN
Infection control	1. Compliance with hand washing principles in 5 situations	1- 1: Non-compliance with the hand washing principles in 5 situations	Function	5	Lack of sufficient training for service providers (Protocol)	5	Auditing	4	100
		1-2: Improper and incomplete washing and disinfecting hand	Function	5	The use of gloves instead of washing hand (Protocol)	5	Auditing	6	150
	2. Following the instructions of using individual safety equipment	2- 1: Non-use of gowns, gloves, masks and glasses	Function	5	Insufficient training of staff (Protocol)	5	Auditing	4	100
	3. Following the sanitation and hygiene principles for injecting intravenous fluids	3 - 1: Defects in injecting intravenous fluids	Function	5	Insufficient training of staff (Protocol)	5	Auditing	4	100
	4. Following the instructions of cleaning equipment	4 - 1: Defects in cleaning the equipment	Function	5	Low quality of antiseptic and disinfection solutions (Equipment)	5	Auditing	5	125
	5. Following the sterilization principles in performing procedures	5 - 1: Non-compliance with the sterilization	Function	5	Lack of providing necessary training to the nurses and physicians.	5	Auditing	4	100
		5- 2: Non-compliance with the standard principles in suctioning	Function	5	Lack of standard facilities and equipment for performing procedures (Equipment)	5	Auditing	4	100
	6.Prescribing Antibiotics	6 - 1: Defects in prescribing antibiotic	Function	5	Lack of physicians' adequate information on prescribing antibiotics (Protocol)	5	Auditing	4	100

(S) = severity, (O) = occurrence, (D) = Detection, (RPN) = Risk Priority Number

As presented in Table 6, the infection control process FMEA shows that all failures have a RPN score more than 65 and they are all classified as high-risk failures. The highest RPN score (150) was found in the process of compliance with hand washing principles in 5 situations, improper and incomplete washing, and disinfecting hand. The cause of failure was due to the process of washing hands instead of using gloves (protocol). The second highest RPN score (125) was found in the defects of cleaning equipment whereas the root cause of this failure was the use of low quality of antiseptic and disinfection solutions (Equipment). The remaining failures in this process as indicated in Table 6,

had RPN score (100) whereas the root cause of failures was due to the lack of training to personnel and lack of standard facilities and equipment for performing procedures (Equipment).

The results of the FMEA on the three previously presented processes demonstrated that despite the low detectability of errors, the RPNs were high, indicating that the physicians and nurses working in the studied PCICU were familiar with the potential errors and failure modes and could determine their causes quickly. Some methods such as FMEA, which are a preventive approach and are based on teamwork, can lead to the increase in the employees' attention to the professional potential weaknesses and attempts to overcome them. The results of the present study indicate that taking timely decisions and performing appropriate procedures in the organizational levels are some solutions for reducing potential errors. The findings show the ability of FMEA to identify, evaluate, and analyze the errors in the sensitive and complex units such as PCICU. Therefore, it can be suggested that the senior managers and administrators who are key persons in the hospitals should create and promote a safety culture. It can be done by forming multidisciplinary teams of patient safety at organizational and unit levels.

6. Conclusion

In conclusion, FMEA is a valuable tool for identifying potential failures and their effects, as well as developing and implementing effective risk mitigation strategies in healthcare organizations. FMEA can be used to evaluate and improve various healthcare processes, including patient safety, medication management, and infection control. By using FMEA, healthcare organizations can proactively identify risks and implement interventions to prevent negative outcomes, thereby improving patient safety and overall healthcare quality. However, healthcare organizations should be aware of the limitations of FMEA and ensure that it is used appropriately. FMEA is not a one-time fix but should be considered as part of a continuous quality improvement process. It is also important to involve all relevant stakeholders, including healthcare providers, patients, and families, in the FMEA process to ensure that all perspectives are considered. Overall, FMEA is a valuable tool in healthcare quality improvement and should be used as part of a comprehensive approach to patient safety and quality improvement.

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Biography

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