Proactive Risk Management using Healthcare Failure Mode Effect Analysis Tool to Improve Medication Management Process

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ABSTRACT

Abstract:
Proactive risk management program is essential to maintain the quality and safety of patient care, treatment, and services within a healthcare system. According to the Joint Commission, hospitals need to adopt a proactive approach for risk management and develop risk mitigation strategies to reduce or eliminate the potentially harmful impact of possible risk. There are multiple tools that can be used for proactive analysis. Leaders of Evercare hospital Dhaka selected Healthcare FMEA tool to identify the potential failure modes in the current medication management process as it is one of the complex and high processes in healthcare settings. A multidisciplinary Healthcare FMEA team was formed comprising physician, nurse, pharmacist, quality, IT personnel and senior managements of EHD to conduct Healthcare FMEA. After completing Healthcare FMEA, twenty failure modes(n-20) and fifty-nine potential causes(n-59) of failure modes were detected in existing medication management process of EHD. The hazardous score was Two hundred & seventeen (n-217). There were Twelve major failures modes with higher hazardous score. Healthcare FMEA team members decided to eliminate major failures and actions were taken to control these failures. The main objective of this study is to maintain the medication error of EHD within the target (2/1000 patient days) by implementing required strategies and redesigning existing medication management process. The limitation of this study was it is a time-consuming process, it only helps to identify the possibilities of fail; it does not eliminate them, additional efforts are required to develop corrective action.

Key words: *Healthcare FMEA, Proactive, Risk reduction, Risk assessment, Medication errors, Medication management process, Safety, Failure mode, Evercare Hospital Dhaka EHD, Healthcare system.*

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INTRODUCTION

Proactive risk management program is essential to maintain the quality and safety of patient care, treatment, and services within a healthcare system. There are four key components of risk management program that are risk identification, risk prioritization, risk reporting and risk management (Figure-1).

Risk management program helps to identify and to proactively reduce unanticipated adverse events and other safety risks to patients and staff. According to the Joint Commission, hospitals need to adopt a proactive approach for risk management and develop risk mitigation strategies to reduce or eliminate the potentially harmful impact of possible risk [1]. There are wide range of risks in hospital setting for example risk can include with clinical care such as diagnostic, surgical, medication errors or can include with environment, facility, equipment etc.

Figure 1: Essential Components of Risk Management

Medication error is one of the leading causes of injury and avoidable harm in health care systems across the world. It may be due to human errors, but it often results from a flawed system with inadequate backup to detect the mistakes. According to the National Coordinating Council for Medication Error Reporting and Prevention, medication error is defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer"[2].

RATIONALE OF THE STUDY

At Evercare Hospital Dhaka, there were one hundred & twenty-seven (n-127) medication administration errors and three hundred & twenty-two (n-322) medications related near miss events were reported in the year 2022. It was also observed that average dispensing Turn Around Time (TAT) for routine medications was 180 mins and triggering delay in medication administration to the patient. It was evident that multiple indents were given for the same patients and average patient indent ratio per day, n-1:10, which affected extra workload in central pharmacy. Therefore, leaders of Evercare hospital Dhaka decided to conduct proactive risk assessment to identify risks and the potential causes of the risks in existing medication management process.

MATERIALS & METHODS

There are multiple tools that can be used for proactive risk analysis such as Healthcare Failure Mode and Effects Analysis (HFMEA), Hazard Vulnerability Analysis (HVA), Hazard Identification and Risk Assessment (HIRA), Infection Control Risk Assessment (ICRA), Pre-Construction Risk Assessment (PCRA) etc. Healthcare FMEA tool was selected to identify the potential failure modes in the current medication management process. Healthcare FMEA is a prospective assessment that identifies and improves steps in a process and reasonably ensures a safe and clinically desirable outcome[3]. There are five basic steps of healthcare FMEA which include topic selection, team formation, graphically describing the process, hazard analysis and determining action and outcome measure[3] (Fig-2). A multidisciplinary healthcare FMEA team was formed involving relevant stakeholders such as physicians, nurses, pharmacists, quality & IT personnel to conduct proactive risk management**.**

OBJECTIVES

The main objective of this study is to maintain the medication error of EHD within the target (2/1000 patient days) by implementing required strategies and redesigning existing medication management process.

Figure 2: Five Basic Steps of HFMEA

RESULTS

After completing Healthcare FMEA, twenty failure modes(n-20) and fifty-nine potential causes(n-59) of failure modes were detected in existing medication management process of Evercare Hospital Dhaka. The hazardous score was Two hundred & seventeen (n-217). There were Twelve major failures modes with higher hazardous score such as; there was no process to record current medication list in HIS, there was no documented process for prescription review criteria in IP pharmacy, Master drug list in HIS was huge, Neonatal drug chart was not updated, Multiple indents for the same patients, A bulk number of indents comes at a time, Staff can indent high alert medicine without any warning, Electrolytes are dispensed in concentrated form to patient care unit, Labelling stickers contain incomplete information. A few initiatives were taken by healthcare FMEA team members to control the identified major failure modes (Table 1). We are successfully able to maintain medication error within the benchmark 2/1000 patient days after conducting Heathcare FMEA (Figure-3). The Medication management process of EHD was redesigned and implemented based on the results of the risk reduction exercise.

Table. 1: List of Initiatives after HFMEA

Process	Major Failure Mode	Initiatives Taken
Prescribing Process	1. Drug charts are not uniform throughout the hospital. Neonatal drug chart is different from adult & paediatric. 2. There is no process to record the current medication list in HIS. 3. Noncompliance of prescription review process in IP pharmacy	1. Revised the Neonatal drug chart. 2. Current medication list is incorporated in HIS. 3. Prescription review criteria is incorporated in HIS
Transcribing process	1. Master drug list in HIS is huge and contains items which are physically not available in stock. 2. Multiple indents for the same patients 3. A bulk number of indents comes at a time.	1. Drug formulary is updated in HIS 2. Customized admission kit for patients. 3. Fixed the time for routine indent for different location such as ward area 11-1pm & critical area 3-5pm.
High alert medication safety	1. Staff can indent high alert medicine without any alert. 2. Concentrated Electrolytes 3. Electrolytes are dispensed in concentrated form to the patient care unit.	1. Automated warning arises in HIS during indent of high alert medication. 2. Updated and implemented Electrolyte Replacement Therapy guideline both for adult & paediatric patient. 3. Diluted concentrated electrolytes in pharmacy before dispensing to the patient care unit.
Dispensing process	1. Labelling stickers contain incomplete information. 2. More workload as maximum indent requests are going to IP pharmacy. 3. Delay in transportation	1. Revised the medicine sticker with all necessary information such as doses form, issue number, batch number. 2. Fixed pharmacy distribution for routine, discharge & urgent medication dispension. Routine medicine will be dispatched from IP pharmacy, discharge & urgent medicine will be dispensed from 6c pharmacy. 3. Dedicated to two pharmacy aids for medication transportation for different locations.

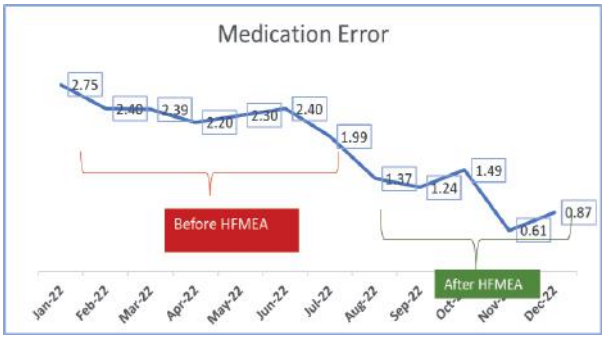

Figure 3: Medication Error

DISCUSSION

Failure Mode and Effect Analysis (FMEA) is one of the most widely adopted techniques for conducting proactive risk assessment. According to Institute for Healthcare Improvement, Boston, Massachusetts, USA, Failure Modes, and Effects Analysis (FMEA) is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, to identify the parts of the process that are most in need of change. FMEA includes review of the following[4].

- Steps in the current process
- Failure modes (What could go wrong?)
- Failure causes (Why would the failure happen?)
- Failure effects (What would be the consequences of each failure?)

The Veterans Health Administration (VHA), National Center for Patient Safety (NCPS) adopted and modified the traditional FMEA tool & incorporated other quality and safety tools in 2001. The tool was named Healthcare Failure Mode and Effects Analysis (HFMEA) which is appropriate for proactive risk assessment of healthcare processes[5]. HFMEA streamlines the hazard analysis steps by combining the detectability and criticality steps of the traditional FMEA. It also replaces calculation of the risk priority number (RPN) with a hazard score [6]. Five basic steps of Healthcare FMEA were followed to complete proactive risk assessment. It starts with topic selection and team formation. HFMEA team members developed a flow diagram of the process and identified the area of the process to focus on. All the possible/potential failure modes and potential causes of failure modes of each subprocess steps were listed. The Severity of each effect was selected based on the impact / danger to the patient and the probability ranking was estimated based on availability of the data. Severity & probability guideline is adapted from Healthcare FMEA severity guideline (Figure 4). Hazard score is adapted from Healthcare FMEA criticality matrix (Figure 5).

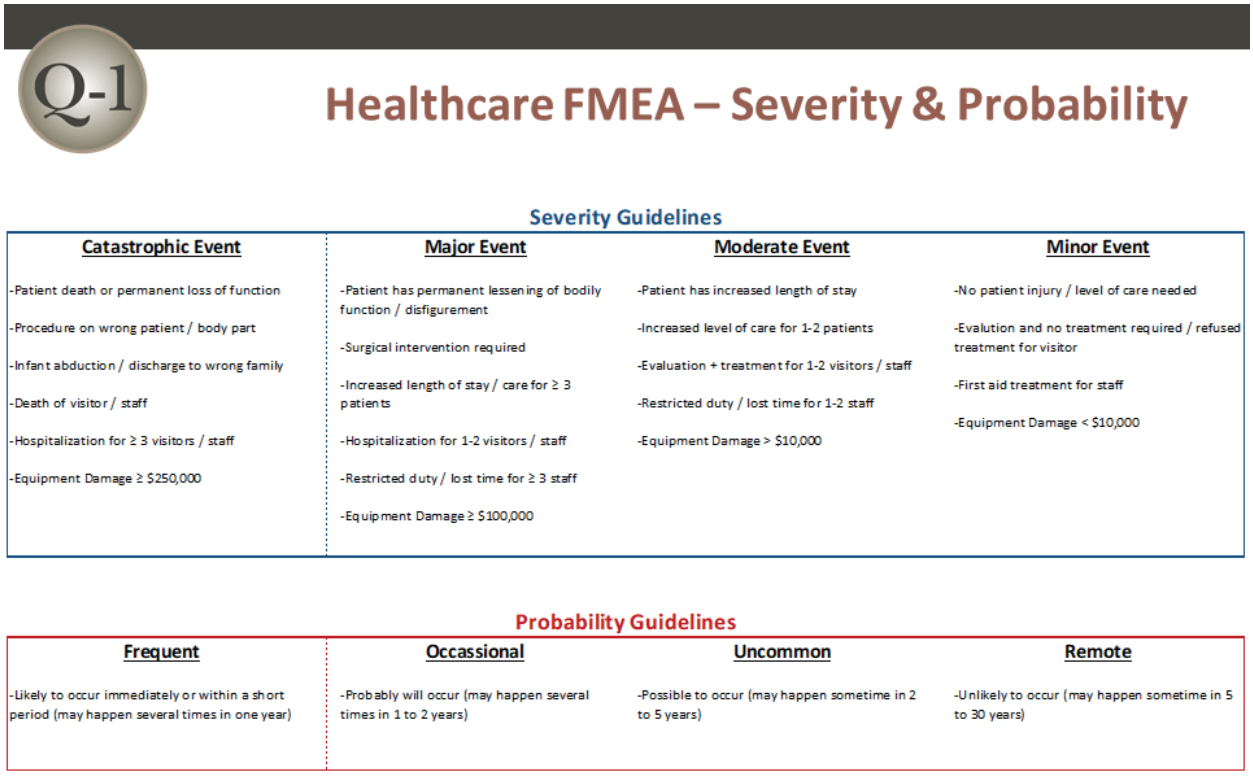

Figure 4: Severity & probability guideline. Adapted from the Healthcare FMEA chapter of Quality-one.com. downloaded the image on 10.09.2023. https://quality-one.com/hfmea/

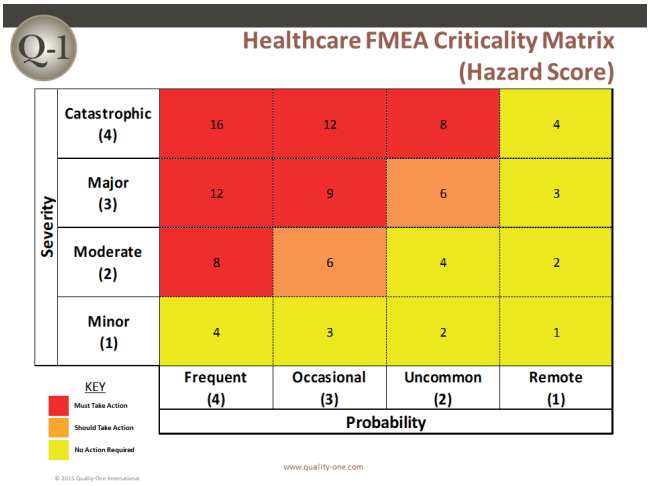

Figure 5: HFMEA Hazard Matrix Adapted from the Healthcare FMEA chapter of Quality-one.com. downloaded the image on 10.09.2023. https://quality-one.com/hfmea/

The Decision Tree is utilized to determine if the failure is a single point or multi point. Single point failure is more common as the probability of a single event is much greater than one where two or more individual causes are present simultaneously. If the risk is low, the analysis may stop at this point. If the hazard score is high further actions are taken to eliminate the risk. There were Twelve major failures modes(n-12) that were identified with higher hazardous score in existing medication management process at EHD. As per HFMEA Decision Tree, actions were taken and implemented to eliminate major failures. Healthcare FMEA team members redesigned the existing process to ensure safe, effective & organized usage of medication throughout the hospital. Examples of Healthcare FMEA tool were described in Table 2.

Table 2: Examples of Healthcare FMEA of Medication Management Process at EHD

	Failure Mode	Potential Causes	Scoring			Decision Tree Analysis				Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
			Severity	Probability	Hazard Score	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?					
1	Unavailability of current medication list in the pharmacy	There is no process to record current medication list in HIS.	2	4	8	yes	no	no	yes	control	A provision is created for the current medication list in HIS.	Medication reconciliation compliance	IT	Yes
2.	Failed to introduce uniform drug chart	Neonatal drug chart is different from adult & pediatric.	2	4	8	yes	no	no	yes	control	Neonatal drug chart is revised and made uniform	Reduce Prescribing error	Physician	Yes
3.	Unavailable items in master drug chart	Master drug list in HIS is huge and contains items which are physically not available in the stock	3	3	9	no	no	no	yes	control	Drug formulary is updated in HIS	Reduce Transcribing error	pharmacist, Nurse	Yes
4.	Failed to provide correct medicine issue slip to the pharmacy	Wrong medicine issue slip is prepared by medical transcriptionist	2	4	8	no	no	no	Yes	Control	Prescription Review criteria is incorporated with the in-patient prescription slip.	Reduce Dispensing error	IT	Yes
5.	Incomplete label	Labelling stickers contain incomplete information.	2	4	8	yes	no	no	yes	control	labelling sticker is revised such as doses form, issue number, batch number	Reduce Dispensing error	Pharmacist	Yes
6.	Failure to dispense medication on time	A bulk number of indents comes at a time.	2	4	8	no	no	no	yes	control	Routine medication Indent time is fixed (Ward Area - 11am to 1 pm and critical area -3 pm)	Reduce dispensing TAT	Pharmacist, nurse	Yes
		Multiple indents for the same patients	2	4	8	no	no	no	yes	control	Customized admission kit for patients is prepared	Reduce dispensing TAT	Pharmacist, nurse	Yes
7	High alert medication	Staff can indent high alert medicine without any interruption. There is no warning system in HIS.	2	4	8	yes	no	no	yes	control	Automated alert is arisen in HIS during indent of high alert medication	Reduce Transcribing Error	IT	Yes

CONCLUSION

Proactive risk reduction prevents harm before it reaches the patient or staff. When conducting a proactive risk assessment, organizations should prioritize high-risk, high-frequency areas. In a proactive risk assessment, the organization evaluates a process to see how it could potentially fail, to understand the consequences of such a failure, and to identify parts of the process that need improvement. According to joint commission risk reduction exercise should be carried out at least once per year and documented. Medication management is one of the complex & high-risk processes in hospital settings. Healthcare FMEA, a systematic approach was carried out to identify and mitigate risks of existing medication management process of EHD. Thus it has been observed that an medication error is within the acceptable benchmark.

LIMITATIONS

Healthcare Failure Mode and Effects Analysis (HFMEA) is a time-consuming process and requires a multidisciplinary team. It only helps to identify the possibilities of fail; it does not eliminate them. Additional efforts are required to develop corrective actions and implements them and redesign the process.

REFERENCES

1. The Joint Commission, on behalf of Joint Commission International. Quality Improvement and Patient Safety (QPS). Joint Commission International Accreditation. Standards for Hospitals Including Standards for Academic Medical Center Hospitals7th. Joint Commission Resources, Oak Brook, Illinois 60523. 2020;173-186.
2. National Coordinating Council for Medication Error Reporting and Prevention. http://www.nccmerp.org 2013. Last accessed February 2013
3. Healthcare FMEA (HFMEA). https://quality-one.com/hfmea
4. Failure Modes and Effects Analysis (FMEA) Tool-Institute for Healthcare Improvement. https://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx
5. Healthcare Failure Mode and Effect Analysis (HFMEA)-A Simple Step by Step Guide (HFMEA Guidebook Companion) January 2021 VHA National Center for Patient Safety. https://www.patientsafety.va.gov/docs/joe/Step-by-Step-Guidebook-HFMEA-January2021.pdf
6. The Basics of Healthcare Failure Mode and Effect Analysis VA National Center for Patient Safety. https://www.patientsafety.va.gov/docs/joe/hfmea_intro_jm_may14.doc.