A Case Study on Recall of used Scopes in the Endoscopy Department by using a Failure Mode & Effect Analysis (FMEA) Proactive Risk Management

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ABSTRACT

Failure Mode and Effects Analysis (FMEA) is the process of reviewing as many components, assemblies, and subsystems as possible to identify potential failure modes in a system and their causes and effects. The study revealed that the Risk Priority Number (RPN) was initially 450 and it has decreased to 90 after implementing all the actions in FMEA.

Keywords: Failure Mode and Effects Analysis (FMEA), Pro-active Risk Assessment, Risk Management.

1. INTRODUCTION :

Failure Mode and Effects Analysis (FMEA) is the process of reviewing as many components, assemblies, and subsystems as possible to identify potential failure modes in a system and their causes and effects. For each component, the failure modes and their resulting effects on the rest of the system are recorded in a specific FMEA worksheet. A FMEA can be a qualitative analysis [1], but may be put on a quantitative basis when mathematical failure rate models [2] are combined with a statistical failure mode ratio database. In the late 1950s, it was developed by reliability engineers to learn troubles that might occur from act up of military systems, which was one of the first highly structured, systematic techniques for failure analysis.

A few different types of FMEA analyses exist, such as:

(a) Functional
(b) Design
(c) Process

It is a core task in reliability, safety and quality engineering and also an inductive reasoning or forward logic with single point of failure analysis. Failure Mode Effect Analysis (FMEA) helps to recognize possible failure modes based on practice with similar procedures. To determine the correct failure modes, functional analyses are considered necessary.

FMEA is a used to mitigate the identified pro-active risks by either failure (mode) effect severity reduction or based on lowering the probability of failure or both. It is a full inductive (forward logic) analysis. The failure probability can only be expected and abridged by accepting the failure mechanism. It includes information on causes of failure (deductive analysis) to decrease the likelihood of incidence by eradicating recognized (root) causes.

2. HISTORY :

United States Armed Forces Military Procedures document MIL-P-1629 [3] (1949) describes the procedures for conducting Failure Mode, Effects & Criticality Analysis (FMECA) which was updated in 1980 as MIL-STD-1629A [4]. The contractors for the United States National Aeronautics and Space Administration (NASA) were using FMECA or FMEA (Failure Mode, Effects and Analysis) under a variety of names [5] by the early 1960s.

The FMEA process was used for the Apollo, Viking, Voyager, Magellan, Galileo, and Skylab projects by NASA [6]. The published Design Analysis Procedure for Failure Mode, Effects and Criticality Analysis (FMECA) ARP926 in 1967 [7] states that the civil aviation industry was an early adopter of FMEA, with the Society for Automotive Engineers. After two revisions, Aerospace

Recommended Practice ARP926 has been replaced by ARP4761, which is now broadly used in civil aviation.

Even though originally it was developed by the military, FMEA methodology is now extensively used in several industries including healthcare [8]. Toyota has taken this one step further with its Design Review Based on Failure Mode (DRBFM) approach. The method is now supported by the American Society for Quality which provides detailed guides on applying the method. [9] To overcome the shortcomings of FMEA and FMECA a Failure Modes, Mechanisms and Effect Analysis (FMMEA) has often been used.

At Krishna Institute of Medical Science (KIMS) Hospitals, Secunderabad, Telangana, India the Endoscopy Department performs following procedures to provide the high-quality endoscopy services to all age group of patients and genders that cover both diagnostic and therapeutic Gastro-Intestinal (GI) Endoscopy procedures with the best possible outcome.

1. Esophago-Gastro- Duodenoscopy (EGD) both diagnostic and therapeutic
2. Colonoscopy Both diagnostic and therapeutic
3. Endoscopic Retrograde Cholangio-Pancreatography (ERCP)
4. Capsule Endoscopy
5. Balloon insertion and removal
6. Polypectomy
7. Endoscopic ultrasound both diagnostic and therapeutic.
8. Bronchoscopy.
9. Percutaneous Endoscopic Gastrostomy (PEG) tube insertion and replacement.
10. pH monitoring.
11. Foreign body removal.

The Endoscopy Department has scopes to perform all kinds of endoscopies as well as bronchoscopies.

3. REVIEW OFLITERATURE :

The team has reviewed the relevant literature to know the Severity, Occurrence and Detection. Approximately 1 out of 1.8 million Gastro-Intestinal (GI) endoscopy procedures [10] get the health care-associated infection.

The actual occurrence rate of dissemination of health care-associated infection through endoscopy may go unestablished because of technically insufficient monitoring, no monitoring at all, low frequency, or the absence of clinical symptoms [11]. In the studies of endoscopy-related infections between 1966 and 1992 in the United States, 281 patients were infected after GI endoscopy [12]. After GI endoscopy in 116 hospitals, Gorse and Messner [13] reported 6% iatrogenic infections. 251 patients infected after GI endoscopic procedures were reported in the United States during the period of 1974 to 2004 with 30 outbreaks of endoscopy-related infections and cross-contaminations [14]. Two leading causes of post endoscopic infection and contamination are inadequate decontamination procedures and equipment malfunction. The studies revealed that quality control systems could prevent around 91% of the infections identified.

Microbial Sources of infection: Exogenous

A flexible endoscope or accessories used in an endoscopy procedure introduce microorganisms which develops the exogenous infections into the patient's body. However, use of approved or evidenced based reprocessing guidelines can prevent such infections. Below listed are the numbers of sources from where the exogenously acquired microorganisms may originate:

1. Use of inadequately cleaned and or improperly reprocessed previously used endoscopes.
2. During reprocessing there could be a contamination due to environment, organisms or water to the endoscope, accessories, or automated endoscope re-processor.
3. During final handling and storage after re-processing, there could be contamination due to environment or skin microorganisms to the endoscope and accessories.

The suction/biopsy channel or any other channel in the flexible endoscope [15], the water bottle and tubing used for endoscopy procedures [16], components of the reprocessing procedure [17], tap water used for the final rinse after disinfection/sterilization[18]may be the reservoirs for exogenous micro-organisms [19]. Maximum guiding principle [20] nowadays commend that, if possible, the final rinse water should be sterile, filtered or purified free of bacteria. Flushing the

channels with 70-90% alcohol after the rinse is critical if tap water is used for the final rinse, which helps to eradicate any remaining water microorganisms presented from the tap water rinse [21].

In Bronchoscopic procedures, the flushing process results in a higher probability of infection rising from any exogenously presented microorganisms. It merely imitates the higher probability that exogenous microorganisms presented into the lung in amalgamation by a certain degree of trauma will result in an infection associated to the same event occurring in the gut.

Poor endoscope design, which leads to an inability to effectively clean and disinfect the endoscope. Cêtre et al. reported Pseudomonas aeruginosa in Broncho Alveolar Lavage (BAL) cultures from 117 of 418 patients having bronchoscopy [22]. A fault was found in the bronchoscope design that led to persistent pseudomonas contamination at the entry port of the biopsy channel. Similar events occurred simultaneously in two other large centers necessitating the recall of these bronchoscopes. The issue of poor equipment design is also relevant to rigid sigmoidoscopes where there is a risk of cross contamination arising from the air insufflation bellows [23], unless an in-line filter or single-use bellows are used.

Pseudomonas infection has recently been associated primarily with flexible bronchoscopy [24] and attributed to damaged bronchoscopes [25], non-removal of biopsy valves, poor biopsy channel port design [26], ill-fitting or incorrect Automated Flexible Endoscope Reprocessor (AFER) endoscope connectors and defective AFER [27]. The reports of the 2001 outbreak of pseudomonas infection from faulty bronchoscopes included the possible contribution to the death of three patients [28] and described the recall of approximately 14,000 bronchoscopes worldwide.

Experience in Australia and New Zealand has shown that the published recommendations for interpretation of positive findings have allowed users to deal appropriately with insignificant contaminants, and that negative cultures at a time of minor infection control breakdowns have helped to avoid unnecessary patient recall and testing. The published positivity rate of routine endoscope surveillance cultures has varied from high to very low [29]. The recommendations for surveillance cultures below represent the minimum expected of an Australasian endoscopy unit.

The Reprocessing of Flexible Gastrointestinal Endoscopes standards of infection control commend that the below listed parameters should be documented in the patient's record for all endoscopy procedures:

1. The procedure date &time
2. The patient's name & medical record number
3. The endoscopist
4. The endoscope model & serial number
5. The AER (Automated Endoscope Re-processors-if used) model & serial number or other identifier
6. The staff member(s) reprocessing the endoscope

This information needs to be recorded whether reprocessing is done manually or in Automated Endoscope Re-processors (AERs) [30].

Records of the use of each endoscope, including model number and serial number. Records should document the date and time of use, the type of procedure involved, model number and serial number of the scope used and the initials of the person(s) responsible for reprocessing the scope [31].

The risk assessment is a part of Joint Commission International Accreditation and other several national accreditations as well. The research studies conducted to study the impact of accreditations revealed that there is positive impact on the healthcare services.

The Impact of Hospital Accreditation on the Ambulance Services Satisfaction [32], Completeness of Personnel Files in Human Resource Department [33], the Number of Occurrence Variance Report or Incident Reports [34].

Patient's Satisfaction of Physiotherapy Department Services [35], Dietary Services [36], Laboratory Department Services [37], Emergency Department Services [38], In-Patient Department Services [39], Haemodialysis Department Services [40], Radiology Department Services [41], Pharmacy Department Services [42], and Out-Patient Department Services [43].Impact of

National Accreditation on the Patients' Experience of Ambulance Services: A Case Study [44] and Hemodialysis Department: A Case [45].
The Impact of Planetree Certification on a Nationally and Internationally Accredited Healthcare Facility and its Services [46]. A Comparative Study on Laboratory and Blood Bank Performance by Using the Quality Indicators [47], the impact of CBAHI accreditation on critical care unit outcome quality measures: a case study [48].

4. METHODOLOGY:

The FMEA includes below steps as follows:
Step 1: Select a high-risk process and assemble a team.
Step 2: Diagram the process:
Step 3: Brainstorm potential failure modes and determine their effects.
Step 4: Prioritize failure modes.
Step 5: Identify root causes of failure modes
Step 6: Redesign the process
Step 7: Analyze and test (Pilot) the new process
Step 8: Implement and monitor the redesigned process.

Step 1: Select a high-risk process and assemble a team.

The Quality Improvement Team has selected the Failure Mode Effect Analysis (FMEA) on Recall of Used Scopes in Endoscopy Department, as it is a High Risk, High Cost and Problem Prone subject. However, till date there is not a single incident on post endoscopy infection in which we recalled the used scope, hence we never ever had such incident at our facility. We noticed that we are not documenting the scope model and serial number in the patient records and in the scope cleaning/disinfecting logbook, to recall the used scope post endoscopy.

Table 1 : Criteria for Severity-Occurrence-Detection Ratings

Rating	Criteria		
	Severity	Occurrence	Detection
1	Not noticeable to customer	Highly unlikely (< 1 in 1.5 million opportunities).	Almost certain to detect failure.
2	Some customers will notice. Very minor effect on product or system.	Extremely rare. (1 in 150,000 opportunities)	Excellent chance of detecting failure:99.9%
3	Most customers notice. Minor effect on product or system.	Rare (1 in 15,000 opportunities)	High chance of detecting failure : 99.9%
4	Customers slightly annoyed. Product or system slightly impaired.	Few (1 out of 2000 opportunities)	Good chance of detecting failure: 95%
5	Customers annoyed. Noncritical aspects of product or system impaired.	Occasional. (1 out of 500 opportunities).	Fair chance of detecting failure: 80%
6	Customers experience discomfort or inconvenience. Noncritical elements of product or system inoperable.	Often. (1 out of 100 opportunities).	Mitigate detect failure: 50%
7	Customers very dissatisfied. Partial failure or critical elements of product or system. Other systems affected.	Frequent. (1 out of 20 opportunities)	Unlikely to detect failure : 20%

8	Customers highly dissatisfied. Product or system inoperable, but safe.	Repeated. (1 out of 10 opportunities).	Very unlikely to detect failure:10%
9	Customer safety or regulatory compliance endangered, with warning.	Common. (1 out of 3 opportunities)	Highly unlikely to detect failure:5%
10	Catastrophic. Customer safety or regulatory compliance endangered, without warning.	Almost certain. (> 1 out of 2 opportunities)	Near certain not to detect failure, or no controls in place.

There is no threshold value for RPNs. In other words, there is no value above which it is mandatory to take a recommended action or below which the team is automatically excused from an action.

Table 2 : Various designations in the Department

Sr. No.	Designation
1.	Head of the Department of Gastroenterology and Endoscopy
2.	Head Nurse of Endoscopy
3.	Medical Director
4.	Director of Nursing
5.	Quality Manager
6.	Risk Manager
7.	Infection Control Practitioner
8.	Infection Control Link Nurse -Endoscopy
9.	Quality Link Nurse- Endoscopy

Step 2: Diagram the process:
The team studies all the entire processes, Sub processes for the selected topic of the FMEA as elaborated in the below diagram number-1.

Step 3: Brainstorm potential failure modes and determine their effects.
The brainstorm sessions were conducted with all the team members to know the potential failure modes. It was revealed that in the Procedure Room, neither the nurses nor the doctor documents the scope model and serial number in the patient records during or post procedure. Also, after this process, the concern nurse takes this used scope to cleaning area where she again never documents the patient name, ID number, scope model and serial number, which fails to recall the used scope in case a patient return to the department or OPD with post endoscopy infections.

Step 4: Prioritize failure modes.
The team prioritized the below failure modes:
1. Failure to document the scope model number and serial number in the patient's record.
2. Failure to document the Patient Name, ID Number, Scope Model, Serial Number, and Doctor Name in the scope cleaning record.
3. No competencies on scope cleaning and documentation.

Step 5: Identify root causes of failure modes.
The root causes of failure modes includes:
1. There is no policy and procedure on documenting the Scope Model, and Serial Number of the used scope at present.
2. There is no documentation of Scope Model and Serial Number in the scope cleaning/disinfection logbook.
3. No education and training on recall of used

scopes.

Step 6: Redesign the process

The team redesigned the process based on the identified potential failure modes. Please refer to the Diagram-3.

Step 7: Analyze and test (Pilot) the new process.

The team analyzed and tested the modified process for the compliance, and there were no issues in documenting the scope model and serial number of the scope used in the patient record and also the scope cleaning document is revised to incorporate all the requirements. The team analyze the FMEA by using the above table (please refer to the FMEA).

Step 8: Implement and monitor the redesigned process.

The team implemented the modified process and compliance monitored in the form of a quality indicator.

Formula = Total number of patients with documented scope model and serial number in the patient record in one month X 100 / Total number of procedures performed in the same month.

Discussion:

Diagram No-1 explains the entire process and sub-processes from Endoscopy Reception to the Discharge of Patient from the department.

Reception:

At reception, the staff put the Patient Identification band on the patient's right wrist, check for Nil Per Os (NPO) /Bowel Status, completes the fall risk assessment, checks procedure consent, checks sedation consent, checks high risk consent (if applicable), checks invoice and secures the valuables of the patient.

Changing/Enema Room:

In the Changing/Enema Room the staff cleans and disinfects the scopes but does not document scope model, scopes serial numbers in the scope cleaning log book.

Procedure Room:

In the procedure room, the staff connects the patient to the monitors to monitor and document the vital signs of the patient during the procedure and the doctor will assess patient to ensure that the patient is ready for discharge.

Scope Cleaning Room:

In the Scope Cleaning Room, the staff cleans and disinfects the used scopes. However, staff does not document the scope model, scope serial number in the scope cleaning log book.

Recovery Room:

In the Recovery Room, staff the staff connects the patient to the cardiac monitors to monitor and document the vital signs of the patient, and the doctor assess the patient to ensure that the patient is ready for discharge based on the set criteria.

Discharge from Endoscopy Recovery Room:

The patient is discharged from the Endoscopy Recovery Room once the patient meets the requirements of discharge from the recovery room. In this process, the staff provides education to the patient and or family about what things should be done and what not to be after discharge. Also, the report and a Compact Disk (CD) are given to the patient or family and the staff removes the patient Identification Wrist Band.

Diagram No-2 explains the failure modes in Changing/ Enema Room as in this Room the staff cleans and disinfects the scopes but does not document scope model, scopes serial numbers in the scope cleaning log book, which is a failure mode where we should take actions to improve the process.

Diagram No-3 explains the failure modes in Scope Cleaning Room as in this Room the staff cleans and disinfects the used scopes but does not document the scope model, scope serial number in the scope cleaning log book, which is a failure mode where we should take actions to improve the process.

FMEA Number-1 (October 5th, 2007):

The first Pro-Active Risk Assessment was conducted on October 5th, 2007 by using the FMEA tool which revealed that the potential failure mode was Nurses failed to document Name and Serial Number of the used scope in the patient's medical record. The Potential Effect(s) of Failure could be- difficulty in recalling the used scope for the patient, post endoscopy. The severity was 9, Occurrences core was 10, Current Process Controls were Operator training and instructions, Detection was 5 and Risk Priority Number (RPN) was 450.

FMEA Number-2 (November 1st, 2007):

On November 1st, 2007 the second FEMA was conducted after implementation of the planned actions. The recommended action(s) were to document the Name and Serial

Number of the used scope in the medical record of the patient and in the scope cleaning logbook. The Head Nurse and Head of the Department of Endoscopy were responsible and they have completed the action as per the given timeframe. After implementation, the Severity Action Results were measured once again which were as follows: Severity-9, Occurrence-1, Detection-10 and RPN became 90.

5. CONCLUSION :

It is very evident that the Risk Priority Number (RPN) which was 450 initially has decreased to90 after implementing all the actions as listed in the FMEA. The occurrence score has decreased from 10 to 1, detection from 5 to 10 and Risk Priority Number (RPN) from 450 to 90. However, the severity score remains the same.

6. LIMITATIONS OF THE STUDY :

This study is limited to the Krishna Institute of Medical Science (KIMS), Secunderabad, Telangana State, India.

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8. DISCLAIMER :

This publication contains information obtained from authentic and highly regarded sources. Reasonable effort has been made to publish reliable data and information, but the author and the publisher cannot assume responsibility for the validity of all materials or for the consequences of the use.

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Appendices

DIAGRAM-2: ENDOSCOPY SUB-PROCESSES FLOW DIAGRAM:

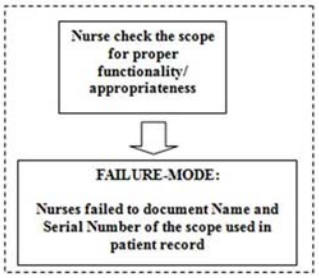


DIAGRAM-1

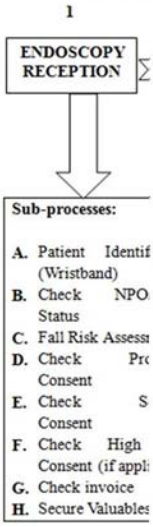
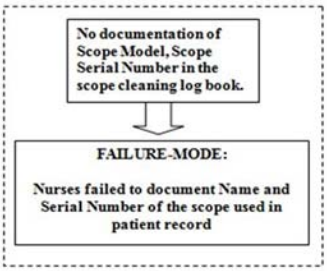


DIAGRAM-3: ENDOSCOPY SUB-PROCESSES FLOW DIAGRAM



FAILURE MODE AND EFFECTS ANALYSIS

FMEA Number: 1
FMEA Date: October 5 th, 2007

Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s)/ Mechanism(s) ofFailure	Occurrence	Current Process Controls	Detection	RPN	Recommended Action(s)	Responsibility and Target Completion Date	Action Results				
										Actions Taken	Severity	Occurrence	Detection	RPN
Nurses failed to document Name and Serial Number of the scope used in patient record	It is impossible to recall the used scope for the patient post endoscopy.	9	No documentation of Scope Name and Serial Number in the patient record	10	Operator training and instructions	5	450	To document the Name and Serial Number of the scope used in the medical record + in the Logbook of cleaning.	Head Nurse and Head of the Department of Endoscopy					

FAILURE MODE AND EFFECTS ANALYSIS

FMEA Number: 2
FMEA Date: November 1 st, 2007

Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s)/ Mechanism(s) of Failure	Occurrence	Current Process Controls	Detection	RPN	Recommended Action(s)	Responsibility and Target Completion Date	Action Results				
										Actions Taken	Severity	Occurrence	Detection	RPN
Nurses failed to document Name and Serial Number of the scope used in patient record	It is impossible to recall the used scope for the patient post endoscopy.		No documentation of Scope Name and Serial Number in the patient record		Operator training and instructions			To document the Name and Serial Number of the scope used in the medical record + in the Logbook of cleaning.	Head Nurse and Head of the Department of Endoscopy	Nurses document	9	1	10	90