



Research Article

**A STUDY OF THE MEDICAL RECORDS DEPARTMENT PROCESSES ACCORDING TO NABH IN A TERTIARY CARE SUPERSPECIALITY HOSPITAL IN THE UNION TERRITORY OF JAMMU AND KASHMIR**

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**ABSTRACT**

Background: Medical Records Department (MRD) is a vital supportive service of any health care organization. Patient care requires a chronological record of care and treatment and this enables hospital administrator to evaluate the quality of medical record department services. Objective: To carry out Failure mode and effective analysis (FMEA) study of the processes of MRD at Shri Mata Vaishno Devi Narayana superspeciality Hospital (SMVDN). Study Design: It is an applied Descriptive study. Methodology: The analysis was done using primary and secondary data during the period from 1 January to 31<sup>st</sup> July 2022. The tool used was the FMEA worksheet. The parameters in the worksheet were collected. The results of each step were recorded in the FMEA Worksheet. Results: In 5% of the files, MRD checklist was not present and in 95% of the files, the checklist was present. 83% of the files were without ICD Code and remaining 17% were with ICD Code. 80% of the files were without Medico Legal Stamps and 20% of the files were with stamps. About 62% of the death files were not stored in the locker and only 38% of the death files were stored in locker. 73% of the files reached on time within 24 hours while 27% of the files do not reach on time. Conclusion: FMEA can be used as a tool for continuous improvement of quality of products and services in the hospitals.

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**INTRODUCTION**

The history of FMEA dates back to more than 30 years ago. It was first introduced in 1960s in the aerospace industry. The use of the technique then extended to different companies and industries. [1] There are several methods to assess the potential risk. One of the most reliable methods is FMEA Analysis that is used for risk management and reduction of effects. The primary use of FMEA in the field of health care goes back to early 1900s, when it was used for preventing medication error in hospital. [1] FMEA technique increases staff precision and focus their attention to their possible professional weaknesses in recording medical errors and preventing failures. [1] Failure Mode and Effect Analysis (FMEA) has been widely used in high-risk industries to evaluate and mitigate process weaknesses [2, 3, 4, 5]. FMEA has been effectively applied to examine and mitigate risks and failure modes in many healthcare processes [6, 7]. Medical Record is the systematic documentation of the patient's personal and social data, history of his or her clinical findings, investigations, diagnosis, treatment given account of following up and outcome. Medical Record is of importance to the hospital for the evaluation of its service for quality patient care. Medical Record include a variety of documentation of

patient's history, clinical findings, diagnostic tests result, operation notes, post operative care, and daily notes of patients progress and medication. To improve the performance MRD and to provide effective services and better performances, manager of medical record section must have expertise and adequate knowledge of management principles. Recognition of obvious and hidden problems of medical record section and providing appropriate solutions are important tasks. [8] In the study of FMEA method, Nobari *et al.* showed that, establishing a computerized system to record medical orders would result to reduced prescription, administration, and distribution errors. [9] Days *et al* in his study stated FMEA as an effective tool to assess and prioritize areas of risk in clinical practice. [10] The present study was planned in 230 bedded SMVDN Hospital to conduct FMEA study of Medical Record Department processes of the Hospital. The study will throw more light on improving the processes of the medical record department and to provide effective services and better performance, recognition of the hidden problem of medical record section and providing appropriate solutions. [11]

**MATERIAL & METHODS**

The study was conducted at Medical Record Department of SMVDN Hospital and was an applied descriptive study

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analyzing the effects of error using FMEA methodology. This study was performed from 1 January to 31<sup>st</sup> July 2022 on selected processes of Medical Record Department. The Source of data was Primary and Secondary data. Primary Source included Data collected through the prepared Worksheet. Secondary Source included Journals, articles and websites. The tool used for this study was the FMEA worksheet. FMEA worksheet was the major instrument for collecting data for the study. The worksheet was carefully structured and designed in order to ensure easy answering. The parameters in the worksheet were personally collected for analysis and analyzed to aid reasonable findings and conclusions for the study. The targeted population of this study consisted of the MRD Staff. The results of each step were recorded in the FMEA Worksheet. The study was carried out in five stages.

**Stage1. Selection of processes**

At this stage, based on the need of the hospital, processes at risk were selected.

**Stage2. Drawing process Chart**

After the selection stage, Process chart were designed and approved by the Project Supervisors. The activities were recorded in the FMEA Worksheet.

**Stage3. Brainstorming of potential scenario and determination of error type**

At this stage, potential errors or possible errors of any of the processes were studied and their type was determined.

**Stage4. Prioritizing Error**

At this stage all identified errors conditions were prioritized by their Risk Priority Number [RPN]. For each error condition, RPN was calculated by multiplying three indicators of the severity of the error, the probability of the occurrence and failure detection.

**Stage5. Identifying Root cause of error**

At this stage, Root cause of error was identified by using ECM. Two types of Error were classified. One is Latent error including Technical and Organizational error and second is Active Failures in which human errors and others were included.

The error types are

Technical error:

- Physical structure error.
- Equipment
- Materials

Organizational Error:

- Information System
- Protocol and Procedure
- Management Decision

Human Errors

- Knowledge
- Monitoring
- Performance

**Stage6. Proposing Strategies**

At this stage, error condition >400 in the process were proposed according to the score obtained from the three indicators S, O, D and their causes.

Risk priority number (RPN) after the foregoing basic steps, risk assessors calculate Risk Priority Numbers (RPNs). These influence the choice of action against failure modes. RPN is calculated from the values of S, O and D as follows:

$$RPN = S \times O \times D$$

RPN should be calculated for the entire design and/or process and documented in the FMEA. Results should reveal the most problematic areas, and the highest RPNs should get highest priority for corrective measures.

The study employed the statistical tools for data analysis. MS Excel

Data represented through Simple percentage & Pie charts  
Total 200 files were audited: These were the tables, according to them rankings of Severity, Likelihood of occurrence and Failure detection were given and Risk Priority Number was generated at last by multiplying all of them. Severity is the seriousness of failure consequences of failure effects. Usual practice rates failure effect severity (S) on a scale of one to 10 where one is lowest severity and 10 is highest. The following table shows typical FMEA severity ratings and their meanings

**Table 1** Assessment of Medical Record Error and FMEA Detection

Severity: Determine severity, seriousness of failure, how much it affects the process.		
Severity	Ranking	Criteria
No Effect	1	Do not cause any serious effect to the process.
Minor Disruption	2	Slightly inconvenience to process Can cause inconvenience to process
Moderate Disruption	3 to 4	Cause effect to process.
Significant Disruption	5 to 6	Can cause severe effect to process.
Major Disruption	7 to 8	
Failure to meet requirements	9 to 10	Failure that cannot be prevented.

**Table 2** Likelihood of Occurrence: Examine cause of failure and how often the failure occurs; calculated by percentage through pie charts

Occurrence	Ranking	Percentage
No documented Failure	1	1 to 15%
Low relatively few failures	2	15 to 25%
Moderate some occasional failures	3	25 to 45%
High relative failures	4 to 6	45 to 55%
Very high failures almost certain	7 to 8	55 to 80%
Very high failures	9 to 10	80 to 100%

**Table 3** Failure Detection: After all the observations, Failure detected at source.

Failure Detection	Ranking	Criteria
Almost Certain	1	Detection not applicable, no failure.
Low failure	2 to 4	Error detected and can be prevented.
Moderate failure	5 to 7	Problem detected at source.
High Failure	8 to 9	Problem detection post processing
Severe	10	Very high failure, not preventable.

**RESULTS AND OBSERVATIONS**

Firstly, based on brainstorming, processes of MRD were selected and the errors were identified and analyzed using FMEA technique. Activities were drawn and recorded in FMEA worksheet. The error condition was recorded in the final worksheet. An FMEA worksheet comprising of requirements, failure modes, recommendations and then the severity, likelihood of occurrence and failure detection was developed. Then, RPN [Risk Priority Number] was calculated

by multiplying all the severity, likelihood of occurrence and failure detection. 10 major activities and their sub activities were identified and listed in the FMEA worksheet. The detected errors were classified into four types of errors which were as follows: -

1. Performance Error
2. Recording Error
3. Decision making Error
4. Informing Error

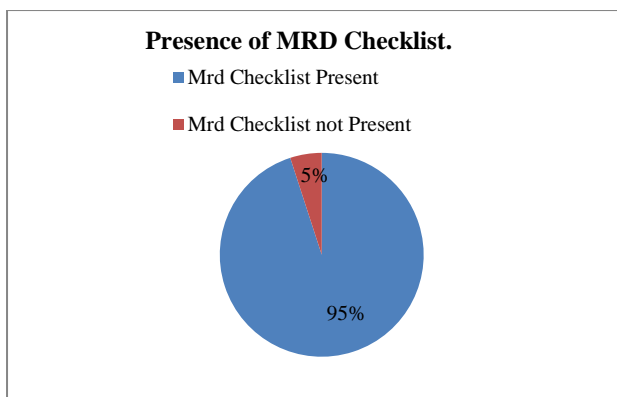
Then, 9 failure modes were detected and recorded in FMEA Worksheet. In the next step, the S, O and D were recorded and then the RPN was calculated. Nine errors with RPN more than 400 were detected as high-risk unacceptable errors and included:

1. File Audits being done by MRD
2. Files arranged in order
3. Medico legal records files stored in order
4. Medico legal files stored in locker
5. Medico legal stamps used
6. Death files stored in locker
7. Passage for Fire exit
8. Tracer card used to send file.
9. Signature of MRD Staff

These errors were detected as high-risk errors. In the fifth step, the root causes of errors with high risk were detected after brain storming based on Eindhoven Classification Model (ECM Model) and recorded in FMEA Worksheet. Finally, suggestions were provided so that the necessary measures would be developed to reduce the error. Amongst all the detected errors in the process a major part of potential error was performance errors. [Nine errors] Also, of the total nine high risk errors, were Performance Error. Based on ECM Model, it can be found that the root cause of most risk high error is Seven human Error [77.9%] and others are [Physical 11.1%] and [Material 11.1%]. However, by holding training, we can correct these errors.

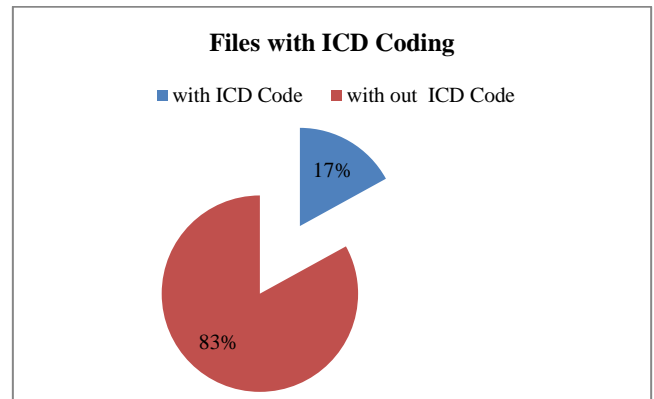
***Below are the findings of the study which were represented through pie charts***

In 5% of the files, MRD checklist was not present and in 95% of the files, the checklist was present. (Figure 1)



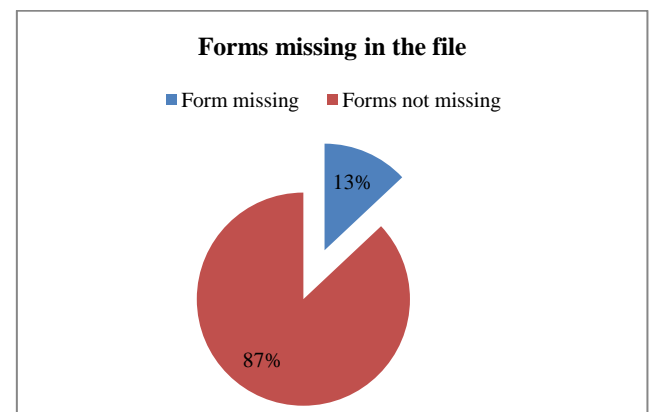
**Figure 1** Presence of MRD Checklist.

As far as International code of disease 11 (ICD 11) is concerned it was found that 83% of the files were without ICD Code and remaining 17% were with ICD Code (Figure 2)



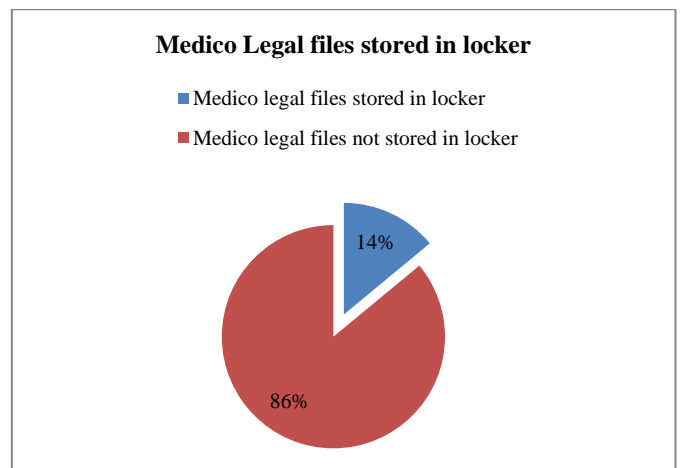
**Figure 2** Files with ICD Coding

It was observed that about 87% of the forms were present in the files and 13% of the forms were missing. (Figure 3)



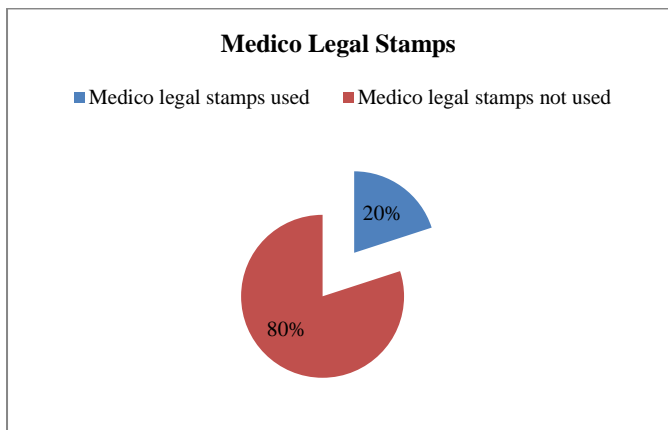
**Figure 3** Forms missing in the file

Regarding storage of Medicolegal file it was found that 14% of Medicolegal files were stored in the locker whereas 86% files were not stored in the locker. (Figure 4)



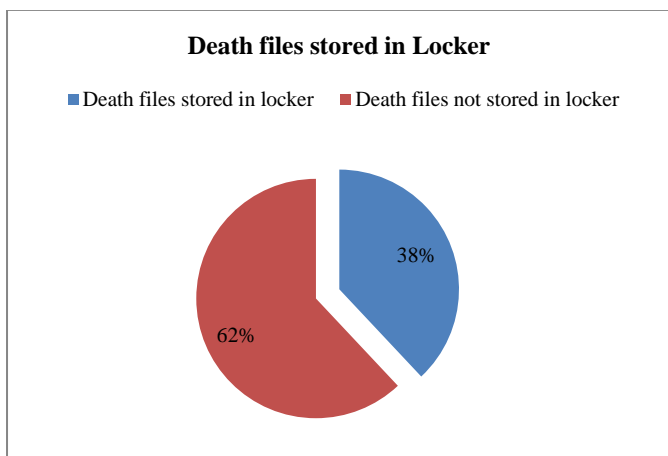
**Figure 4** Medico Legal files stored in locker

While searching for Medico legal files it was observed that 80% of the files were without Medico Legal Stamps and in 20% of the files stamp was applied. (Figure 5)



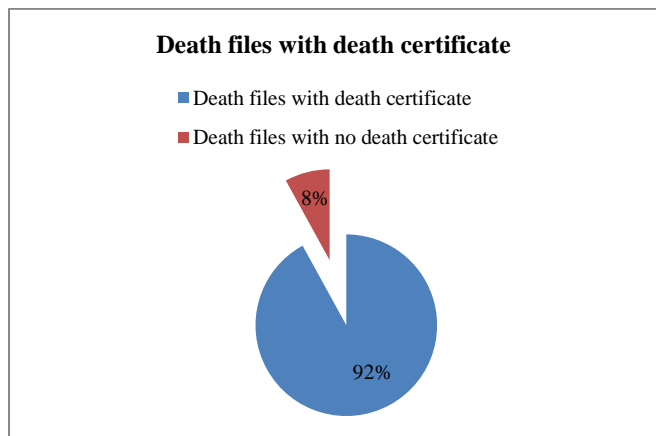
**Figure 5** Medico Legal Stamps

It was observed that about 62% of the death files were not stored in the locker and only 38% of the death files were stored in locker. (Figure 6)



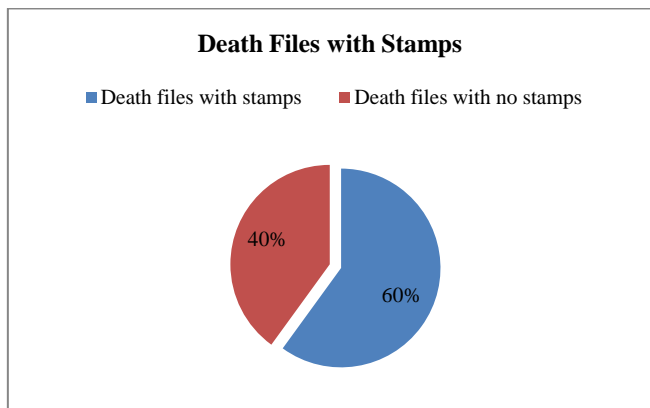
**Figure 6** Death Files stored in locker

In 92% of the files death certificate was present and only 8% of the death files were without death certificate. (Figure 7)



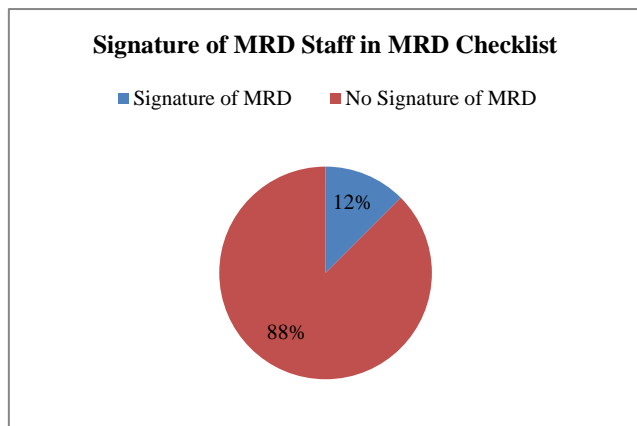
**Figure 7** Death files with death Certificate

In 40% of the death files were without stamps and in about 60% of the files stamp was applied. (Figure 8)



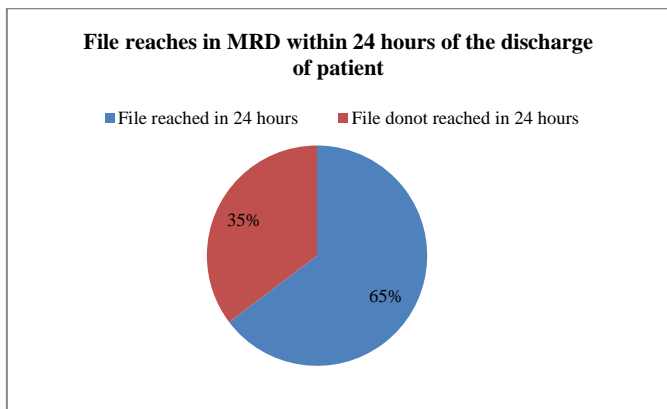
**Figure 8** Death files with Stamp

In only 12% of the files there were signatures of MRD staff on the MRD Checklist and 88% of the files were without signature of the MRD Staff on the checklist. (Figure 9)



**Figure 9** Signature of MRD Staff in MRD Checklist

It was observed that about 35% of the files do not reach on time, Rest 65% of the files were on time, i.e it reached the MRD within 24 hours of the discharge of the patient. (Figure 10)



**Figure 10** File reached in MRD within 24 hours of discharge of patient.

As far as return of files from MRD to ward is concerned it was observed that 73% of the files reached on time within 24 hours from the MRD to Wards, while 27% of the files did not reach on time. (Figure 11)

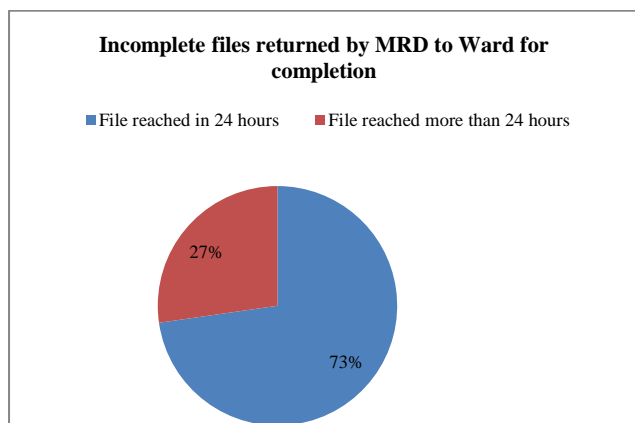


Figure 11 Incomplete files returned by MRD to ward for completion within 24 hours.

## DISCUSSION

As the results indicate, the highest RPN is related to Medico legal files stored in locker and Medico legal stamps used. Amongst all the detected errors in the process, the major part of potential error is performance error, the passage of fire block [Nine Errors]. Also of the total nine high risk errors, were Performance Error. Based on Eindhoven Classification Model [ECM], it can be found that the root cause of most high-risk errors is of Seven human Error [77.9%] and others are [Physical 11.1%] and [Material 11.1%]. However, by holding training, such errors were controllable. FMEA mechanism should be carried out continuously. The reason was that by reducing the risk of an error. The risk number of another Error may change. Thus, reviewing Risk Priority Number [RPN] after performing modifying action was necessary both to monitor the effectiveness of measures and to determine change in other error indicators associated with other errors. A study was conducted by Anjalee *et al.* on FMEA including Two independent teams (Team A and Team B) of pharmacists for two months in the Department of Pharmacy of a selected teaching hospital, Colombo, Sri Lanka. Each team had five meetings of two hours each, where the dispensing process and sub processes were mapped, and possible failure modes, their effects, and causes, were identified. A score for potential severity (S), frequency (F) and detectability (D) was assigned for each failure mode. Risk Priority Numbers (RPNs) were calculated ( $RPN=S \times F \times D$ ), and identified failure modes were prioritised. Team A identified 48 failure modes while Team B identified 42. Among all 90 failure modes, 69 were common to both teams. Team A prioritised 36 failure modes, while Team B prioritised 30 failure modes for corrective action using the scores. Both teams identified overcrowded dispensing counters as a cause for 57 failure modes. Redesigning of dispensing tables, dispensing labels, the dispensing and medication re-packing processes, and establishing a patient counselling unit, were the major suggestions for correction. The Non compliances in the current projects includes: There was no MRD Checklist present in the 5% of the files which was due to the carelessness of MRD staff. 83% of the files were without ICD coding which was again clearly the mistake of MRD Staff. The files which were placed in the racks were without MRD Staff audit. That means there were major non compliances in the MRD. An audit of 200 files was done in MRD where 100% of files were not in the order. 100% of the Medico Legal

record files were also not stored in the order. 86% of the files were not stored in locker. Many death files were not stored in order. All the non-compliances in this study were because of the MRD Staff.

## CONCLUSION

In General, Technique such as FMEA which has a team based preventive approach increases process accuracy and brings their attention to the weakness in the process. The advantage is that the employees are not seen as wrong doing in the systematic view of mechanism. Instead by finding root cause particularly for human error a safe environment without any risk is tried to be provided for the employee. Also tracking high risk error in this study by one of the RCA methods called ECM has helped in reducing the impact of some limitation of FMEA such as time-consuming process and thus increase the efficiency and effectiveness of the method.

## Limitations

Medical Record section in SMVDN was recently shifted to the basement and their record system was not up to the mark. The methodology has not been compared with results from the traditional FMEA technique.

## Recommendations

As the results indicate, the highest RPN is related to the passage of fire block, Medico legal records files stored in order and Medico legal files stored in locker. Amongst all the detected errors in the process, the major part of potential error is performance error. Hence it is recommended that Daily audit should be included in the routine to follow the compliance better. A Public address system (PAS) should be installed in the MRD office. Fire fighters/security service providers should take proper handover.

## Disclosure Statement

The authors did not receive any funding for this study.

## Consent for Study

Informed consent was taken from all participants.

## Conflict of Interest

The authors have no conflict of interest to declare.

## Authors' Contributions

The research concept was given by Dr. (Brig) RS Saini. The research was carried out by Dr Mukul Gupta with supervision of Dr Khalid Mehmood. Dr. (Brig) RS Saini was the facilitator to conduct the FMEA discussions. Dr Mukul Gupta wrote the manuscript in consultation with Dr Akshita Abrol. All authors iteratively read the manuscript, revised and agreed with the final version of the manuscript.

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