Integrating FMEA, QFD and Lean for Risk management in hospitals

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Abstract. The purpose of this paper is to help hospital administrative managers or decision makers understand and effectively mitigate the hospital wide risks by developing and implementing strategies, before they turn detrimental to the firm. This paper done as a case study deals with risk identification, measurement, assessment, mitigation and control of risks present in hospitals. We have applied FMEA and Quality function deployment (QFD) methods for risk quantification and assessment. Using these techniques critical risk agents which create risk events in the hospital were identified. Mitigation plans were developed based on expert opinions. We analysed the integration of lean thinking principles in the risk control process and found that the risk control by implementing lean techniques has a scope for productivity improvement and better customer satisfaction in hospitals.

1. Introduction

Businesses today are facing tremendous amounts of risk. It is prone to risks from several internal sources like resource crunch, technical problems, employee issues. External political scenario or even natural calamities develop several other types of risks. To survive in such environments it is essential that companies understand and evaluate these risks beforehand so that the effects can be reduced though it cannot be nullified. According to Sinha \textit{et al} \cite{1} risk is an event of uncertainty and the impact of an event. Organizations suffer in terms of service level and also financially if risks are not handled properly. According to Patrik Herrscher \textit{et al} \cite{2} risk exists in all areas where people work and are prone to errors. For the healthcare sector the risks they face can literally be a life-and-death issue. For the same reason Risk management in hospitals is of utmost significance. Most healthcare organizations do have a history of identifying, analysing and prioritizing risks. But Risk quantification, monitoring and control outside the traditional clinical arena have mostly been overlooked because it could not be convincingly articulated to show a measurable value. This study was taken up as we found a profound absence of literature involving a Hospital wide risk assessment which involves clinical as well as non clinical risks. Here we present a proactive risk management
method based on studies conducted at three hospitals in South India.

2. Methodology

Our paper depicts a proactive model for risk management in hospitals. Risk management method involves risk identification, risk assessment, risk mitigation and control. The causes of various risks in the enterprise which are the risk agents are identified proactively and those are prioritized. Risk agents are then prevented from occurring which would stop the occurrence of many risk events. Here the well-known Failure Mode and Effect Analysis (FMEA) is used to quantify these risks. The QFD principles are used to prioritize the risk agents, determine the correlation matrix and to select the feasible and effective proactive actions in order to reduce the risks and their effects. House of risk as defined by Nyoman [3] involves assimilation of these methods. The core activities in the hospital are studied and risk events in various processes are identified. The risk agents many of which could create more than one risk event are identified and the probabilities of their occurrence are assessed. The aggregate severity of impacts caused by each risk agent (Aggregate risk potential for each risk agent) is calculated. Based on this numerical value risk agents are prioritized and preventive measures can be identified, prioritized and the feasible most effective actions are to be implemented. Finally for risk mitigation we bring into our model the Lean thinking principles and practices which can be truly integrated into the system of risk management as quality has high priority throughout the hospital operations and lean enforces quality through continuous process improvements. Our paper depicts where and how lean can be implemented for successful results. By controlling risks, the management can be assured that processes are improved and customers pull value from the activities.

2.1. Failure Mode and Effect Analysis (FMEA)

According to Mahdi, Danial and Mojtaba [4], NASA in 1963 first proposed FMEA tool for their reliability needs calculations. FMEA tool is presently used as a proactive engineering tool which helps to detect and counter weak factors in the earlier stages of product conception itself. Basic FMEA involves identifying three factors which are probability of occurrence of failure, severity of failure if occurred and capacity to detect failure before it occurs. Three factors when multiplied generate the Risk Priority Number (RPN). Chang et al., [5] gave ratings for severity indices and occurrence indices as represented in Table 1.

| Rank | Possible failure rate | Probability of failure          | Severity of effect |
|------|-----------------------|---------------------------------|--------------------|
| 10   | >1 in 2               | Extremely high, failure almost inevitable | Hazardous         |
| 9    | 1 in 3                | Very high                       | Serious            |
| 8    | 1 in 8                | Repeated failure                | Extreme            |
| 7    | 1 in 20               | High                            | Major              |
| 6    | 1 in 80               | Moderately high                 | Significant        |
| 5    | 1 in 400              | Moderate                        | Moderate           |
| 4    | 1 in 2000             | Relatively low                  | Low                |
| 3    | 1 in 15000            | Low                             | Minor              |
| 2    | 1 in 150,000         | Remote                          | Very minor         |
| 1    | <1 in 1,500,000      | Nearly impossible               | None               |

Based on the value of the Risk priority number the risks are ranked and the ones with large values are considered critical. This method basically classifies risks as those which are harmful and
unacceptable to the firm’s existence and risks which are acceptable as it may not have any disastrous consequences on the enterprise.

Ookalkar et al., [6] suggested using FMEA in a specialized hospital unit to decide process requirements, identify causes of failures, and quantify associated risks with every cause. The actions implemented provided better controls, reduced risks and better patient welfare.

2.2. Questionnaire data for FMEA in hospitals

The House of Risk model developed by Pujawan and Geraldin [3] considered the probability of occurrence of risk agents, severity of risk events if occurred and the correlation between risk event and risk agent.

Three hospitals were considered for the risk assessment study. These hospitals catered to multitudes of patients daily. These together had more than 500 employees, around 100 bed facilities in each, pharmacy with individual supply chains, laboratory pathologists, technicians and specialist doctors. Complete study of the three hospitals on their daily operations was made. Several brainstorming sessions were conducted which brought out the risks the hospitals face in their daily operations when doctors, quality managers, lab technicians and pharmacy personnel, operations managers, nursing staff and maintenance staff were required to fill out the questionnaires. Risk events \(E_1 - E_{29}\) and risk agents \(A_1 - A_{29}\) were identified and are shown in Table 2 and Table 3 respectively.

Questionnaires required three inputs from the respondents. They were asked to give a rating of the severity of risk events if it occurred on a scale of 1 – 10. They also had to give a rating on a scale of 1– 10 for the probability of occurrence of risk agents. The third input was the correlation value between the two.

| Processes | Risk event No | Risk Events | Severity of risk events if occurred - Scale of (1 – 10) |
|-----------|---------------|-------------|-----------------------------------------------------|
| Demand forecasting | 1 | Large forecast error - \(E_1\) | |
| Planning for operations and scheduling | 2 | Sudden changes in the plans based on unexpected demand - \(E_2\) | |
| | 3 | Limited /no information visibility across various departments - \(E_3\) | |
| Inventory control for materials in pharmacy, laboratory and emergency rooms | 4 | Discrepancy between recorded and available stocks \(E_4\) | |
| Medicine / Material purchase risks in pharmacy | 5 | Medicines transported from suppliers without meeting the proper conditions getting damaged fast - \(E_5\) | |
| | 6 | Late arrival of new stock in pharmacy - \(E_6\) | |
| | 7 | Wrong items delivered to pharmacy - \(E_7\) | |
| Patient safety / clinical risks | 8 | Excessive waiting for patients at several locations during treatment - \(E_8\) | |
| | 9 | Wrong patient identification - \(E_9\) | |
| | 10 | Complete patient medical history not studied before surgery / improper patient assessment - \(E_{10}\) | |
| | 11 | Infections spread while inside hospital (inpatient and outpatient) - \(E_{11}\) | |
| | 12 | Patient fall incidents - \(E_{12}\) | |
| | 13 | Sterilization of medical equipment not effective \(-E_{13}\) | |
| | 14 | Ambulance non-availability during emergencies - \(E_{14}\) | |
| | 15 | Outbreak of fire and related safety issues - \(E_{15}\) | |
| | 16 | Improper communication to patients/ family members regarding treatment and associated |
## Table 3. List of risk agents identified

| Sl No | Risk agents                                                                 | Probability of occurrence of risk agents (1 – 10) |
|-------|------------------------------------------------------------------------------|--------------------------------------------------|
| 1     | Sudden increase in demand - $A_1$                                            |                                                  |
| 2     | Natural calamities - $A_2$                                                  |                                                  |
| 3     | Improper auditing in pharmacy leading to mismatch in actual and recorded medicines in stock - $A_3$ |                                                  |
| 4     | Information technology not fully incorporated into the system - $A_4$        |                                                  |
| 5     | Pharmacy supplier inefficiencies - $A_5$                                    |                                                  |
| 6     | Improper /lack/missing of identification tags to patients - $A_6$           |                                                  |
| 7     | Scarcity of resources like lotions and antiseptics that aid in infection control - $A_7$ |                                                  |
| 8     | Lack of precautionary measures while dealing with blood / body fluids - $A_8$ |                                                  |
| 9     | Lack of patient care /insufficient patient assessment and diagnosis - $A_9$  |                                                  |
| 10    | Using sterile equipment after expiry period of sterilization - $A_{10}$      |                                                  |
| 11    | Sterilization done inappropriately - improper procedural setup or can be even improper packaging after the process - $A_{11}$ |                                                  |
| 12    | Inexperienced / unqualified staff - $A_{12}$                                |                                                  |
| 13    | Lack of training for fire and safety personnel - $A_{13}$                   |                                                  |
| 14    | Look alike / sound alike medicines in the pharmacy- $A_{14}$                |                                                  |
| 15    | Verbal prescription over phone - $A_{15}$                                    |                                                  |
| 16    | Absence of high alert medicine list in pharmacy - $A_{16}$                 |                                                  |
| 17    | Inefficiencies in inventory management and control - $A_{17}$               |                                                  |
| 18    | Absence of normal reference values for various lab tests - $A_{18}$         |                                                  |
| 19    | Lab specimen spill during transport from different locations - $A_{19}$      |                                                  |
| 20    | No / faulty labelling in lab specimen tubes - $A_{20}$                      |                                                  |
| 21    | Faulty equipment / calibration errors / procedural errors / lack of maintenance of equipment - $A_{21}$ |                                                  |
| 22    | Lack of quality inspections and checks in lab procedures and                 |                                                  |
Quality Function Deployment

QFD was first implemented in Mitsubishi’s shipyard in Japan in 1972. It was used to select the design features of a product to satisfy the customer requirements and then to prioritize those features in the design process (Fisher and Schutta, [7]). It was then implemented mainly in manufacturing settings in the United States.

A critical aspect of QFD is gathering Voice of the Customer (VOC) by asking the customers what they need in the product / service and “why” is repeated until the respondent responds with the same answer every time. VOC is gathered through interviews with potential customers. This is the starting point for QFD when customer requirements are expressed by them in their own language.

2.4. Relationship matrix

After the survey results are gathered on customer consequences and the technical requirements needed, a matrix is developed to highlight the relationship between the two. This matrix forms the body of the House of Quality. This matrix uses a scale of 1-3-9 to define the correlation between the customer consequence and the technical requirements which suggests how much the technical requirement helps to attain the customer consequence. 9 means a strong relation, 3 means moderate, 1 means weak relation.

2.5. Degree of technical difficulty

Once the relationships are established, the next stage is to decide target values for the engineering characteristics, a rating of the difficulty of achieving that target and an importance rating for the engineering characteristics. Level of difficulty is specified on a scale of 1 – 5 with 5 being the most difficult to attain. The target values set should ensure that the customer requirements are satisfied. If not they should be modified.

3. House of Quality (HOQ) methodology applied to hospital study

In Hospital risk assessment we have identified Risk events which are considered similar to the customer consequences. These risk events and occurrences should be addressed properly or else it can turn disastrous to the firm. The risk agents that create the risk events are similar to the technical requirements which cater to the customer needs. In our model the risk agents are given high priority in order to ensure that their probability of occurrence is very less which further ensures they do not create any risk event. Hence for this it is essential that we understand the relationship between each risk event and risk agent. This is similar to the relationship matrix in QFD. One agent can be the cause for several risk incidents. That means there is a relation between that agent and the risk event it creates with varying degrees of relation. Similarly one risk event can be created by more than one agent.

According to Pujawan et al., [3] this is termed as the House of Risk model. A questionnaire required the input in the form of relationship matrix between risk events and risk agents (Table 4). Here the values input were 0, 1, 3 or 9. A value 0 meant no relation between a risk agent and an event which means that particular risk agent will not induce that risk event. Value of 1 meant there is a weak relation or low chance. Similarly value of 3 meant a moderate chance and 9 meant high relation.

| equipment - A₁₂ |
|------------------|
| 23 Lab procedures done without ensuring proper test conditions - A₁₁ |
| 24 Non-compliance with laboratory standards and guidelines - A₁₄ |
| 25 Patient details wrongly captured in the system - A₁₅ |
| 26 Insurance policy details not fully communicated to the patient/caretakers - A₁₆ |
| 27 Inefficient usage of Incinerator - A₁₇ |
| 28 No proper waste segregation by the house keeping and waste management staff - A₁₈ |
| 29 Interrupted electricity supply - A₁₉ |
Since one agent can induce several risk events and the impact of those events if occurred are different it is essential to calculate the Aggregate Risk Potential for risk agents. This would help to prioritize which agents are to be removed in the earlier stages itself so that the severity of negative impact due to risk events can be minimized if not eliminated.

The last column in Table 4 shows the input given by experts regarding the severity of risk events (S_i) if it occurred. This was on a scale of 1 – 10. The table also shows the expert rating on the probability of occurrence of a risk agent (O_j) on a scale of 1 – 10. These values are obtained from experts as input to the details in Table 2 and Table 3. Correlation input from experts (R_{ij}) formed the body of the matrix in Table 4. These three ratings are utilized for calculating the Aggregate Risk Potential number for each risk agent.

3.1 Calculation of Aggregate Risk Potential number

From the Questionnaire data collected through several interactions with hospital staff Aggregate Risk Potential number for each Risk agent was calculated. The rating for the severity of each risk event i was termed as S_i. Another input was the probability of occurrence of each risk agent j which was termed O_j and the main body of the matrix represents the relationship matrix R_{ij} with a score of 1, 3 or 9.

If O_j is the probability of occurrence of risk agent j, S_i is the severity of impact if risk event i if happened and R_{ij} is the correlation between risk agent j and risk event i, then Aggregate Risk Potential of event j is given by

\[ ARP_j = O_j \sum S_i R_{ij} \]

A sample calculation of ARP value is shown in Table 4.

ARP value for risk agent 5 which is A_5 is calculated as

\[ ARP_5 = 2 \times [3 \times 5 + 9 \times 5 + 1 \times 4 + 9 \times 4] = 200 \]

Here 2 corresponds to probability of occurrence (O_j) of Risk agent 5 as shown in Table 4. Table 4 shows the Correlation values for agent 5 with each of the events which is 3 for event 5, 9 for event 6, 1 for event 7 and 9 for event 24. Again these values are multiplied by the corresponding Severity of impact value (S_i) for each of the risk event. This as shown in Table 4 is 5 for E_5, 5 for E_6, 4 for E_7 and 4 for E_24. Similarly the values are found for all risk agents.

Based on the ARP values for each agent j we ranked the risk agents and prioritized them for prior consideration for effective risk reduction. From the ARP values obtained in Table 4 it is observed that there are four risk agents with ARP values more than 1500. Five of them have a value ranging from 1000 – 1500. There were three agents with values between 500 – 1000 and seventeen of the agents were having ARP values less than 500. Detailed analysis shows that first seven agents based on the rankings constitute slightly more than 50% of the total ARP values and around 75% of the ARP is constituted by only 11 risk agents. These Risk agents are shown in Table 5 prioritized according to the ARP values.

3.2 Development of the preventive actions to reduce risks

From the analysis it is clear that all the risk agents are very different in their aggregate risk potential. This means that some risk agents with high ARP values are more harmful than the ones with low values, as they might be inducing more serious risks to the firm. Hence through proper Risk management programs efforts should be more on reducing those agents first. Hence we selected the first eleven risk agents according to the ARP values as the significant ones for which preventive actions have to be identified and prioritized (Table 5). This was because these 11 agents contributed to around 75% of the Aggregate ARP values of all the 29 risk agents. This means they are highly significant in inducing risk events and in terms of the severity of risk effects on the firm.

3.3 Prioritizing the mitigation plans based on the House of Quality principles

For each prioritized critical agent the mitigation plans were developed in consultation with experts. P_1 – P_{16} in Table 5 represents the proactive action plans suggested. Few mitigation plans could be a
solution for more than one risk agent occurrence. If risk agents are eliminated then the risk events will not happen. Hence this forms the root cause identification process for each risk event.

This forms the second part of the House of Quality model where the correlation matrix is again developed by using input collected from experts using questionnaires. The expert inputs were collected which is represented as the correlation score in Table 5. The experts were required to give a rating of 1, 3 or 9. This score measures the importance the experts associate with each plan when used to mitigate that particular risk agent. A score of 1 means low correlation (means that specific plan has a low chance of removing/minimizing that particular agent but may still be effective), 3 means moderate chance, and 9 means high correlation which means that plan/activity will certainly avoid/minimize that agent if implemented.

Table 4. Questionnaire for data collection
Table 5. Risk agents prioritized with risk mitigation plans

| Sl no | Critical risk agents | Risk mitigation plans | Correlation score |
|-------|-----------------------|-----------------------|-------------------|
| 1     | Non-compliance with lab standards and guidelines \( (A_{24}) \) | Perform periodic quality checks and reviews \( (P1) \) | 9 |
|       |                                                     | In house laboratory employee training to ensure they are up to date with changing regulations and procedures \( (P2) \) | 3 |
| 2     | No/faulty labelling in lab test specimen \( (A_{20}) \) | Use bar codes instead of patient name / MR No in specimen tubes \( (P3) \) | 3 |
|       |                                                     | Avoid hand written labels and have printed ones \( (P4) \) | 3 |
|       |                                                     | Match specimen and tube and label the tube immediately after the test is done \( (P5) \) | 3 |
| 3     | Faulty equipment/ calibration errors/ lack of equipment maintenance in lab \( (A_{21}) \) | Conduct periodic maintenance of lab equipment \( (P6) \) | 9 |
|       |                                                     | Perform periodic quality checks and reviews \( (P1) \) | 9 |
| 4     | Lab procedures done without ensuring proper test conditions \( (A_{13}) \) | Perform periodic quality checks and reviews \( (P1) \) | 9 |
|       |                                                     | Availability of Quality manual in the lab \( (P7) \) | 3 |
|       |                                                     | Ensure good suppliers and quality materials \( (P8) \) | 3 |
|       |                                                     | Validate the test results under different environmental conditions \( (P9) \) | 3 |
|       |                                                     | In house laboratory employee training to ensure they are up to date with changing regulations and procedures \( (P2) \) | 9 |
| 5     | Inefficient usage of incinerator \( (A_{27}) \) | Conduct effective waste reduction programs and reserve incinerator usage for most dangerous types of hospital waste \( (P10) \) | 9 |
| 6     | No proper waste segregation \( (A_{25}) \) | Properly trained , thoughtful hospital staff \( (P11) \) | 3 |
| 7     | Improper / no Identity tags to patients \( (A_{6}) \) | Provide good quality ID tags to patients \( (P12) \) | 9 |
| 8     | Lab specimen spill during transport to different locations \( (A_{19}) \) | Provide safe secured containers for specimen collection in lab \( (P13) \) | 9 |
|       |                                                     | Properly trained , thoughtful hospital staff \( (P11) \) | 9 |
| 9     | Lack of precautionary measures while dealing with blood / body fluids \( (A_{11}) \) | Provide gloves, masks, protective face shields (if needed) , gowns, aprons to avoid splashing \( (P14) \) | 9 |
|       |                                                     | Properly trained , thoughtful hospital staff \( (P11) \) | 3 |
| 10    | Unqualified / Inexperienced staff \( (A_{12}) \) | Ensure strict regulations for quality recruitment of staff \( (P15) \) | 9 |
|       |                                                     | Properly trained , thoughtful hospital staff \( (P11) \) | 3 |
| 11    | Sudden increase in demand \( (A_{1}) \) | Properly trained , thoughtful hospital staff \( (P11) \) | 3 |
|       |                                                     | Improve planning and inventory control performance \( (P16) \) | 9 |

It was noticed that few actions could eliminate more than one risk agent as can be seen in Table 5. The proactive actions mentioned above \( (P1 – P16) \) to mitigate the risk agents should be effective and at the same time acceptable to the management in terms of the financial requirements and resource availability. Taking this into consideration the degree of difficulty of performing each action is classified into three: low with a score of 3, moderate with a score of 4 and high with a value of 5. Score of 3 means the difficulty of performing that particular mitigation plan is low. This means in terms of the financial and other resource requirements this plan may be easier to achieve. For a score of 4 the difficulty level is higher and is highest for a score of 5.
Table 6 shows the identified proactive action P1 – P16, the prioritized 11 risk agents to be eliminated and the correlation score (From Table 5) given to each plan in relation to each agent. Inputs provided by the respondents in terms of the difficulty level of performing the various identified mitigation plans is also shown. ARP values are reproduced from Table 4.

| Critical risk agents | P1 | P2 | P3 | P4 | P5 | P6 | P7 | P8 | P9 | P10 | P11 | P12 | P13 | P14 | P15 | P16 | ARP |
|----------------------|----|----|----|----|----|----|----|----|----|-----|-----|-----|-----|-----|-----|-----|-----|
| A24                  | 9  | 3  |    |    |    |    |    |    |    |     |     |     |     |     |     |     | 1848|
| A20                  |    |    |    | 3  | 3  | 3  |    |    |    |     |     |     |     |     |     |     | 1728|
| A21                  | 9  |    |    |    |    |    |    |    |    |     |     |     |     |     |     |     | 1701|
| A23                  | 9  | 9  |    |    | 3  | 3  | 3  |    |    |     |     |     |     |     |     |     | 1590|
| A27                  | 9  |    |    |    |    |    |    |    |    |     |     |     |     |     |     |     | 1404|
| A28                  | 3  |    |    |    |    |    | 9  |    |    |     |     |     |     |     |     |     | 1170|
| A6                   |    |    |    |    |    |    |    |    |    |     |     |     |     |     | 9   | 9   | 1132|
| A19                  |    |    |    |    |    |    |    | 9  | 9  |     |     |     |     |     |     |     | 1085|
| A8                   |    |    |    |    |    |    |    |    | 9  |     |     |     |     |     |     |     | 1002|
| A12                  |    |    |    |    |    |    |    |    |    |     |     |     |     | 3   | 9   | 9   | 940 |
| A1                   |    |    |    |    |    |    |    |    |    |     |     |     | 3   | 3   | 3   | 9   | 940 |

| Total effectiveness of proactive action (Tek) | 46251 | 19854 | 5184 | 5184 | 5184 | 51309 | 4770 | 4770 | 4770 | 4770 | 12636 | 21675 | 10188 | 9765 | 9180 | 8460 | 7560 |
| Difficulty in attaining the plan (Dk) | 5 | 4 | 4 | 3 | 3 | 5 | 3 | 4 | 5 | 4 | 3 | 3 | 3 | 3 | 4 | 5 |
| Effectiveness to difficulty ratio (Tek/Dk) | 9250.2 | 4964 | 1296 | 1728 | 1728 | 3062 | 1590 | 1193 | 954 | 3159 | 7225 | 3396 | 3255 | 3060 | 2115 | 1512 |

Total effectiveness of proactive action value in Table 6 is calculated as an aggregative value for each mitigation plan by multiplying the corresponding ARP values of those agents which it help to mitigate, with the correlation score of that agent and the plan. Effectiveness / difficulty ratio is then calculated for each plan. The higher the ratio, more effective is the plan in eliminating the risk agents. Hence the higher valued mitigation plans are prioritized for consideration by the management so that risk mitigation is effective. Table 7 shows eight mitigation plans ranked according to the decreasing Effectiveness to difficulty ratio.

Table 7. The proactive risk mitigation plans in order of the rankings

| Rank | Risk mitigation plans prioritized based on the Effectiveness to difficulty ratio |
|------|---------------------------------------------------------------------------------|
| 1    | Perform periodic quality checks and reviews (P1)                                |
| 2    | Properly trained , thoughtful hospital staff (P11)                              |
| 3    | In house laboratory employee training to ensure they are up to date with changing regulations and procedures (P2) |
| 4    | Provide good quality ID tags to patients (P12)                                  |
| 5    | Provide safe secured containers for specimen collection in lab (P13)             |
| 6    | Conduct effective waste reduction programs and reserve incinerator usage for most dangerous types of hospital waste (P10) |
| 7    | Conduct periodic maintenance of lab equipment (P6)                              |
| 8    | Provide gloves, masks, protective face shields (if needed) , gowns, aprons to avoid splashing (P14) |

4. Results Analysis and Lean integration

Analysing the Major risk agents, we understood that it is possible to eliminate the risks at the source itself if Lean principles and lean tools implemented. The most significant mitigation plan suggested was proper conduct of periodic Quality checks and reviews. Quality management techniques are very significant in lean as the ultimate goal is to eliminate waste in the value stream and remove non-value added activities. Lean manufacturing initiatives focus on the problem identification as and when it occurs, does a root cause analysis of the problem and corrections are done at the earliest. Lean management principles in combination with Six sigma
has immense scope in the lab, where several risk exists, by reducing process variations and enhancing quality and performance.

Almost all the existing research on lean in hospitals is focused on specific departments like operating rooms, emergency department etc. Vignesh et al [8] studied lean implementation in service industries. Virginia Mason Medical center has applied lean thinking to improve safety and quality in surgical sterile instrument processing. In Wisconsin, Thedacare community hospital implemented lean to attain continuous improvement and could reduce process variations, follow standardised work and increase productivity. Smith et al., [9] explains how a Lean Kaizen methodology could improve the scheduling time of nurses that resulted in reduced operational costs and better working conditions. Vegting et al., [10] confirms how lean thinking helped reduce cost of unnecessary testing in clinical practice by following simple measures. He suggests expansion of techniques hospital wide. Many research papers are available which shows positive results of lean implementation in small departments inside hospitals. But few papers do exist which suggests not all lean implementations done in hospitals are successful. Oskar P. R., et al [11] shows that all lean interventions are not able to sustain the positive results in terms of continuous improvement. Their study focused on a series of lean interventions at a hospital laboratory and their influence on the throughput time at subsequent periods. They claimed only a few interventions could provide improved results.

According to Jeffrey, K [12] the popular lean wastes are the ones due to Waiting, over processing, over production, piled up inventory, defects, unwanted motion, unused creativity and unwanted transportation. Saleeshya, et al., [13] in a case study conducted at a surgical equipment manufacturing company showed how Value stream mapping (VSM) tool can be used to identify the lean wastes held up at the various manufacturing stages.

Our paper is unique in that we suggest lean integrated as a tool to control Enterprise wide risks and thereby increasing productivity. An integrated Lean - risk management process is suggested. Our study identified the top risk factors in the hospital. Mitigation plans to be implemented were identified. We suggest lean tools implementation as we believe it would facilitate the mitigation plans to be more effective and bring a Kaizen (continuous improvement) approach into the system. Each risk agent identified could be directly linked to few lean principles which could help prevent the occurrence of it. It was evident that the risk agents and events create several wastes which can be categorised into the familiar lean wastes as shown in Section 4.1.

4.1. Lean wastes created in hospital operations by each of the risk agent

- Non-compliance with lab standards and guidelines
  - Defects: Defective test results and reports.
- No/faulty labelling in lab test specimen
  - Defects: Wrong patient identification and wrong/defective reports.
- Faulty equipment/calibration errors/lack of equipment maintenance in lab
  - Defects: Defective results/reports
  - Waiting: Specimen samples wait for processing
  - Overprocessing: Wrongly calibrated machines might result in overprocessing
- Lab procedures done without ensuring proper test conditions
  - Defects: Faulty results and defective reports
  - Overprocessing: Samples may be processed more than needed.
- Inefficient usage of incinerator
  - Inventory: Piled up inventory
  - Waiting: Hospital waste waiting to be burnt
  - Transportation: Unwanted transportation of waste occurs if all wastes are transported to incinerator. Not all need to be burnt there.
- No proper waste segregation
  - Unwanted motion: Workers moving unnecessarily to different locations
will enforce Quality and can eliminate many wastes like defects (wrong reporting or diagnosis), and waiting for lab reports.

Lean focuses on proactive maintenance operations using planned and scheduled maintenance activities through Total productive maintenance (TPM). TPM can reduce the risks due to lack of machine maintenance in the laboratory and operation rooms, calibration errors and faulty equipments in the lab.

- Poka yoke or mistake proofing is possible by using bar code system Improper / no Identity tags to patients
  - Waiting: People wait at several locations
  - Unwanted motion: People transported to wrong locations
- Lab specimen spill during transport to different locations
  - Waiting: Lab staff waiting for new specimen
  - Unused creativity: Lab staff doing repetitive tasks and not being creative
- Unqualified / Inexperienced staff
  - Overprocessing: Reports may carry extra information that patients did not ask for
  - Unused creativity
  - Defects: May deliver wrong reports / products
- Sudden increase in demand
  - Defects: People tend to make errors when overloaded
  - Overproduction: People may tend to overproduce and stock inventory

5. Integrating lean into risk management

Lean has to be a company strategy. Top management commitment is essential and transforming people through lean training and awareness is significant. The first step when implementing lean is to have a solid plan of action. Since lean would be a new idea to the case under study proper lean training should help them understand the benefits attainable. The more benefits they visualize the easier it would be to adapt to the new management strategy.

5S activities done initially should help visualize the wastes effortlessly. 5S would benefit the largest part of the organization in the least time just by getting things organized and sustaining it that way. This should be practised throughout the hospital including the front desk, pharmacy, laboratory, material handling department, operating rooms.

Standardisation of work helps a long way in identifying the wastes that are not easily visible. Standardization in lab procedures in lab specimen tubes so as to prevent the faulty labelling and further mismatch between patient, treatment and medical supplies.

Visual control like display boards and charts, indicator lights expresses information that everyone can understand and thus control the actions of members. Visual controls can be installed to alert when wrong patient is identified preventing errors at later stages.

Facility layout improvement can be suggested to eliminate the risk of specimen spill. The location proximity of labs to the specimen collection area can reduce the risk to a large extent.

Heijunka (Work load levelling) to be done at the laboratory to ensure technicians are not overloaded especially during peak demand time. Heavy load might result in errors while performing tests and reporting results.

Table 8 shows the lean tools which can be beneficial in eliminating the risk agents at the source.

| Critical hospital risk agent                                    | Lean principles effective for risk agent control |
|-----------------------------------------------------------------|--------------------------------------------------|
| 1. Non-compliance with lab standards and guidelines             | Quality management system                        |
| 2. No/faulty labelling in lab test specimen                     | 5S                                               |
|                                                                 | Visual control                                   |
|                                                                 | Poka yoke                                        |
6. Conclusions

The proactive risk management method developed here for hospitals identifies, measures, evaluates and prioritizes the risk agents. This is proactive due to the prior knowledge of areas that need more vigilant check if risks are to be minimized if not completely eliminated. Critical risks based on Risk Priority Number are identified. Non-critical ones are ignored as they are considered not disastrous to the firm. Then mitigation plans are developed for those critical risk agents. These plans are checked for feasibility in terms of cost and effectiveness in mitigating each risk agent and feasible ones are prioritized.

A further look into these risk agents showed the possibility of risk control using Lean practises in the hospital. By implementing specific lean tools which would effectively eliminate the eight lean wastes, the risk agents would be controlled. The laboratory was prone to several detrimental risks. This was brought to the concern of the hospital management. Management and staff were convinced of the fallacies that were being practised and were keen on implementing lean tools for productivity improvement.

Lean management strategies should be incorporated in the planning stage itself if it has to be effectively practised in risk control and mitigation. Management support in identifying and eliminating waste to continuously improve the processes is essential so that value addition happens in each operation. Wastes identified at different processes if curtailed would remove all the risk agents from various locations and thus ensure an effective risk management in place.

7.0 Limitations of the study

The research is limited in that it is focused on three specialized hospitals. These hospitals are among the few JCI accredited hospitals in the State with good infrastructure and Quality assurance in operations. A hospital situated in rural India would be exposed to much higher and different risks as that they cater to a wider range of patients and wider requirements in terms of treatments and services. Hence the model cannot be generalized. But in the latter case we feel the integration of lean would positively be able to show better results in controlling and mitigating risk. For academic continuity this paper provides useful guidelines for effective risk management in hospitals and shows how Lean can be integrated into the hospital system.
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