



Study on RCA and HFMEA in Patient Safety with Measurable Outcomes: A Case Scenario

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Author's contribution

The sole author designed, analysed, interpreted and prepared the manuscript.

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Case Study

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ABSTRACT

Introduction: Safety concerns of outborn neonatal infant babies during transportation to the NICU had been a concern. Better team coordination and improvement in the technical competency of the care providers helped implement the ambulance policy.

Methods: With the background of the Donabedian model and Juran's Trilogy concepts, process improvisation was performed. The RCA (Root Cause Analysis) and HFMEA (Healthcare Failure Mode and Effects Analysis) as tools were used for better deliverables.

Results: The measurable outcomes in terms of time taken for departure before and after were compared, which showed considerable significance. By measuring the baby temperatures, a significant difference was seen in clinical aspects.

Discussion: Lack of infrastructure, equipment for neonatal transportation was a challenge that required prioritization of budget allocation. The procurement policy of equipment had to be relooked for user-friendly strategies. Lack of trained staff and doctors, which were major issues, required an intense training and development module. The challenges of hypothermia, ventilation issues during transportation of neonates were of major concern, were tackled using quality tools.

Application: To minimize the mortality and morbidity of neonates, infants by Specialized Pediatric Critical Care Transport (SPCCT) ambulance policy was implemented. The value addition was to minimize the risks and prevention of hazards.

Conclusion: Improvement in the Technical competency of nurses and caregivers was observed. Nurses were well exposed to handling transporting sick babies. Logistics, equipment handling was performed properly. With better team coordination, the babies were safe. The trust and confidence among the members of the community at large improved. The patient footfall increased in numbers.

Keywords: Patient safety; quality tools; ambulance policy; improvement; critical care; community.

1. INTRODUCTION

The safety of outborn neonates, infants, and babies is of major concern. The infant mortality in India is about 32 deaths per thousand births in 2020. Among all the babies born today, about three percent of the infants do not make it to their first birthday. The babies born in rural or suburban India require adequate care, compassion, and medical attention [1]. Today, in India, the Lack of infrastructure and equipment for neonatal transport hinders shifting these outborn babies to tertiary care centers for better care.

There are various causes for the infant mortality rate being so high. The major causes are hypothermia and ventilation issues during the transfer of neonates. Temperature regulation and maintaining them warm throughout the transient time is an important care aspect that needs constant monitoring [2]. Shifting these babies to neonatal intensive care (NICU) or Pediatric ICU (PICU) requires dedicated ambulances. Specialized pediatric critical care transport (SPCCT) ambulances are the need of the hour.

Lack of trained staff and doctors for neonatal transport is a major concern. There is a huge gap in the availability of trained staff and doctors who are exclusively dedicated to transferring neonates [3]. Training and hands-on experience to handle emergencies require proper supervision and well-defined objectives as outcomes.

Many times, the day-to-day management of drugs, medications, and consumables are to be properly handled. Replacing the used medication requires a proper checklist and monitoring. At the transport ambulance, missing or forgetting medications/consumables required during transportation hurt the functioning of the process. Rather than report adverse events and sentinel events, [4], it's better to properly implement a well-defined medication and consumable checklist and monitor the same at each shift.

Keeping the standards and incorporating best practices, two-way communication has to be established. Well-defined Ambulance protocols for communication have to be structured with inputs from the team members. These have to be

customized as per the organizational requirements.

The physical facilities, the upkeep of vehicles are to be maintained properly with timely maintains. Specifications of SPCCT ambulances were incorporated in a well-defined manner [5].

Lack of tracking system leads to disco-ordination and delays in reaching the higher centers for medical management. In this Digital era, GPS tracking of the vehicle needs to be implemented as these outborn babies need additional care and support during travel. This will invariably affect the patient footfall in NICU/PICU.

2. MATERIALS AND METHODS

Considering all issues, a prospective study for evaluation of the systems and processes was undertaken as a case study.

The problem statement was formulated in jest as follows:

- Hypothermia/ ventilation issues during the transfer of neonates
- Lack of trained staff and doctors for neonatal transport
- Lack of infrastructure and equipment for neonatal transport
- Lack of tracking system
- Missing or forgetting medications/ consumables required during transport

Representing the problem statement with root cause analysis (RCA) diagrammatic manner was performed. The Root cause analysis (RCA) [6], a basic tool for the improvement of quality care, was implemented to understand the causes and the effect for the analysis of the situation. Since there were multiple causes, diagrammatic representation by fishbone analysis would aid in providing clarity of the situation [7]. As setting the process was of prime importance, we were concerned in the formulation of the protocol and standardizing the same as per the organization's requirement. Since each cause was to be handled in a well-defined strategic manner, the top management commitment was sought out. The effect was primarily on the safety issues of the out-born babies during transportation.

Our approach was more of a bottom-up approach. Keeping in mind the safety of the Outborn babies during transportation and during to be shifting then to NICU/PICU, all the requirements were sorted out. Directions and pathways for solving the problem were provided in all discussions and meetings professionally held at regular intervals [8]. The basic tool of quality was applied in this situation as it was easy to implement. This tool was understandable to the nursing staff and other service providers at large. Since accepting the out-born babies born in rural and sub-urban areas was not established in this unit, the concept required proper planning, monitoring, coordination, and implementation.

considering tackling the problem with solutions, a dedicated team was built. The team comprised of the following members whose roles and responsibilities were well defined, and the strategies were discussed in detail for process improvisation. Table 1 represents NICU team members for transportation.

With the background of the Donabedian model for Clinical transformation, understanding the culture to implement the change strategies was incorporated. Organizational changes can be based on various theories and models [10]. This model is used as a framework encompassing three elements that are interrelated in evaluating and effecting change. The elements of structure, process, and outcome were considered in broad aspects to improvise the systems. Fig. 2 represents the Donabedian model of evaluation.

Fig. 1 shows Root cause analysis of the cause and effect of safety during transport of Outborn babies to NICU [9]. As in this case scenario,

Analysis: Tools and measurement - Fish bone analysis

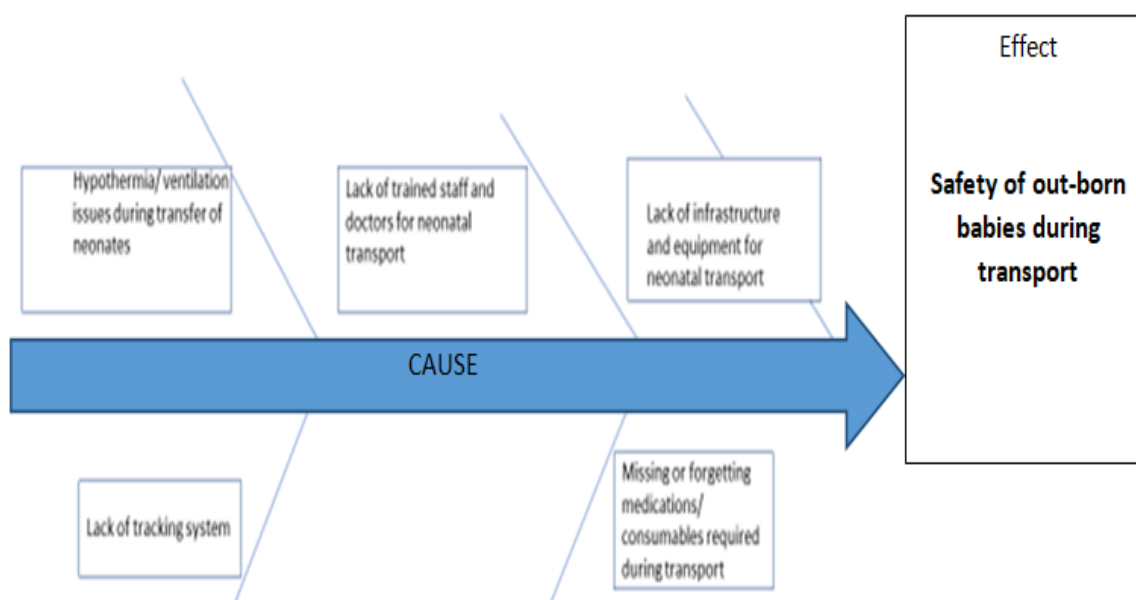


Fig. 1. Analysis tools and measurement

Table 1. NICU Team members for transportation

NICU/ PICU Transport Team	Specialized Pediatric care transport team members
Team Leader	Dr. X
Champion	NICU In-charge
Other team members	NICU Consultant
	NICU Staff On-call for transport
	Pediatric Coordinator
	Biomedical In-charge
	FMS Manager

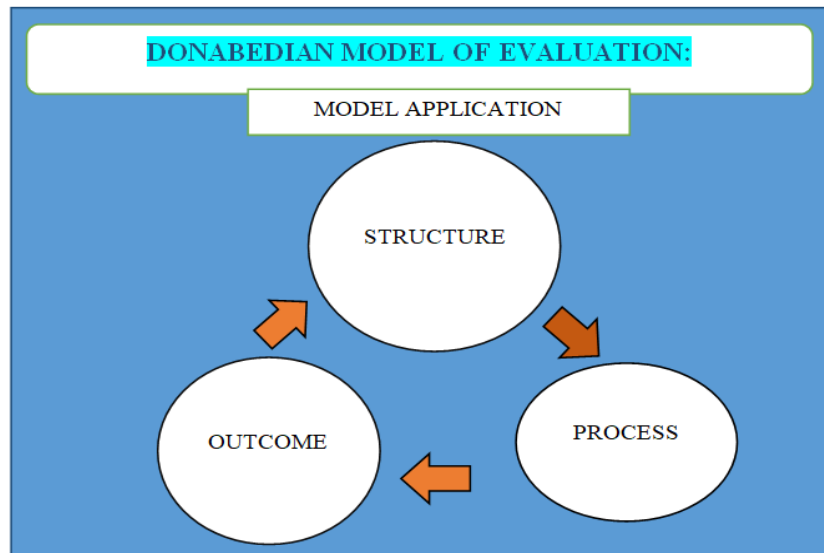


Fig. 2. Donabedian Model of Evaluation

We defined structural elements like the following:

- Budget allocation for set process
- Infrastructure facilities such as SPCCT ambulance with bassinets, ventilator support system, etc.
- Equipment's for neonatal resuscitation and oxygen supply.
- Manpower allocation such as staff nurses, doctors, Pediatric Coordinator, Biomedical In-charge, and other team members.

- The temperature of the baby was maintained before and after the implementation of the Intervention.
- Outborn admissions before and after Intervention by taking the consideration of numbers.
- Risk Priority Number (RPN) and prioritization.
- Recommendations were provided for better implementation and to reach deliverables.

The process which was to set included:

- Standard Operating Procedure (SOP)
- Checklist for drugs and medications, consumables, daily checklist of oxygen cylinders
- Schedule and roster for manpower allocation in shift rotation
- Protocol for Bi-directional Communication flow
- Training and development of the staff & doctors with certification (NALS & PALS).
- Maintains specialized pediatric critical care transport with Annual maintains contract.
- Feedback form for process improvisation by in-house employees.

The measurable outcomes as targets to be reached were as follows:

- Time is taken before and after departure

For process improvisation and betterment, changes in the system had to be established. Multidisciplinary meetings were conducted, and brainstorming sessions with valuable inputs for betterment were sorted out. The multidisciplinary team comprising of Team Leader, HFMEA Facilitator, clinicians, Recorder, staff nurses, Experts on the process are considered and nominated. If clinical and medical issues were to be addressed, at least one nurse & one doctor are entrusted with the tasks [11]. To include all areas involved in the process, improvisation was undertaken. Top management personnel and Hospital leaders with decision-making ability are involved. The elite "Outsider" to be neutral and with the vision of betterment of organization are involved in the committee which meets regularly. About 6 to 10 members are ideal for creating the core committee. The multidisciplinary team was selected for the meeting to take recommendations from each member in their respective field. Collating the same, we were able to formulate multidimensional improvements [12].

Table 2. Changes and why do you think it will improve care?

Change	Why do you think it will improve care?
Equipment was procured -Transport incubator	Temperature and breathing support provided
Transport Committee established	Team leader identified with role of all team members
Transport meeting once a month	To identify and discuss issues during transport and implement changes
Training staff and doctors on globe trotter	New equipment so all staff underwent training
Mock drills	For training and identification of process issues
Allocating a transport nurse for each shift	Staffing concerns addressed
Creating a process flowchart for transporting babies	All staff know the process as soon as call for transfer made
GPRS Tracking system	Better communication, Reaching destination on time without any hassle.
Transport kit with check list	No missing medicines/ consumables

To formulate the customized protocol for an ambulance brainstorming session was undertaken. This group technique generated a large number of ideas quickly involving all the stakeholders. All the members were encouraged to state the gap/problem. Then, all the members were encouraged to provide the causes of the problem.

- Safer transfer of babies
- Better team coordination
- The competency of Nurses improved
- Nurses are well exposed to handling transporting sick babies and equipment.

The measurable outcomes were as follows.

Table 3. Measurable outcome

Outcome	Before	After
Time taken fo Departure	1 Hour	20 mins
Temperature of baby	34°C	36.6°C

All the committee members' suggestions were documented. Everybody had to speak to all the ideas that are exhausted [13]. No suggestions were criticized. Table 2 represents changes and why do you think it will improve care?. Fig. 3 represents the Communication flow after the call originated for NICU. Taking everybody consensus, the pattern for the flow of communication was designed, and the blueprint of the same is depicted as follows.

3. RESULTS

The measurable outcomes were obtained, keeping the J.M.Juran's Trilogy concepts in mind, which comprises quality planning, quality improvement, and quality control as the basic framework [14].

Table 3 shows Measurable outcomes in terms of time taken for departure & temperature of the baby measured in degree Celsius. Improvement in the Technical competency of nurses and caregivers was observed. Nurses were well exposed to handling transporting sick babies. Logistics and equipment handling was performed properly. With better team coordination, the babies were safe [15].

As the key result areas were focused on the following aspects:

The outcomes in terms of numbers when compared before initiation of quality improvement program and after initiation of quality improvement program depicted as follows.

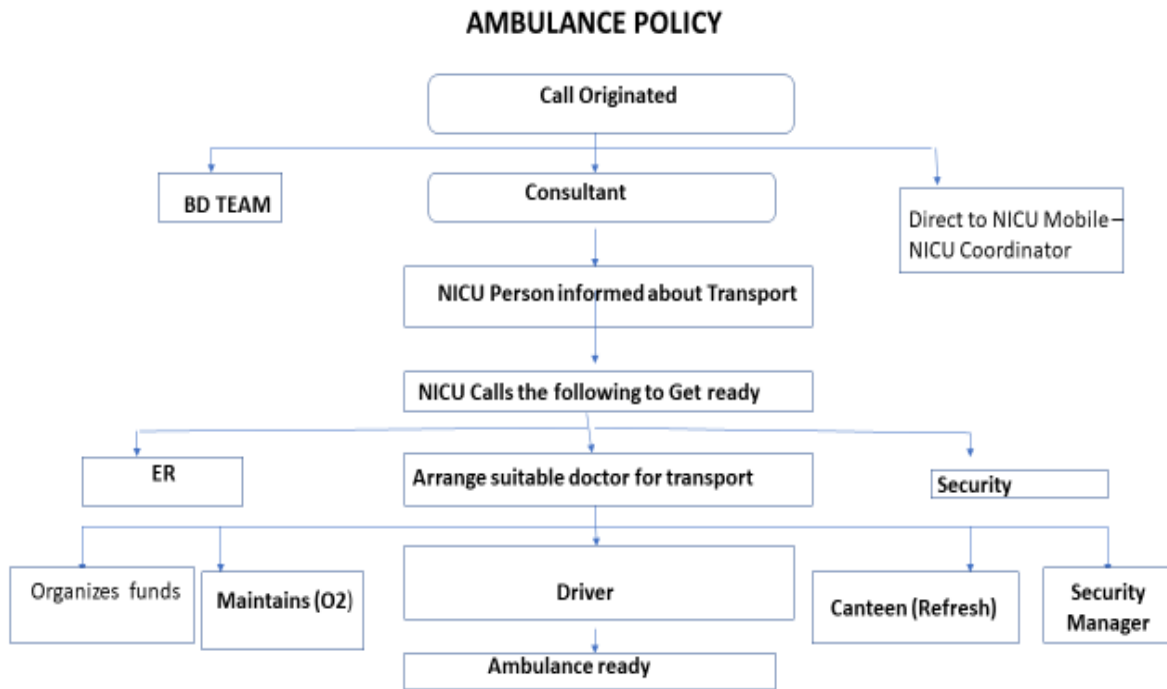


Fig. 3. Communication flow after the call originated for NICU

OUTCOME

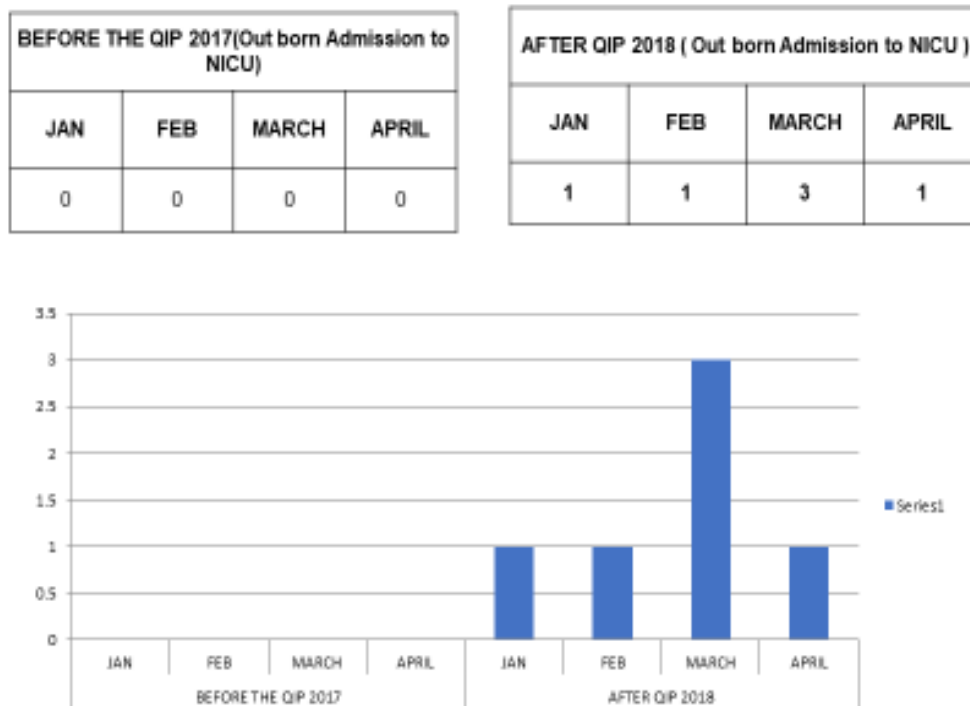


Fig. 4. Patients' footfall in the number of Outborn admission to NICU before and after QIP

4. DISCUSSION

During the process of brainstorming sessions, three major questions were kept as an insight to formulate the flow chart of communication. These questions are:

1. What shall we monitor and observe when the systems do fails?
2. How does failure make an impact on the customers?
3. What is the cause's failure?

As root cause analysis (RCA) is one of the basic tools of quality which are having its limitations. The major drawback of RCA was utilized in the retrospective time frame [16]. RCA focuses on individual cases. The advantage of the RCA is it answers "what happened and why?"

The limitations of RCA include hindsight bias and the findings that may be applied to specific cases. This may not have broader implications for the entire system. It may require a larger workforce in terms of relation to the output.

As per JCAHO – Quality of care can be defined by the following: "The degree to which health services for individuals and population increase the likelihood of desired health outcomes and are consistent with current professional knowledge." As we were able to find the root cause of the problems and wanted to go beyond the obvious [17], Healthcare failure mode effective analysis (HFMEA) was initiated. FEMA was preferred as it was an advanced tool in quality. FEMA is an effective tool and also a proactive risk reduction technique. Doing it right the first time and every time reduces and minimizes patient adversities and harm. This improves patient perspective outcomes were the main aims of introducing FEMA [18]. The advantages of HFMEA are many as it can be utilized prospective manner. It focuses on process improvisation. FEMA is used annually in the high-risk process. The major advantage is to bring a valuable impact on the entire system end to end. This doesn't require the events to occur before the study but Prevents adverse events before they happen [19]. FEMA is a pre-problem solving methodology. FEMA provides an opportunity to record what could go wrong before it does. Taking action before the failures is an appropriate step. FEMA can implement both predictive and preventative measures. By imagining the consequences before they ever occurred, we, as the hospitalist concerned with patient safety, decided to

conduct an HFMEA [20]. An interdisciplinary team was asked the question, "What can go wrong with this process, and how can we prevent failures?"

The goal of HFMEA was as follows:

- To prioritize the risks and failures and focus on the improvements and problems.
- Anticipate the possibility of failure.
- Exclude and eliminate unavoidable errors.
- Mitigate and minimize unavoidable errors.

To make the systems more fail-proof, the tool HFMEA contributes in:

- Identify the ways and means that a process may fail.
- What are the reasons for failure?
- The possible effects and outcomes of the failure
- Prioritizing the failures for further actionable and deliverables.

The limitation of HFMEA is its labor intensity. Thus HFMEA is a proactive quality tool that systematically addresses the issues in a team-based approach. HFMEA does impact the process and does not fix failures. Fig. 5 represents the depicting: when to use HFMEA?.

Fig. 6 shows Depicting Major 9 steps of HFMEA. The major nine steps of HFMEA which were implemented are as follows.

As step 5 was in place, we proceeded to the next step of 6 for implementation. In HFMEA, Prioritizing the failure modes Risk Priority Number (RPN) was a major task in improvisation.

To calculate the risk priority number (RPN), the formula used:

$$RPN=S*O*D; \text{ Severity } \times \text{ Occurrence } \times \text{ Detectability.}$$

Importance of RPN:

- The RPN determines and provides information on where is the greatest danger lies and can be predicted.
- By detecting the risks, the implementation of best practices and quality concepts can be performed.

- Detectability is difficult in outsourced resources, whereas it's easy to involve partial or complete subcontracted resources.
 - If there is a high patient-to-nurse ratio which can negatively affect and reduce the possibility of detecting the hazards confined in the clinical environment.
 - The major element that is being considered is the response timeliness for detectability.
- After finding the RPN, prioritizing them as per severity is required to improve the resources. High RPN is more serious, has to be addressed as a priority, and deserves more effort and resources. Table 4 represents RPN prioritization. As per the case scenario RPN was prioritized and depicted as follows.
- After RPN prioritizing, step 7: redesign the process/design controls was undertaken by the following measures:

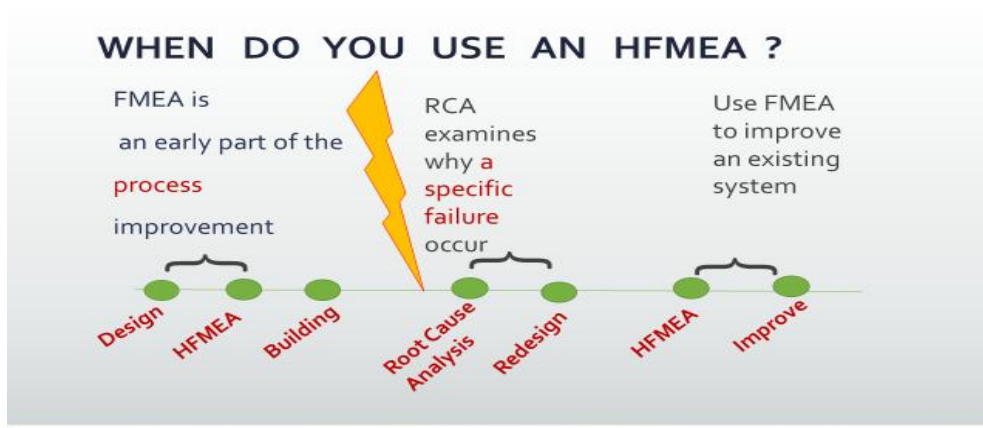


Fig. 5. Depicting: When to use HFMEA?

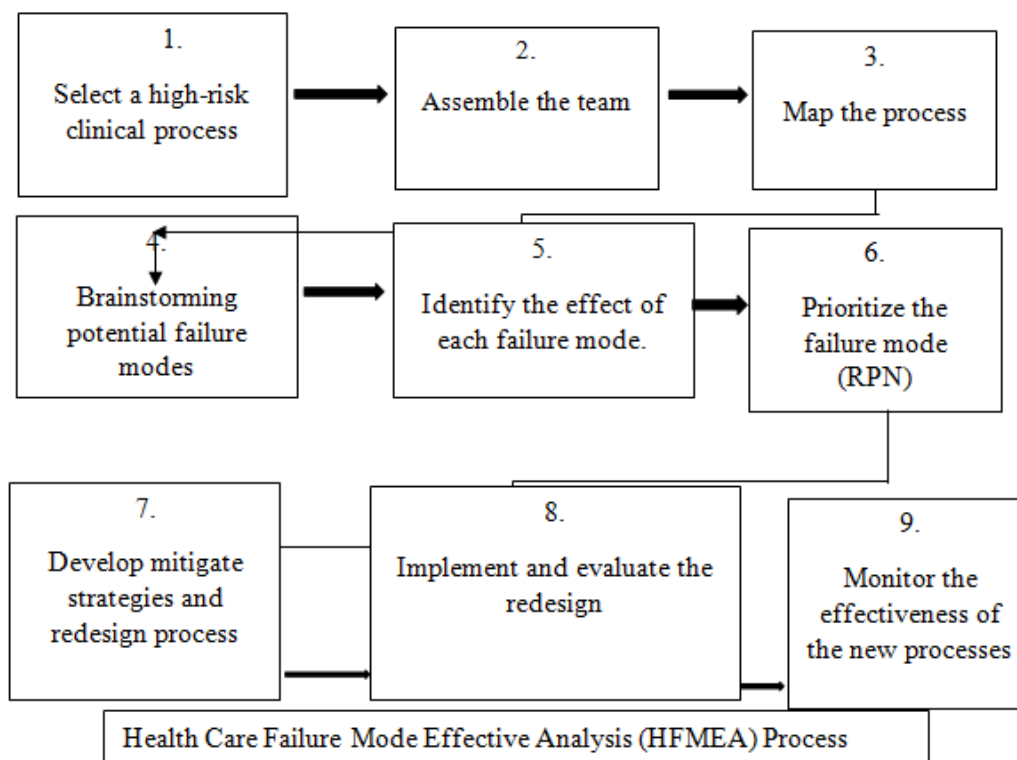


Fig. 6. Depicting major 9 steps of HFMEA

Table 4. RPN prioritization

Failure mode (What we monitored and observed as and when the failures occurred)	RPN	Rank
Response timeliness	158	3
Communication lapse	360	1
Drugs and consumables missed	54	4
Non-availability of trained staff and doctors	210	2

Table 5. Strategies for implementation and to reach deliverables

1. Strategies used to reduce severity by:	2. To improve detectability, the following steps were implemented:	3. To prevent the occurrence- for example:
Warning and message, Critical alerts, and SMS. Backup and redundant systems	Real-time process check rather than post-process Automated checks and early detecting warning alarms	Continuous improvement and problem-solving methodologies Increasing the capability and capacity building by process performance management Addressing multiple causes with desirable results
Usage Protective devices – hand gloves, masks, eyeglasses, face shields During Emergency: automatic shut-offs, fail-safe sirens alarms, and operational devices Patient positioning	Wristbands for patients, barcodes with name and date of birth Better devices for measuring along with calibration reports System full proofing with verification and validation, double checks with reports	Implementation of checks earlier in the set process Staff training and education, creation awareness, process re-engineering Cross audits and error-proofing
Alternative material usages To conduct Patient education and coordinate family awareness programs By utilizing multiple resources, expanding the touch base of suppliers. Evaluation of supplier and constant monitoring Continuous improvement and problem-solving methodologies	Usage of shapes, colors to identify the appropriate materials Equipment and validation of process with benchmarking techniques Audit, system testing, and monitoring Real-time process check rather than post-process Implementation of checks earlier in the set process	Better data collection, analyzing the data, to publish the same Inventory management, protective storage, and preventive mishaps Addressing multiple causes with desirable results Increasing the capability and capacity building by process performance management

Brainstorming sessions can provide detection and also address failure modes with high RPN (Risk Priority Number)

1. Mitigate the risks, if possible
2. Minimize risk if it cannot be eliminated.
3. Find out opportunities for 'Failure proof analysis'.

Step 8 of HFMEA is to evaluate the new process and implement the following: In this step, the most important actionable item is to assign a specific person for due completion of tasks. Following actionable items are to be

implemented: Ticketing, time targets – deliverables, closures, and sign-off. Follow-up on assigned actions has to be performed stringently. Verifying the actions taken have intended results. Table 5 shows Strategies for implementation and to reach deliverables. As we proceeded, step 9 includes monitoring the set process at regular intervals and reassesses the process, and follows up.

The recommendations were provided for better implementation and to reach deliverables are as follows.

5. CONCLUSION

Team dynamics and coordination were the most important factors in implementing RCA and HFMEA in improving patient safety. Dashboard analysis and re-audits play an integral role in improving patient safety culture. Regular clinical audits of both concurrent and retrospective audits are a value addition to improvise the processes.

Formulating a common protocol was the main intention of these quality improvement programs. The choice of technique has to be clear and focused. Avoiding individual preferences is to be kept in mind for determining the tasks. Always backup support has to be planned and kept as a reserve. The channel of communication has to be two ways.

By regular clinical meets with multidisciplinary committees, better systems and processes can be incorporated. Incident reporting provides us an opportunity to develop trust and confidence in the set process.

System full proofing methods by managerial audits have to be customized depending upon the organizational culture. The management and leaders in health care organizations have to imbibe and foster a safe culture.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Author has declared that no competing interests exist.

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