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To Study the Maintenance of Ventilators at a Tertiary Care Teaching Hospital in North India

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Abstract

Background: Maintenance is a core function of biomedical engineering and is essential for the optimum functioning of equipment. This study was undertaken with the objective to determine whether the current maintenance practices are effective in reducing equipment breakdown and increasing the life of critical equipments such as ventilators.Methodology: All the ventilators installed by a single firm at AIIMS were studied. A total of 179 ventilators supplied and installed in various inpatient areas across the hospital were studied. It was a retrospective descriptive study. Equipment related data was abstracted from the various service reports collected and compiled from the vendor and the nursing counters.

Index terms— breakdown maintenance, preventive maintenance, critical equipments, medical equipments.

1 Introduction

n the current scenario of rapidly evolving health care, modern medical technologies have been instrumental in creating an environment wherein despite failure of vital organs; life can be sustained with the help of advanced, sophisticated equipment's like dialysers, ventilators, heart/lung machine etc. Medical Devices are health technologies that are not medicines, vaccines or clinical procedures but are used in diagnosis, prevention, treatment and detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. (1) Chapman et al has categorized equipment into three types namely electric, electronic and mechanical instrumentation based on the branch of engineering possessing the skills to maintain these equipment. (2) Proper maintenance of medical equipment is essential to obtain sustained benefits and to preserve capital investment.(3) Moreover, inadequately maintained medical equipment creates an unacceptable high risk of patient injury. All these equipments account for a major part of any hospital project cost along with hospital furniture biomedical equipment accounting for nearly 50 percent of the cost. As per the study in a Canadian hospital 15-20 medical equipment are required per bed at a capital cost of 200-4,00,000 $. (4). Hence, it is imperative to ensure maximum utilization of the equipment with minimum downtime.

What constitutes appropriate maintenance and how to plan for medical equipment maintenance has been discussed and debated for many years without reaching any consensus. ??3, 5 -13) Ministry of Health and Family Welfare (MOHFW) has classified Maintenance into two types namely Corrective Maintenance and Planned Preventive Maintenance. (3) Some authors have also classified maintenance into inspection, preventive maintenance (PM) and corrective maintenance. (3,14,15) (PM) is a mix of two procedures: Safety testing (ST) and Performance Verification (PV). Planned Maintenance is a mix of Scheduled maintenance including cleaning and/or decontamination, Performance verification including calibration and Safety testing. Predictive maintenance which is a new emerging concept is a forecasting technique to determine the rate of failure of certain types of replaceable components like batteries, valves, etc.

Primary purpose of any (PM) program is to provide assurance that the facility's critical devices are functioning properly and safely at the time of their need (3,14). M Kalaf et al has stated that it is crucial not only to improve the life of the equipment but primarily to improve patient care. (15) For an effective maintenance program, it is imperative to develop a Monitored equipment maintenance program and the devices that should be I included in this program are either those critical devices that can cause injury if they do not function properly or those which are maintenance sensitive, i.e. they have significant potential to function improperly if they are not provided with an adequate level of "Preventive Maintenance". (14) Appropriate maintenance intervals also play a very crucial role in determining the effectiveness of equipment maintenance. One school of thought advocates that manufacturer recommended maintenance intervals should be followed, whereas another school of thought advocates that criticality and usage should be the factors which should determine the frequency of maintenance. Ventilators being used 24 hours a day will require frequent visits than ventilators being used once in a while. **??**2, 4, 16 -17] It is important to determine how the risk of adverse consequences might vary with different maintenance types and frequencies which are further determined by the number and nature of the devices non-durable parts in order to ensure their timely restoration before they can have a significant adverse effect on the functioning of the device. (14) The choice of approaches (in house by the hospital, contact outsourcing and contact with the manufacturer) for maintenance depends upon the complexity of the equipment.(3) For specialized and advanced equipment like PET scan, MRI, it is no costeffective to develop in house services at hospital. The manufacturer shall provide maintenance services through a combination of on-call services and a (PM) contract, negotiated at the time of the purchase. Maintenance Outsourcing is concept which is in its nascent stage of development and evolution. Hence, a cafeteria approach, with a mixture of all is widely adopted for the BME maintenance and is adopted at the Healthcare organization under study. A number of authors have deliberated on the pros and cons of Maintenance Outsourcing. [18,19, **??**0,4] The study was undertaken with the following objectives: ? To study the process of maintenance of ventilators by the vendor and to further assess the effectiveness of the existing process of maintenance ? To determine whether the current maintenance practices are effective in reducing equipment breakdown and increasing the life of critical equipments such as ventilators at a 2500 bedded tertiary care teaching autonomous healthcare organization.

The study further aimed at streamlining the current Equipment maintenance programme being followed in the Institute.

2 II.

3 Methodology

The study is a retrospective descriptive study. The study was carried out in an autonomous tertiary healthcare institute over a period of six months (December 2014 to May 2015). All the 179 ventilators serviced in the institute by a single supplier, over a period of 27 months (January 2013 to March 2015) were included in the study. The reliability of the data was established by cross checking 89 reports collected from the company with the reports available with the Sister In charges of wards responsible for maintaining the ventilators.

The data for the study was obtained from the service reports and it was compiled to help determine the parameters to measure effectiveness of maintenance. These under mentioned parameters were identified by Review of literature so as to reach a decisive conclusion. Unstructured Interviews were conducted with the BME responsible for maintaining these equipments in the Institute as well as with other engineers from the industry to further understand the reasons of breakdowns and to understand the financial implications of these maintenance programmes. The rates of the spare parts were collected from market with the help of a private company working in the field of providing biomedical engineering solution to the hospitals. Help was sought from various BME on a number of occasions for their expert opinion and guidance. Data was entered using Microsoft Excel and Data was analyzed using SPSS Version 20.0. Cross tabulations were done to determine the significance of the visits with the nature and frequency of breakdown.

4 Conflict of Interest: None

Limitation: The retrospective nature of the study was a limitation to the study as some of the service reports collected from the company and the inpatient wards were not complete in all respects.

5 III.

6 Observations/ Results

The maintenance of ventilators is outsourced to the manufacturer in the hospital. In each of the visit undertaken for the maintenance, a data sheet containing all essential details related to equipment maintenance was filled by the BME.

It was observed that a total of 692 maintenance visits were undertaken for 179 ventilators over a period of 27 months by 6 BME. These 179 ventilators were of 5 different models and have been installed over a period of 14 years (18-12-2000 to 29-09-2014). Due to lack of documentation, the installation dates of 19 ventilators could not be determined.

Amongst these maximum numbers of ventilators were of Model A (48%) and minimum number of ventilators belonged to model B (5%).The number of maintenance visits in relation to each these 5 models have been depicted in Table No.1. The number of Maintenance visits per equipment per year was taken as dependent factor and its relation with 5 different model of the ventilator was studied. It was observed that the mean visits varied from 2.6 visits for the model E to a high of 4.5 visits for model A. This was found to be statistically significant on applying ANOVA with a p value of 0.00.

7 a) Outcome of the Maintenance Visits

Out of the total maintenance visits undertaken by the BME, 88.36% were for Breakdown Maintenance and 11.64 % were for Preventive Maintenance.

In 71.50 % visits the defect was corrected during the visit and the equipment was made functional, whereas in 23.56% visits defect could not be corrected and in the remaining 4.77%visits, the outcome could not be defined due to ambiguity in the language of the in service reports. Out of all the (PM) visits, 39% were within the warranty period and 16% were during the CMC/ AMC period. This implies that during the initial years of purchase that is during the warranty period, the manufacturer provides better (PM) as compared to its later years.

The outcomes of each of these visits were assessed in correlation to the BME attending the call using ANOVA. The p-Value was found 0.000, indicating that the outcomes have a significant correlation with the knowledge, skill and training of BME attending the call.(Table **??**)Hence, this draws attention to the fact that hospitals need to frame guidelines about the skill sets of manpower that will be deployed for providing maintenance of ventilator.

8 Frequency of the breakdown and life cycle of the equipment:

The analysis of the breakdown frequency reveals that there are two peaks in the breakdown of the equipment, one during initial period varying from 0-12 months and the other during 80-90 months as can be seen in Figure **??**. The later peak can be attributed to the age of the equipment whereas the initial peak could be due to lack of training to operate the new model / new type of ventilator. Thus the findings conclude that with advancement of the technology the learning curve for the equipment is slow and the duration for training increases. This observation demonstrates the importance of proper induction of the new equipment with the staff. These finding are in consonance with the World Health Organization report on Medical Devices: Managing the mismatch (August 2010) where it has been described that increasing complexity of medical technology has important bearings on the consequences for training and outcome for care.

9 b) Downtime Period and Response Time

On calculating the downtime of the ventilators, it was observed that the downtime ranged from 0 to 55 days with an average of 2.60 days / ventilator per year. Out of the 612 Breakdown calls, data on response time of the engineers was available for 528 breakdown visits and out of these 528 visits, 488 visits were attended on the same day with a cumulative delay of 467 days. Such prompt response time and low downtime was possible due to the stationing of two full time BME at the hospital.

10 c) Effective Preventive Maintenance

As per the guidelines laid down by the hospital, (PM) has to be done quarterly. Total number of expected Preventive Maintenances during the study period was computed by taking the date of installation and four (PM) yearly. The expected (PM) visits was calculated (for date of installation before 01-01-2013 it was 9 and for the equipment installed after that the no. of completed month till 31-03-2015 were divided by 3 and decimals being neglected.) to be 686 during the study period whereas there were only 80 (11.67%) preventive maintenance. Which is a far cry from the expected numbers. Despite negligible preventive maintenance, it was observed that the downtime per equipment was well within the acceptable limit of 5%. It can then be inferred that that the role of (PM) was negligible in the efficient maintenance programme of ventilators being studied. This indicates that in the current scenario where hospitals are increasingly procuring software and microprocessor driven equipment which possesses the ability to detect and display errors on a real time basis. The need of the hour is to move away from the conventional method of (PM) and instead create an in-house team trained to perform and analyze the self tests and coordinate with BME of the manufacturer. Thus, there is also a need to revisit (PM) as per the maintenance schedule recommended by the manufacturer.

11 d) Yield of PM

Preventive Maintenance Yield is the percent of (PM) visits where problems were found that affected equipment operation or safety = (No. of PM visits in which problem identified/(PM) visits)*100

Yield was identified as an important indicator by Ridgway M et al. it is stated that when a device is tested at a particular interval, the number of completed tests (usually expressed as a percentage) that are found to be outside the acceptable performance limit is defined as the "yield" at that particular interval and this performance deterioration is a result of the failure of small components.

In the 80 (PM) visits, 10 Spares were changed during 9 (PM) visits and none were changed during the remaining 71 visits. Due to the absence of any other indicator, to determine the effectiveness of preventive maintenance, Yield was used as a proxy and was calculated as 11.25%. However, it is felt that more studies are required to determine the importance of (PM) in correlation to yield for Critical equipments.

12 e) Man-Hours Spent to Maintain the Ventilator

There were only 664 working days in the study period, during which a total of 692 visits were done which translates into 1.07 visits per day. Amongst these visits the detail of man-hours utilized for the maintenance of ventilators was available for 457 visits and was found to be 523 hours and 45 minutes ranging from 10 minutes to 5 hours 15 minutes with a mean of 1 Hour 8 minutes man hours.

On calculating the percentage of time the BME spent on repair and maintenance using the following formula:

Repair time of BME utilized for one repair * mean number of repair done per day / the total available working hour of BME = 68 min (time to attend one visit) * 1.07 (no of visits per day) *100/ 60 min * 8hrs = 72.76 *100 / 480= 15.15 % It was observed that only 15.15 % of the available time of the BME was being spent on the maintenance. The above findings indicate that if the time is optimally utilized by the personnel engaged in carrying out maintenance related tasks, they could effectively undertake many more PM related activities of ventilators in the available time.

13 f) Replacement of Spare in Relation to Maintenance Contract

Out of 692 visits, 488 spares were changed in 418 visits. On calculating the number of spares replaced per equipment during the study period, it was observed that 2.73 spares were replaced per equipment. It was also observed the spares were more likely to be changed when the equipment was out of warranty. On further probing, it was observed that 2.8 spares and 1.6 spares were replaced per equipment when the equipment was under warranty or under CMC and 3.2 spares were replaced when the equipment was neither under warranty nor under CMC.

Amongst all the commonly replaced spares, the expiratory sensor was the most commonly replaced spare (80 times) followed by the oxygen cell (69 times), and expiratory valve (22) and these 3 spares accounted for 35.33 % of all the spares replaced during the study period. This indicates that it is imperative for hospitals to identify such spares at the time of procurement so that a mechanism could be devised to ensure that these spares are readily available and this will help in keeping the equipment downtime to a minimum. Identification of such spares will also help the organization to negotiate their cost with the vendor at the time of procurement which will thus be instrumental in reducing costs of maintenance.

14 g) Human Factor in Relation to Maintenance of Equipment

One of the potentially important factors responsible for the quality of maintenance is the attitude, knowledge and skill of the manpower engaged for providing these services. ANOVA was applied to determine the difference in quality of maintenance between different BME. The factors taken to conclude the quality of maintenance were time taken and breakdown. Amongst these time taken by the BME to attend one call was found to be statistically significant .Although Post Hoc test indicate a statistically significant difference (indirect indicator of the ability of the BME), the real difference was in fact just 20 min.

This implies that is the attitude, knowledge and skill of the manpower engaged for providing maintenance services are important and further research is required to identify the importance of each of these factors individually.

IV.

15 Conclusion

In this paper the authors have attempted to gain an insight into the existing system of Maintenance of ventilators. The following conclusions can be drawn from the study: 1. The knowledge, skill and training of BME attending the call have an impact on the outcome of the visit.

Hence, it make it imperative for healthcare organizations to define and frame guidelines regarding the skill sets of manpower that will be deployed for providing maintenance of ventilator. per the maintenance schedule recommended by the manufacturer. 5. Time being spent on maintenance was sub optimal, which points towards the fact that if the time is optimally utilized by the personnel engaged in carrying out maintenance related tasks, they could effectively undertake many more (PM) related activities of ventilators in the available time. 6. It was found that there were a few common spares that were being replaced time and again making it imperative for hospitals to identify such spares at the time of procurement. So that a mechanism could be devised to ensure that these spares are readily available and this will help in keeping the equipment downtime to a minimum. Identification of such spares will also help the organization to negotiate their cost with the vendor at the time of procurement which will thus be instrumental in reducing costs of maintenance.

The most significant finding of this study is the need for further research in the field of maintenance of medical devices especially in terms of the (PM) Yield and Human factors which influence the maintenance strategies adopted by the organization. Further, attention needs to be drawn to the fact that costs incurred in the maintenance of such equipments needs to be looked into so as to enable one to draw more factual conclusions and design a cost effective and efficient equipment maintenance programmes.

in
which problems identified/PPM scheduled)*100
6. Percentage of Biomedical engineer (BME) time spent on the maintenance of one ventilator was calculated as recommended by % BME time spent on maintenance = 100% * [Time spent on inspection, incoming testing, PM, and corrective maintenance] / [2,080 hours * number of technicians] (21)

*[Note: (have we calculated it) 3. Mean Time to Repair: Average of all repair time (The time between the start and finish of repair) 4. Periodic Preventive Maintenance(PPM) completion rates: The completion rate is percentage of procedures completed = (Number of PPM completed/Number of PPM schedule)*100 5. Periodic Preventive Maintenance (PPM) Yield: It is the percent of scheduled PPM procedures performed where problems were found that affected equipment operation or safety = (Number of WO]*

Figure 1:

Figure 2:

[Keil ()] , O Keil . *Évolution of the clinical Engineer' Biomed Technol. Manag* 1994. 5 p. .

[Kalaf et al. ()] 'A study of current maintenance equipment in hospitals in relation to patient outcomes'. K Kalaf , P Gibson , J Flanagon . *International Journal of Social* 2013. 7 (10) p. . (Human Science and Engineering)

[Chapman] *Biomedical Equipment Maintenance and Repair Naval Regional Medical Center Camp Pendleton*, J Chapman . California.

[Ridgway Ph and Cce ()] *Classifying medical devices according to their maintenance sensitivity: a practical, risk based approach to Preventive Maintenance program management*, Malcolm Ridgway Ph , D Cce . BIT2000.

[Fennigkoh and Smith ()] 'Clinical Equipment Management'. L Fennigkoh , B Smith . *JCAHO PTSM Series #* 1989. 2.

[Cruz and Rincon] *Decision Support Medical device maintenance outsourcing: Have operation management research and management theories forgotten the medical engineering*, Miguel Cruz , A , Rios Rincon , A .

[Berek (1999)] *Interpreting the Environment of Care Standards' BiomedInstrum Technol*, B Berek . 1999 Nov/Dec pgs 531 -3.

[Introduction to Medical Equipment inventory management, WHO Medical Device Technical series (2015)] *Introduction to Medical Equipment inventory management, WHO Medical Device Technical series*, http://whqlihttp://apps.who.int/medicinedocs/documents/s21565en/s21565en.pdf.bdoc.who.int/publications/2010/9789241564045_eng.pdf 2015. June 2015. (Internet)

[Jamshidi et al. ()] 'Medical devices Inspection and Maintenance; A Literature Review'. A Jamshidi , S Rahimi , D Ait-Kadi . *Proceedings of the 2014 Industrial and Systems Engineering Research Conference*, (the 2014 Industrial and Systems Engineering Research Conference) 2014.

[Medical Equipment maintenance manual, Ministry of Health and family welfare (2010)] *Medical Equipment maintenance manual, Ministry of Health and family welfare*, Oct.2010. (Internet)

[Medical equipment maintenance programme overview WHO Medical device technical series (2011)] *Medical equipment maintenance programme overview WHO Medical device technical series*, http://apps.who.int/medicinedocs/documents/s21566en/s21566en.pdf 2011. May 2015. (Internet)

[Anon (2000)] *Medical Equipment Maintenance' Joint Commission Environment of Care News*, Anon . Jan/Feb 2000 pgs 2 -3.

[Rios-Rincón and Haugan ()] 'Outsourcing versus in-house maintenance of medical devices: a longitudinal, empirical study'. Miguel-Cruz A Rios-Rincón , A Haugan , GL . *Rev Panam Salud Publica* 2014. 35 (3) p. .

[Taghipour et al. ()] 'Prioritization of medical equipment for maintenance decisions'. S Taghipour , D Banjevic , Aks Jardine . *Journal of the Operational Research Society* 2010. p. .

[Capuano and Koritko ()] *Risk Oriented maintenance' BiomedInstrum Technol*, Capuano , S Koritko . 1996. 30 p. .

[Keil ()] *The buggy Whip of PM' Biomed Technol Manag*, O Keil . 1995. 6 p. .

[Moorman and Poage ()] 'We beg to Differ: PM Does Add Value' Biomed Technol'. B Moorman , T Poage . *Manag* 1995. 6 p. .

[Wang and Levenson (2000)] 'Équipment Inclusion Criteria -A New Interpretation of JCAHO's Medical Equipment Standard'. B Wang , A Levenson . *J. ofClin. Engin* 2000 Jan/Feb pgs 26 -35.

[James ()] 'Éstablishing Maintenance Intervals based on Measurement reliability of Engineering Endpoints'. P James . *Biomed Instrum Technol* 2000. p. .