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HEALTHCARE FAILURE MODE & EFFECT ANALYSIS: PRE-ANALYTICAL ERRORS AT BLOOD COLLECTION CENTER

Healthcare

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ABSTRACT

HFMEA (Healthcare failure mode & effect analysis) is a systematic, proactive, multidisciplinary team-based approach of identifying and preventing problems. This can also be used in the laboratory for improving processes to enhance patient safety. **Aim:** A study to reduce pre-analytical errors at blood collection center in OPD of a public sector tertiary care teaching hospital.

Objectives:

1. To identify the various failure modes and effects at the blood collection center which can lead to pre-analytical errors.
2. To carry out the risk assessment of the identified failure modes by assigning a numeric value known as Risk Priority Number (RPN).
3. To prioritize various types of failure modes & suggest recommendations to avoid such events.

Methodology:

Various failure modes were identified & their potential to cause patient harm was evaluated using the HFMEA tool. Only pre-analytical errors are included in the study. RPN were compared before and after the implementation of corrective actions. **Results:** A total of 08 failure modes were identified. There was a drastic decrease in RPN of all identified failure modes. **Recommendations:** Under technology and infrastructure: Barcoding of samples, automation in the form of HIS/LIS, installation of Pneumatic tube system. Under HR management: Qualified staff and training to staff **Conclusion:** HFMEA technique can be applied to the processes of a medical laboratory & offers a high potential for improvement. To prevent a risk, it has to be identified first.

KEYWORDS

HFMEA, Pre-analytical errors, Blood collection center

INTRODUCTION

Laboratory provides diagnostic clues, assists in therapeutic decision-making and determines clinical progress for patients.[1] An efficient laboratory service also helps in prompt disposal of OPD cases and also reduces the average length of stay of admitted patients.

Provision of a sample collection facility in the outpatient department of large hospitals is necessary because of the high quantum of OPD investigations.

Processes in a laboratory are divided into three phases on the basis of workflow:

(a) Pre-analytical phase: from requisition of investigations till processing of sample in an autoanalyser.
(b) Analytical phase: from processing of sample till the result.
(c) Post-analytical phase: consist of dispatch of reports or intimation of critical lab reports to treating doctor or patient.

Errors arising in a laboratory are classified into pre-analytical, analytical, and post-analytical, depending upon their source and time of presentation.[2]

Nowadays diagnosis is very much dependent upon reliable laboratory data. It is therefore pertinent to ensure the credibility of the results before reaching to the diagnosis.

Healthcare Failure Modes and Effects Analysis (HFMEA) is a prospective proactive approach that identifies and improves steps in a process thereby ensuring a safe and clinically desirable outcome. HFMEA is a tool to enhance patient safety.[4-7]

Elements of HFMEA:[9]

Failure: When a system performs in a way which is not intended.
Effect: Impact or consequences of the failure mode.
Severity: Intensity of harm caused failure mode
Occurrence: How often will the failure occurs i.e. probability of occurrence.
Detection: Ability to know that the failure has happened.

AIM:

The aim of this study was to implement HFMEA tool to prevent pre-analytical errors at blood collection center in OPD of a tertiary care hospital.

Steps of HFMEA Implementation:

Various steps of HFMEA are shown in the Fig. 1.

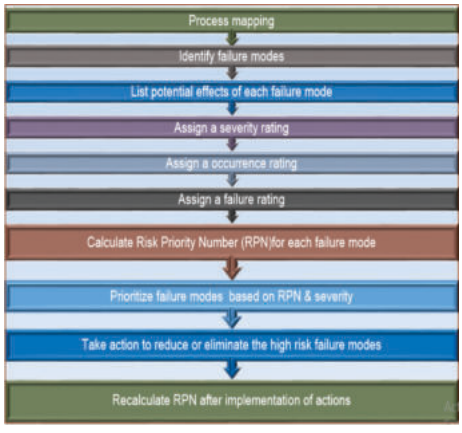

Fig. 1: Steps of FMEA

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MATERIALS AND METHODS:

This interventional study was conducted at blood collection center in OPD of a tertiary care hospital in Pune, Maharashtra.

This Blood collection center receives an average of 6000 samples per month. A multidisciplinary team consisting of health care professionals i.e. Medical Officers-02, Nursing Officers-03, Trainee nurses-02 and Lab Technician-04 were recruited. Training was given to all team members to identify failure modes at Blood collection center.[3] Two lectures (01 hr each) were conducted for the same.

This study included the pre-analytical errors only which constitutes about up to 68% of total lab errors.[2] After training, two Brainstorming session were conducted to identify various failure modes. After that individual member was asked to numerical value from 1 to 5 based on occurrence (O), severity (S) and detection (D).

Each failure mode was given a numerical value as per rating scale as depicted in Table 1 and RPN (Risk Priority Number) was calculated.

Control Measure for each failure mode were identified and action was taken accordingly. After 30 days of implementation of actions, HFMEA analysis was done again.

Table 1: Rating Scale for HFMEA

Criteria	Rating	Description
Severity (Description of injury)		
Negligible	1	No adverse clinical outcome: Unchanged patient management
Minor	2	No adverse clinical outcome: Minor change in patient management e.g. short delay in diagnosis
Moderate	3	Wrong diagnosis with additional intervention required
Critic	4	Wrong with wrong treatment started
Catastrophic	5	Mortality or permanent loss of body function
Occurrence (Failure mode probability)		
Remote	1	Failure occurs annually
Uncommon	2	Failure occurs within 2-6 months
Occasional	3	Failure occurs monthly
Frequent	4	Failure occurs weekly
Continuous	5	Failure occurs daily
Detection (Likelihood of detection)		
High	1	Failure detected immediately
Occasional	2	Failure detected intermittently at the moment of occurrence
Moderate	3	Modest failure detection at the time of occurrence
Low	4	Lowest failure detection at the time of occurrence
Nil	5	No failure detection at the time of occurrence

RESULTS:

During this study, a total of 08 failure modes were identified at Blood collection center as shown in Table 2.

Table 2: Risk failure modes with Risk Priority Number (RPN)

S.No.	Failure mode	OI	SI	DI	RPN (OxSxD)
1	Wrong test ordered	3	2	3	18
2	Wrong/ incomplete requisition form	4	2	3	24
3	Wrong labelling of container/ Vacutainer	2	4	5	40
4	Samples taken in wrong container/ vacutainer	2	2	3	08
5	Hemolysis/Lipemic sample	5	2	2	20
6	Insufficient sample volume	5	2	2	20
7	Insufficient inversions	4	2	4	32
8	Non-maintenance of cold chain	4	2	3	24

OI: Occurrence index, SI: Severity index, DI: Detection index Control measure or action taken for each failure mode is depicted in Table 3.

Table 3: FMEA analysis of Failure modes (Before action plan)

S.No.	Failure mode	Cause	Effect	Control Measure/ Action Taken
1	Wrong test ordered	Doctor in hurry	Useless result	Increased awareness among doctors/ Recommendation for CPOE
2	Wrong/ incomplete requisition form	Staff at clinical dept in hurry/ inefficient staff	Test not performed leading to Unnecessary delay	Staff training & education
3	Wrong labelling of container/ Vacutainer	Staff at BCC in hurry	Wrong diagnosis established for wrong patient	Awareness created and staff training on effective communication was given. Double check of patient name and Identification. Clean & organised work area to avoid human factors errors.
4	Samples taken in wrong container/ vacutainer	Inefficient staff	Test not performed leading to unnecessary delay	Staff training & education
5	Hemolysis/ Lipemic sample	Wrong technique of taking sample	Useless result/ test not performed	Staff training & education
6	Insufficient sample volume	Wrong technique of taking sample	Test not performed leading to unnecessary delay	Staff training & education
7	Insufficient inversions	Eqpt not available	Useless results	Roller laboratory machine was procured
8	Non-maintenance of cold chain	Eqpt malfunction, staff not trained	Sample discarded leading to unnecessary delay	Continuous temp monitoring was ensured

BCC: Blood collection center, CPOE: Computerized physician order entry

Table 4 and Fig. 2 shows a significant decrease in RPN value of failure modes after implementation of corrective actions. After implementation of actions, occurrence probability was reduced drastically and likelihood of detection was increased. However, as it is obvious that there was no change in severity of effect due to failure mode.

Table 4: FMEA analysis of Failure modes (After action plan)

S.No.	Failure mode	OI	SI	DI	RPN
1	Wrong test ordered	2	2	2	08
2	Wrong/ incomplete requisition form	2	2	3	12
3	Wrong labelling of container/ Vacutainer	1	4	2	08
4	Samples taken in wrong container/ vacutainer	1	2	2	04
5	Hemolysis/Lipemic sample	2	2	1	04
6	Insufficient sample volume	2	2	1	04
7	Insufficient inversions	1	2	2	04
8	Non-maintenance of cold chain	2	2	1	04

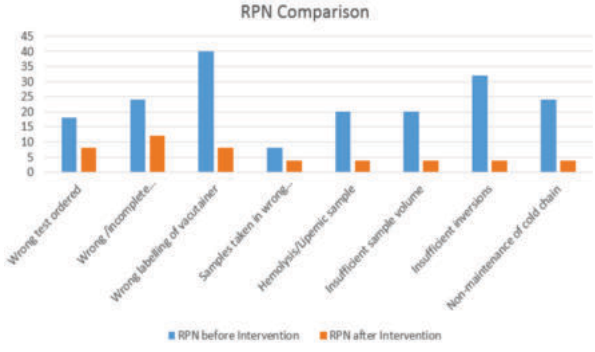

Fig. 2: RPN of failure modes before and after intervention

Apart from control measure/ actions taken as mentioned in Table 3, following structural and procedural elements should be made available.

Under technology and infrastructure:

Barcoding of samples, automation in the form of HIS/LIS, installation of Pneumatic tube system.

Under HR management:

Qualified staff by credentialing and privileging at the time of recruitment.

DISCUSSION:

The awareness and understanding of medical errors have increased rapidly 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.[8] Major message from IOM report : 'the cause of medical errors

and preventable deaths was not careless or incompetent people but bad systems'.

HFMEA (Healthcare failure mode & effect analysis) is a systematic, proactive, multidisciplinary team-based approach of identifying and preventing problems. This can also be used in the laboratory for improving processes to enhance patient safety. To prevent a risk, it has to be identified first.

Limitations:
As this is a single institution study, the findings of the study reflect the care delivery model in a particular setting. So, results of the study can be generalised but not completely to all other organisations. Care should be taken while creating the HFMEA team because successful completion is highly dependent on the team member's aptitude and commitment to introduce corrective measures. Therefore, it is important to create team of front-line people who know the process perfectly.

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Conflict of interest:
Authors declare no conflict of interest.

Disclaimer:
Views expressed in this paper are those of Authors and do not represent views or position of Indian Armed Forces.

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