APPLICATION OF LEAN SIX-SIGMA APPROACH TO REDUCE BIOMEDICAL EQUIPMENTS BREAKDOWN TIME AND ASSOCIATED DEFECTS

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ABSTRACT

BACKGROUND

Lean Six Sigma is an advanced methodology of quality management and quality improvement. Lean Six Sigma implementation in equipment maintenance can be a good solution, which can reduce the waste and variation through the DMAIC cycle. It is a need of time to adopt Lean Six Sigma methodology at all the levels of healthcare ubiquitously, since this methodology has worked wonders in other sectors like information technology, industry, education, both online and offline retail market, manufacturing etc. Biomedical equipments are the blood vessels of the hospital and it must be made sure that the critical medical devices are safe, accurate, reliable and operating at the required level of performance consistently by reduction of breakdown time and associated defects by adopting Lean Six Sigma approach.

The objective of the study is to reduce the biomedical equipments breakdown time and associated defects by using Lean Six Sigma approach.

MATERIALS AND METHODS

This study was conducted at Yenepoya Medical College Hospital, Mangalore, India over a period of 15 months (March 2017-May 2018) over ninety-nine biomedical equipments in operation at Medical Intensive Care Unit. This study design is experimental. The objective was achieved by using popular DMAIC methodology.

RESULTS

The breakdown time reduced from 19165.83 minutes/month to an average of 14.5 minutes/month after application of Lean Six Sigma. Similarly, the average number of associated defects reduced from 40 defects/month to 6 defects/month. The Sigma level improved from 1.66 to 4.94 levels.

CONCLUSION

Lean Six Sigma approach is an effective and eloquent application in improving the biomedical equipment’s maintenance. Lean Six Sigma approach can be adopted at various levels of healthcare system to increase the productivity, cost-effectiveness which enhances the healthcare service.

KEY WORDS

Lean Six Sigma, Biomedical Equipment, Breakdown Time, Maintenance Process.


BACKGROUND

A Healthcare delivery agency is incessantly affected by the changing paradigm of medical technology. Hospital equipments, especially of new generation has immense role in advancement of modern medical technology and these medical devices are fundamental components of modern health services used for diagnosis, treatment and monitoring of patients. They are progressively being deployed to increase the capabilities of health diagnostic and treatment services. Modern medical devices and equipments have become very complex and sophisticated and are expected to operate under stringent environments. Hospitals must ensure that their critical medical devices are safe, accurate, reliable and operating at the required level of performance.

The World Health Organisation (WHO) estimates that 50% to 80% of such equipments remain non-functional, for which most commonly cited reasons being poor maintenance culture and lack of highly trained technicians. According to statistics on medical equipment’s failure from WHO, about 80% of all medical equipment’s failure cases are caused by preventable factors and failures due to inadequate maintenance alone account for about 60% of all the medical equipments performance cases.

Lean Six Sigma is an advanced methodology of quality management and quality improvement currently. In addition, Lean improvements focuses on process speed and waste removal, while Six Sigma focuses on the removal of process defects and the reduction of process variability. Therefore, it is necessary to go on in-depth studying the thinking of the Lean Six Sigma after analysing the problems existing in quality management of equipment maintenance and taking...
Effective measures to improve the level of equipment maintenance. As to improving the deficiencies and inefficiency of equipment maintenance process, Lean Six Sigma implementation in equipment maintenance can be a good solution, which can reduce the waste and variation through the DMAIC cycle.5

Objective of the Study
To reduce the biomedical equipments breakdown time and associated defects by using Lean Six Sigma approach.

MATERIALS AND METHODS
This study was conducted at Yenepoya Medical College Hospital, Mangalore, India over a period of 15 months (March 2017-May 2018) over ninety-nine biomedical equipments in operation at Medical Intensive Care Unit. This study design is experimental. The objective was achieved by using popular DMAIC method (Define, Measure, Analyse, Improve and Control), which included tools like Project Charter, SIPOC, Voice of Customer, Data collection plan, Pareto chart analysis, Histogram, Process Mapping, 5-Whys analysis, Cause and Effect analysis using Fishbone diagram, Feasibility study and Control chart.

Statistical Analysis
The statistical analysis was done by using Minitab 17, Microsoft Excel and Microsoft Word.

RESULTS
This is an experimental study, where an attempt was made to discover cause and effect relationship between maintenance activities and various kinds of defects. Application of Lean Six Sigma was adopted using well-known and popular DMAIC methodology, in which each one of the 5 phases are the combination of both qualitative and quantitative techniques described in detail below.

A. Define Phase
In define phase, the problem was defined and goals were set to solve the defined problem along with the expected business case and benefits, for which tools like Project charter and SIPOC were used.

I. Project Charter
Project charter acts as a foundation to the Lean Six Sigma project, which specifically describes the business case, initial problem, goals and scope of the study along with induction of team members who can contribute to the study with integrated approach.

Problem Statement
One of the most common problems faced by the medical staff in the MICU of Yenepoya Medical College Hospital were-

- Unavailability of Biomedical equipments as and when required.
- As most of the equipments in MICU are critical, their unavailability can lead to catastrophe to both hospital and the patients.
- Delay in repair process of a biomedical equipment more than the stipulated time.
- Mismangement has led to a surge in the occurrence of number of defects and the breakdown time of biomedical equipments.

Voice of Customers/ Employees
- Engineer= “I have no feedback about actual situation”
- Engineer= “Limited staff members, so difficult to repair equipments on time”
- Engineer= “Service company do not respond on time”
- Engineer= “There is no equipment’s repair history recorded in the past”
- Engineer= “We need to monitor the breakdown time”
- Staff= “Equipment is out of service most of the times”
- Staff= “There is long waiting time for the equipments to get repaired and use it”
- Staff= “I don’t understand how to use some of the equipments”

Goal Statement
1. Reduce the total number of defects by at least 50%.
2. Reduce the breakdown time by 50% by the end of April 2018 and improve the Sigma level to 4 or more.

Scope
Understanding that the hospital is very large in terms of bed strength and huge number of equipments situated in several departments, the boundaries of this study is limited to only Medical Intensive Care Unit.

Business Case and Benefits-
- Biomedical equipments are the blood vessels of the MICU in Yenepoya Medical College Hospital and play a pivotal role for thriving of hospital.
- An effective and proactive biomedical equipments maintenance management system with set protocols and strict adherence to them will not only have positive economic outcome to the hospital in form of surge in the revenue generation by preventing the failure and swiftly repairing the failed equipment, but also elevate the quality of care and hence the reputation of the hospital.

ILIPOC
SIPOC is a visualisation tool with a high-level process map in which the boundaries of the process, measured tasks and activities, key process input and output variables, suppliers and customers are described. A customer refers to both internal and external customers.
B. Measure Phase
The hospital in which the study was conducted has a team of four biomedical engineers trained in maintenance of the biomedical equipment. Most of the major equipments are under service contract from service providers directly. The present maintenance activity is centralised and user has no role other than informing non-functional or partial functional status of equipments to the concerned biomedical engineers. The biomedical engineers were mostly engaged in reactive maintenance rather than proactive maintenance. Tools like histogram and Pareto chart were used to measure the breakdown time and associated defects.

Key Performance Indicators (KPIs)
KP1: Breakdown time (minutes): The time elapsed between the stoppage of equipments due to a defect and the restart of it for normal performance.

Detailed Definition
- Beginning of time: The time when a defect occurs and the equipments fail to meet the required standard forcing the operators to either repair it or call for technical assistance.
- End of time: The time when the defect in the equipment is rectified/repaired in such a way that the equipment meets the required standard and is normally functioning.

KP2: Defects (Counts)
Defects: Defects here are described as reason for equipment’s failure. In other words, the biomedical equipment which is unable to function as and when required to provide patient care.

The documents maintained in MICU, Biomedical Engineering Department related to the maintenance and repair of equipments were verified. Based on voice of customer and problems faced in MICU, total breakdown time along with the number of occurrence of associated defects in biomedical equipments were calculated at the end of every month and it was found that average breakdown time and Sigma level was found to be 19,165.833 minutes and 1.66 respectively, which is depicted in the form of table [Table 2] for breakdown time and in the form of Histogram [Figure 1] for breakdown time and respective Sigma levels.

### Table 1. SIPOC Process Map for Biomedical Equipments Breakdown Maintenance

<table>
<thead>
<tr>
<th>Suppliers</th>
<th>Input</th>
<th>Process</th>
<th>Outputs</th>
<th>Customers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff</td>
<td>Defects</td>
<td>Receive the complaints</td>
<td>Minimize defects</td>
<td>Patient, Hospital, Healthcare team</td>
</tr>
<tr>
<td>Bio-Medical Engineer</td>
<td>Breakdown time</td>
<td>Inspects the equipment</td>
<td>Minimize breakdown time</td>
<td>Patient, Hospital, Healthcare team</td>
</tr>
<tr>
<td>Regional sales manager</td>
<td>Spare parts</td>
<td>Repair the equipment</td>
<td>Used spare parts for repair of equipment</td>
<td>Hospital, Healthcare team</td>
</tr>
<tr>
<td>Logistics</td>
<td>Deliver the spare parts on time</td>
<td>(if spare parts available and if spare parts are not available or repairing out of scope))</td>
<td>On time delivery done</td>
<td>Hospital</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test equipment</td>
<td>Test equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Once the equipment is repaired</td>
<td>Test equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Documentation</td>
<td>Test equipment</td>
<td></td>
</tr>
</tbody>
</table>

### Table 2. Month-wise Breakdown Time and Sigma Level

<table>
<thead>
<tr>
<th>Month '2017'</th>
<th>March</th>
<th>April</th>
<th>May</th>
<th>June</th>
<th>July</th>
<th>August</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total time (For the month in minutes)</td>
<td>44640</td>
<td>43200</td>
<td>44640</td>
<td>43200</td>
<td>44640</td>
<td>44640</td>
</tr>
<tr>
<td>Total Breakdown time (in minutes)</td>
<td>14940</td>
<td>9430</td>
<td>40345</td>
<td>1440</td>
<td>43440</td>
<td>5400</td>
</tr>
<tr>
<td>% Yield</td>
<td>66.53%</td>
<td>78.17%</td>
<td>9.62%</td>
<td>96.67%</td>
<td>2.69%</td>
<td>87.90%</td>
</tr>
<tr>
<td>DPMO</td>
<td>334677</td>
<td>218287</td>
<td>903786</td>
<td>33333</td>
<td>973118</td>
<td>120968</td>
</tr>
<tr>
<td>Z(LT)</td>
<td>0.43</td>
<td>0.78</td>
<td>-1.30</td>
<td>1.83</td>
<td>-1.93</td>
<td>1.17</td>
</tr>
<tr>
<td>Sigma Level(ST)</td>
<td>1.93</td>
<td>2.28</td>
<td>0.20</td>
<td>3.33</td>
<td>-0.43</td>
<td>2.67</td>
</tr>
</tbody>
</table>

I. Histogram

![Histogram of Breakdown Time (Month-wise)](image)

**Figure 1. Histogram of Breakdown Time (Month-wise)**

II. Pareto Chart Analysis

The Pareto chart [Figure 2] elaborates that there were various types of repeated defects, which includes physical defects (32.5%) followed by technical defects (30%), accessories (25%), electrical (7.5%) and unspecified (5%).

![Pareto Chart of reason for defects](image)

**Figure 2. Pareto chart analysis**

C. Analyse Phase

The analysis phase mainly deals with identifying the critical factors embedded in the current operation that could be improved to minimise the waste. This is perhaps the most important phase of study, since researcher verifies the root causes of the defects.

The tools used in the Analysis phase were Process Mapping, 5 Whys analysis and Cause and Effect analysis (using Fishbone diagram).

I. Process Mapping

Process Mapping is a structured method to capture and document a process or activities that yield an outcome. A visual tool depicts the process in terms of sequence of activities that are undertaken to deliver the service. Process Mapping [Figure 3] was done to determine opportunity to eliminate waste and non-value added activities. In this study process mapping was framed after thorough observation, extensive analysis and brainstorming session following which the reasons behind prolonged breakdown time got unfolded.

When equipment breaks down there is a protocol in place to get it repaired which has to be followed diligently and in timely manner, failing to do so will increase the breakdown time. As soon as the equipment breaks down in the MICU, the nursing staff posted in MICU registers a complaint through a phone call to the Biomedical Engineering Department, following which the biomedical engineer reaches MICU and inspects the equipment along with the equipment’s history such as AMC and CMC. If the equipment is under warranty, then the concerned company person is informed. A service engineer from the company visits the MICU who has to come either from a nearby or from a distant place and in either case the equipment will be functionless until the service engineer arrives. Once the service engineer arrives, he checks the equipment, repairs it and hands over the service report of repair. In case spare parts are needed, the bill is estimated and billing amount is approved through proper channels, which negatively affected the breakdown time. If the equipment is not under CMC or AMC/warranty, the hospital biomedical engineer inspects and repairs the equipment if he/she can or else the service engineer is called up and follows the above-mentioned protocol. In case the hospital biomedical engineer requires spare parts during the repair, then the bill is estimated and the billing amount is approved through proper channels and purchase is raised by purchase department.

![Process Mapping of Biomedical Equipment Maintenance](image)

**Figure 3. Process Mapping of Biomedical Equipment Maintenance**

II. 5-WHY'S Analysis

Taichi Ohno, the father of Toyota Production System was an avid proponent of the 5-whys analysis as a tool of root cause problem solving. The idea is simple- By asking the question “Why” one can separate the symptoms from the causes of a problem. This is critical as symptoms often mask the causes of problems. Effective use of the 5-whys analysis technique will determine the root cause of any non-conformances and subsequently lead organisations to develop effective long-term corrective and possibly preventive actions.\(^7\)
**Why Questions** | **3W2H Answers (With What, When, Where, How, How Much)** | **Solution**
---|---|---
Why is the breakdown time of Biomedical equipments more? | Because equipment servicing time is more | Allocate fixed Turn-Around Time (TAT)
Why equipment-servicing time is more? | Because equipment spare parts are not readily available for servicing | By making spare parts readily available
Why Equipment's spare parts readily not available for servicing? | - Because of delay in acquisition of spare parts.  
- Delay in delivery of spare parts | - By following up of ordered spare parts regularly till its delivered  
- Reminder call, E-mail
Why there is delay in acquisition of spare parts? | Because of delay in approval of budget for spare parts | - By shortening process of budget allocation/approval time
Why delay in approval of budget for spare parts? | Because time taken for budget sanction through appropriate protocol by proper channel is more | 

*Table 3. Shows the results of 5-Whys Analysis*

**III. Cause and Effect Analysis**
In this phase, Fishbone diagram was framed based on keen observation, informal interviews and brainstorming session conducted with healthcare team, hospital administrators and biomedical engineers. It was concluded that the major reasons for equipment’s failure were found to be delay in reporting the equipment’s failure to biomedical engineer, other jobs in queue of both healthcare team and biomedical engineer, preventive maintenance not done on time as per schedule, inadequate training programme for doctors, nursing staff and BME to handle the equipments, poor prioritisation of equipments to be repaired, rough handling of equipments, continuous usage of same machine without swapping, improper hopper cleaning, unorganised working place and delay in delivery of spare parts etc. Apart from above-mentioned reasons, other causes were also found which were schematically represented in the form of [Figure 4] fishbone diagram.

![Fishbone diagram for causes of Equipments Failure and Increased Breakdown Time](image)

**D. Improve Phase**
Improve is the phase where solutions are identified, developed and implemented based on the critical root causes determined in the analyse phase. For this phase, solutions were identified by analysing the root causes that were found in analysed phase.
Measures Taken in Improvement Phase

- Daily routine maintenance was introduced into the existing biomedical maintenance system, wherein the biomedical engineer had conducted daily routine inspection of all the equipment in MICU. As most of the equipments in MICU are critical, whenever equipment’s failed measures were taken immediately. This has led to a significant positive impact in reduction of breakdown time and the number of associated defects.
- Do’s and Don’ts instructions were pasted over each equipment separately. Users were trained to follow the instructions strictly, by doing so the equipments were being handled properly.
- The existing process of biomedical equipments maintenance system where complaints regarding the equipments were registered via phone call was replaced by registering the complaints through Hospital Management Information System (HMIS) software. With this new process, the complaints were being addressed rapidly, which is documented in HMIS for future references.
- PPM (Planned Preventive Maintenance) schedule was followed strictly in a timely manner. This had a positive impact on this study as any minor preventive maintenance of modifications done in the equipment will reduce major defects later. This will not only reduce the breakdown time and number of defects, but also reduce the financial burden of equipment’s failure.
- The Equipments Failure Analysis Worksheet was introduced for critical equipments. After this the factors contributing to the equipment’s failure were found and the corrective measures were taken to prevent such failure in future, which was done in the form of appropriate checks when equipments failed which was well documented in Equipments Failure Analysis Sheet for future reference.
- A monthly breakdown time of biomedical equipments were analysed and documented with the unique equipment’s identification number which played a crucial role in assessing the specific cause of failure in each equipment and if repeated issues were occurring in the same equipment, by which such specific equipments can be focused and preventive measures can be in future to reduce the breakdown time and also the number of defects in such equipments.
- Problem frequency analysis was introduced with specific categorisation like physical, technical, accessories, electrical and unspecified for the failed equipments, which was followed accordingly and documented after the repair. This was done to keep a track on the specific type of causes of equipment’s failure, by which the frequent type of defects involved are known so that the preparation of the inventory of specific spare parts is done well in advance and hence reduce the breakdown time of equipment. 5-whys analysis was also adopted to know the root cause of specific types of defects that could lead towards the clue for preventive measures, which could reduce the number of defects and eventually breakdown time.
- A protocol for biomedical equipments handling during hopper cleaning was introduced, which includes periodic training of biomedical equipments handling for hopper cleaners and the compulsion of presence of a biomedical engineer during fumigation and pest control whose responsibility is to make sure that the biomedical equipment is covered appropriately during fumigation which prevents the corrosion of the expensive biomedical equipments and thereby reduces the number of defects and improves the lifespan of the biomedical equipments which will have significant long-term positive financial implication for the hospital.
- Old equipments were identified and condemned as per hospital protocol. During condemnation, the useful spare parts of the old equipments were identified, tested and kept aside after proper labelling for future usage.
- Few biomedical equipments were being used repeatedly and frequently, whereas other equipments were not used at all which increases the wear and tear of the repeatedly used equipment, which is reflected by an increase in the number of defects and thus reduced life span of equipment. This process was modified wherein all the equipments are now used at regular intervals of time and swapped frequently, which has reduced the number of defects.
- The delay in delivery of spare parts of failed equipments was reduced by addition of a process, wherein emails and reminder calls are made regularly to the concerned company of the equipments at regular intervals of time until the spare parts are procured which has reduced the breakdown time of equipments significantly.
- The unorganised workplace for maintenance and storage of equipments in biomedical engineering department was improved by enforcing precisely planned 5S technique. 5S techniques refers to Seiri (Sort), Seiton (set in order), Seiso (Shine), Seiketsu (Standardize) and Shitsuke (Sustain). In biomedical engineering department where equipments and spare parts and various repairing tools were sorted according to their frequency of usage and red tagging of the unused equipments was done with reasons and actions to be taken clearly and were set in organised way with appropriate labelling. Biomedical engineering department was thoroughly made to clean from floor to ceiling and protocol was set in place to maintain the same. An audit was performed to consolidate the positive impact of improvement.
- 5S implementation played a pivotal role in this study in decreasing the breakdown time by improving the work efficiency in the biomedical engineering department (workshop area, equipments and spare parts store room and office). After 5S implementation, the needed spare parts and needed repairing tools were readily available, which subsequently lead to reduction in breakdown time.
- Data was collected after all the appropriate measures that were taken to reduce the breakdown time and associated defects at the end of every month for a period of 6 months and data was tabulated[Table 4] after measuring breakdown time and corresponding Sigma level.
<table>
<thead>
<tr>
<th>Month</th>
<th>Oct '17</th>
<th>Nov '17</th>
<th>Dec '17</th>
<th>Jan '18</th>
<th>Feb '18</th>
<th>March '18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total time (For the month in minutes)</td>
<td>44640</td>
<td>43200</td>
<td>44640</td>
<td>44640</td>
<td>40320</td>
<td>44640</td>
</tr>
<tr>
<td>Total Breakdown time (in minutes)</td>
<td>30</td>
<td>15</td>
<td>12</td>
<td>10</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>% Yield</td>
<td>99.93%</td>
<td>99.97%</td>
<td>99.97%</td>
<td>99.99%</td>
<td>99.99%</td>
<td>99.97%</td>
</tr>
<tr>
<td>DPMO</td>
<td>672</td>
<td>347</td>
<td>269</td>
<td>224</td>
<td>124</td>
<td>336</td>
</tr>
<tr>
<td>Z(LT)</td>
<td>3.21</td>
<td>3.39</td>
<td>3.46</td>
<td>3.51</td>
<td>3.16</td>
<td>3.40</td>
</tr>
<tr>
<td>Sigma Level(ST)</td>
<td>4.71</td>
<td>4.89</td>
<td>4.96</td>
<td>5.01</td>
<td>5.16</td>
<td>4.90</td>
</tr>
</tbody>
</table>

**Table 4. Breakdown time and Sigma level after LSS**

This histogram [Figure 5] shows average breakdown time and Sigma level after application of Lean Six Sigma to be 14.5 minutes/month and 4.94 respectively.

**Figure 5. Shows the Histogram depicting reduction in Breakdown time after Improvement**

The breakdown time reduced [Table 5] to an average of 14.5 minutes/month after the application of LSS as opposed to 19165.83 minutes/month before LSS, which shows a drastic improvement indicated by 99.9244% reduction in breakdown time and the goal of this study to reduce the breakdown time by 50% is not only achieved but surpassed the expectations.

Similarly, the average number of associated defects reduced from 40 defects/month before LSS to 6 [Figure 6] defects/month after the application of LSS indicated by 85% reduction in the number of defects, hence the aim of the study to reduce the percentage of associated defects by 50% is achieved.

The goal of this study was to increase the existing Sigma level from 1.66 to 4 or above level, which is achieved comprehensively after achieving the Sigma level of 4.94 at the end of this study.

**Figure 6. Shows comparison of no. of associated defects before and after LSS**

**Table 5. Shows the Improvement depicted by values before and after LSS**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Before LSS</th>
<th>After LSS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average breakdown time (minutes)/month</td>
<td>19165.833</td>
<td>14.5</td>
</tr>
<tr>
<td>Associated defects</td>
<td>40</td>
<td>6</td>
</tr>
<tr>
<td>Sigma level</td>
<td>1.66</td>
<td>4.94</td>
</tr>
<tr>
<td>% of reduction in breakdown time</td>
<td>99.9244%</td>
<td></td>
</tr>
<tr>
<td>% of reduction in associated defects</td>
<td>85%</td>
<td></td>
</tr>
</tbody>
</table>

**E. Control Phase**

This is the phase where implemented solutions are documented, monitored, tracked and handed over to the responsible process owners prior to the completion of DMAIC project. The challenge of Lean Six Sigma implementation is not in making improvements in the process, but in sustaining the achieved results. The tools like Control chart, Training and Data monitoring plan.

After the improvement phase, the control of the achieved results were followed up and documented which is depicted in the form of graph.

**Figure 7. Shows the I-MR Chart**

Footnote: *UCL= Upper Control Limit, LCL= Lower Control Limit.
In the control chart, [Figure 7] numerical numbers 1 to 15 denotes the period of this study, i.e. 15 months from March 2017 to May 2018. 1-MR chart for biomedical equipments breakdown time was drawn after collecting the data individually on monthly basis depicted as data points in the control chart, which indicates that biomedical equipments breakdown time before application of Lean Six Sigma was outrageously high, which had reduced drastically after the application of LSS and is kept consistently under control.

<table>
<thead>
<tr>
<th>Date</th>
<th>Equipment ID</th>
<th>Last PPM done Date</th>
<th>Problem Identified</th>
<th>Plan of Action</th>
<th>Implementation</th>
<th>Remarks If Any</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Physical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Electrical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mechanical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Accessories</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 6. Data Monitoring Plan**

**DISCUSSION**

Medical services are one of the most basic and most important needs of human societies and medical devices play an important role in providing healthcare services. The proper maintenance of equipment, supplies and devices of the hospital not only makes them easily accessible when needed, but also increases their durability and enhances their efficiency. Since medical equipments play a significant role in promoting the health and safety of the community, its correct and optimal management can have a significant impact on the national development of each country in terms of healthcare economics, medical education and research.

Raid Al-Aomar et al conducted a study at MEM College of Engineering, Abu Dhabi on 'Reducing operational downtime in service processes: A Six Sigma case study' using a core Six Sigma methodology, i.e. DMAIC methodology to reduce the operational downtime, wherein the data was collected at the end of every month and Sigma level was calculated simultaneously data was tabulated, average Sigma level of all the months before implementation of improved phase was calculated and considered which was found to be 2.52. Similarly, the Average Sigma levels of all the months considered together after the application of improved phase, which was found to be 2.935 indicating an improvement in the reduction of downtime in service processes. In this study from the collected data average Sigma level of all the months before and after improvement phase was calculated, which showed an increase in Sigma level from 1.66 to 4.94 levels. This implies a dramatic improvement in the reduction of breakdown time of biomedical equipments in MICU.

Ashkan Karimi et al conducted a study at Isfahan University of Medical Sciences, Iran on 'The effect of Six Sigma program on improving medical equipment’s management of operating rooms in one of the hospitals in Isfahan in 2016' adopted DMAIC methodology and managed to reduce the number of defects in biomedical equipment in the operation theatre from a total of 23 defects (Out of 60 equipment) before Six Sigma application to 13 defects after the Six Sigma application. Similarly, in this study DMAIC methodology was adopted, which lead to reduction in total number of associated defects from 40 defects before Lean Six Sigma application to a total of meagre 6 defects after Lean Six Sigma application and hence attained the goal of this study, which indicates that Lean Six Sigma is an effective tool in reduction of occurrence of defects in the biomedical equipment.

Adnan Al-Bashir et al conducted a study at Jordanian Ministry of Health, Jordan on 'Downtime reduction on medical equipment's maintenance at the directorate of biomedical engineering in Jordanian MOH’ adopted Pareto chart (in which 80% of effects is due to 20% of causes) and stratified the defects specifically on the type of defects like electrical (42.3%), mechanical (22.6%), accessories (8.2%), electronics (6.4%) and calibration (6%) etc. Process Mapping was drawn to know the root cause of defects and fishbone diagram was drawn to analyse cause and effects of the defects and downtime. Similarly, in this study the Pareto chart was used to sort the associated defects, which includes Physical (32.5%), Technical (30%), Accessories (25%), Electrical (7.5%) and Others (5%) by which it was concluded that the specific associated defects like physical, technical defects and defects in accessories were the major causes of equipment’s breakdown which lead towards specific precautionary steps to reduce the number of defects. Process Mapping was plotted after keen observation and conducting intense brainstorming session. The bottlenecks in the existing process were identified and rectified. Fishbone diagram was constructed by which causes and its effects were concluded.

**CONCLUSION**

- Lean Six Sigma approach is an effective and eloquent application in improving the biomedical equipment’s maintenance.
- Fishbone diagram and 5-Whys analysis tools are effective in determining the root causes and its effects of biomedical equipment’s failure.
- Process Mapping is a predominant tool to understand the existing process in healthcare system and plays a cardinal role in eliminating non-value added activities, which amplifies the productivity in healthcare system.
- SS technique is an inevitable tool to escalate the productivity in various organisations such as healthcare, industrial, business, hospitality, educational system etc., which not only has positive financial implications but also ensures the safety, hygiene and optimal utilisation of time at minimal cost.
Equipment Failure Analysis Worksheet is beneficial to analyse the genesis of the equipment’s failure and act as a guide for future.

Hospital Management Information System has played a pivotal role and acts as a blood vessel of the hospital in numerous support services and the services are well documented within the software system.

All the above outcomes of Lean Six Sigma approach can be adopted at various levels of healthcare system to increase the productivity, cost-effectiveness and enhancing the healthcare service.

REFERENCES