Reducing risks by a proactive approach: Failure Mode Effect Analysis (FMEA)

Khin Zay Yar Myint, MBBS, MHS, Quality and Patient Safety Coordinator;
Ikumi Genka, MD, PhD, Quality and Patient Safety Coordinator;
Katsumi Takeuchi, Risk Manager;
Junichi Taguchi, MD,PhD, Chief Medical Director.

Tokyo Midtown Clinic

Minato-ku, Tokyo, Japan.

Introduction

What is FMEA?

- Failure Modes and Effects Analysis (FMEA) is a tool for conducting a systematic, proactive analysis of a process in which harm may occur .
- It has been widely used in the manufacturing industry, especially, in automobile production.
- The ISO9001 quality management standard requires companies to carry out FMEA as a risk management strategy.
- In recent years, it has been implemented in the quality and risk management of healthcare services.
- Healthcare FMEA (HFMEA) was developed by the Veteran Affairs (VA)-National Center for Patient Safety by adding matrix evaluation method of root cause analysis and Decision tree used in Hazard Analysis Critical Control Point developed by Food and Drug Association to FMEA principles.

Rationale

- Data from near-miss and incident reports were rarely analyzed for planning improvement projects.
- In addition, there had been no proactive approach for identifying potential risks of medical errors at the clinic.
- As a result, recommendation to “be careful” or “ensure double checks” had been the most common end results of discussions at the Risk Management Committee.
- Building a proactive culture in the risk management will promote patient safety and improve the quality of services offered at the clinic.

Objectives

- **To prevent errors by taking proactive and systematic approach**
- **To promote patient safety and improve the quality of services**

FMEA

FM=Identification of failure modes

Failure modes
-problem (not a cause)
For example: wrong patient, wrong medication, missing records, etc.

Identification
Examine possible failure modes from multi-perspective and process mapping approach

EA=Evaluation and analysis of effects

Analysis and measures
Analysis of each failure mode by calculating the risk priority number (RPN)and exploring the countermeasures against high scoring failure modes

RPN = **Severity** × **Occurrence** × **Detection**

Materials and methods

Healthcare FMEA steps

- Near misses and incident report data from the Risk Management Committee

Step 1 • Define the topic (potential area of change)

- The team analyzed the previous year’s data

Step 2 • Multidisciplinary team including an advisor

- The Committee recruited members from different departments or professional backgrounds.
- The team members for this project consisted of physicians, nurses, medical technologists, the risk managers and clerks.
- The team members are given lectures and training on FMEA principles.

Step 3 • Graphical description of processes

- The team created FMEA-based improvement projects based on the analysis data, and reported to the Risk Management Committee.

Step 4 • Hazard analysis

- List all the possible failure modes
- Calculate hazard score using the hazard matrix
- Apply decision tree for actions to proceed or not
- Record in HFMEA worksheet

Step 5 • Actions and outcome measures

Hazard matrix	***Severity effect***			
Probability	Catastrophic	Major	Moderate	Minor
Frequent	16	12	8	4
Occasional	12	9	6	3
Uncommon	8	6	4	2
Remote	4	3	2	1

Results

1.Prevention of medical billing error related to *Helicobacter pylori* test

Causes of failure modes

Ambiguous and unstandardized workflow with regards to different visits, and no confirmation system

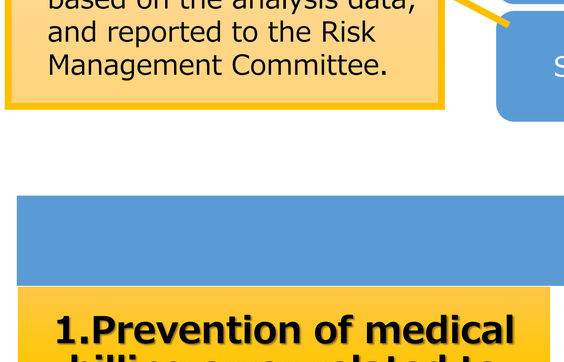
Countermeasures

Developing flow charts, staff education and monitoring

Monitoring and evaluation

NO similar occurrence of the medical billing error since the measures were implemented, except one case in 2017.

Outcome



2. Reduction of fall associated with vaso-vagal reflex

Causes of failure modes

Incomplete assessment, lack of assessment and action guidelines, and incompliance to the procedure due to patient pressure.

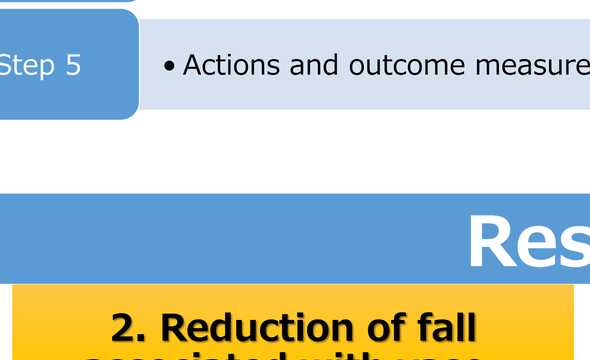
Countermeasures

Guidelines on vaso-vagal reflex, education and monitoring programs

Monitoring and evaluation

Dramatic decrease after the measures were taken; however, difficult to completely eliminate the occurrence.

Outcome



3. Reduction of wrong time signatures

Causes of failure modes

Lack of knowledge, incompliance to policies, negligence and distraction

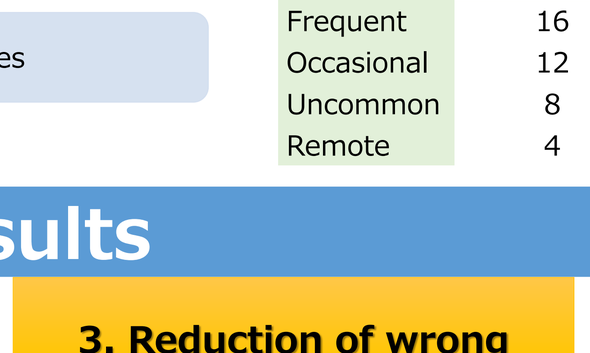
Countermeasures

Processes to ensure correct signatures, and a technological solution if it fails

Monitoring and evaluation

NO significant reduction especially among new staff, consistent education and technological solutions necessary to effectively control these errors.

Outcome



4. Reduction of wrong patient errors at the outpatient department

Causes of failure modes

Non-compliance to patient identification and effective communication policies for verbal and intercom communication

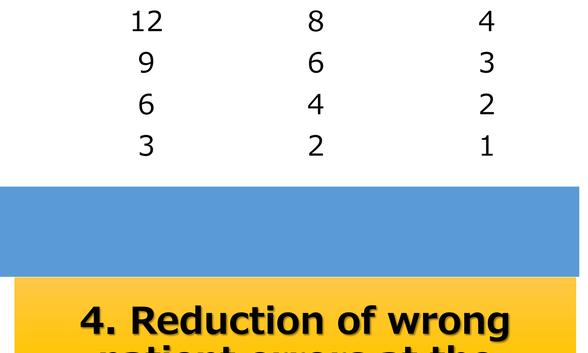
Countermeasures

Processes to comply with the above policies

Monitoring and evaluation

NO similar error after implementation of measures, which might also be contributed by low patient volume due to COVID-19.

Outcome



Discussions and conclusions

Learning points

- Errors could be prevented by taking proactive and systematic approach such as FMEA.
- Errors tend to decline within one year after measures are taken, but tend to rise again after one year. Therefore, we need continuous monitoring for error occurrence.
- Errors are strongly related to the workload of the staff, therefore, we need to consider the ratio of error occurrence to patient volume rather than the number of errors alone.
- Errors cannot be reduced with individual measures such as reassurance and confirmation.
- When we did not take systematic measures against certain errors, it rarely leads to behavior change and achieves the target behavior or maintain the achievement.

Reflection and messages to others

- We have not included patients and families in the planning, implementation and evaluation of the project.
- If we were to start this again, we would make sure we have reached out to the patient and family population how they could report feedback on their inconvenience for such errors.
- Right now we continue monitoring the project. The greatest challenge is staff workload and time.
- For some errors, specific innovative measures are required in additional to conventional measures, focusing on individual approaches.
- However, the leadership needs to be committed to patient safety and quality in order to adopt innovative approaches, which usually require investment in manpower, money and materials.

References

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