Evidence-based approach to medical equipment maintenance monitoring

V. Gonnelli[1], F. Satta[2], F. Frosini[1] and E. Iadanza[1]

[1] University of Florence / Dept. of Information Engineering, Florence, Italy
[2] ESTAR, Dept. of Information and Health Technology / University Hospital of Careggi, Florence, Italy

Abstract— **Maintenance is a crucial part of the life cycle of medical equipment. We applied a specific set of codes to classify the corrective and scheduled maintenance work orders at the University Hospital of Careggi (Florence, Italy). A set of Key Performance Indicators (KPI) (financial, technological and organizational) helps in evaluating the performance of the medical equipment maintenance. The analysis of KPIs (related to costs, age and SM completion rate) revealed some problems in maintenance strategy. The results show, starting from the evidences (i.e. the failures), that the combination of these two methods can give a periodical cross-analysis of the maintenance performance and indicate the most appropriate procedure.**

Keywords— **Evidence-Based Maintenance, Health Technology Management, Key Performance Indicators, Medical Equipment.**

I. Introduction

Maintenance is a crucial part of the life cycle of medical equipment. It is basically composed by two types of activities: ordinary (i.e. scheduled maintenance, SM) and extra-ordinary, both included into the medical equipment maintenance activities of all hospitals. The first includes those activities carried out at predetermined intervals in order to reduce the probability of failure or degradation of a function (preventive maintenance), to verify the compliance with the essential safety requirements and performance specifications declared by manufacturer. The second consists into repairs, the restore of the equipment to a required function (corrective maintenance, CM) or replacements, when repairing it is not possible or economical. [1]

Maintenance is also a crucial aspect of the activities of a Clinical Engineering (CE) department because it involves a lot of resources, both human and financial. Therefore, the evaluation of the effectiveness of its performance is fundamental in order to optimize the use of available resources in CE departments and to put them where most needed. Medical equipment maintenance strategies have been developed according to different philosophies through the years: from the initial extreme attention to electrical safety to more feasible approaches which fix the needs of individual healthcare institutions [2]. The expression "evidence-based" is notoriously referred to medicine, but it can be applied also to maintenance. Evidence-Based Maintenance (EBM) starts from the analysis of evidences (i.e. the failures) to monitoring its effectiveness and making the necessary changes to improve itself. In most hospitals technical reports describe only the failure, the technical intervention and the spare parts used but don't provide any information about the actions that could have been performed to prevent that failure [3]. By the knowledge of the failure stories of medical equipment it is possible to monitor the effectiveness of the actual maintenance strategy and improve it, finding the most appropriate approach. Improving the medical equipment maintenance in terms of effectiveness, reliability and availability means, ultimately, improving patient and user safety.

Starting from Wang et al. work on EBM [3-6] we followed their approach. The first step was the classification of work orders (wo) by using a set of codes. We chose the same small set of codes as [3] with the purpose to standardize and simplify the classification of work orders. Then, we analyzed SM and CM stories of medical equipment to individuate codes unusually high and those related to potential maintenance omissions. We made a comparison between trend of Careggi's analyzed failures and reports available in MAUDE (Manufacturer And User facility Device Experience) database on the US Food and Drug Administration (FDA) web site [7] in order to have an international focus of the Florentine Hospital.

The second step was the individuation of KPIs. Starting from literature we selected those more adapt to our data, available information and context. According to the EN normative [8] we divided the indicators into 3 groups: financial [8-11], technological [8, 11-16] and organizational [11-19].

II. Material and methods

A. Data analysis

The University Hospital of Careggi is provided with 1367 beds and 16.209 pieces of equipment. The maintenance of medical equipment is managed by ESTAR (CE department) with the support of external suppliers and service.

This study started in December 2016. We analyzed two critical departments: Operating Room and Intensive Care Unit and within them we chose 13 classes of medical equipment owned by the hospital. We collected data referred to the last 5 years (from 2012 to 2016) from the whole hospital's

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equipment maintenance management database. In Table 1 we resume the analyzed data and medical devices classes.

Table 1 Data Analyzed.

Device type	#of Units	CM wo	SM wo
Anesthesia machine	162	802	491
Aspirator	377	160	287
Ceiling Mounted Unit	319	284	522
Defibrillator	410	1,463	2,036
Electrocardiograph	356	1,384	947
Electrosurgical	205	287	408
Infusion Pump	1,401	841	2,149
Monitor	900	1,294	3,337
Oximeter	613	557	1,120
Surgical lamp	354	411	1,222
Surgical table	93	520	382
Telemetry	104	99	142
Ventilator	203	796	831
Total data analyzed	5,560	9,110	14,021

We analyzed technical reports about the CM and SM activities, including preventive maintenance, electrical safety tests and quality control. We eliminated from the analysis 14.06% of data because their reports did not provide enough information for a proper classification.

B. Classification

In [3] some codes are assigned by CE staff properly trained and instructed to use them. We made an inverse process. We carefully analyzed every single technical report of CM and SM in order to catalogue the big amount of failures that happens every year. With the help of technicians and CE staff we assigned a unique code, the same used in [3], as resumed in Table 2. If an event could be assigned to more than one code, we carefully analyzed it to choose the most appropriate one.

Table 2 Failure Code

Code	Description	CM/SM
NPF	No problem found	both
BATT	Battery failure	both
ACC	Accessory failure (including supplies)	both
NET	Failure related to network	CM
USE	Failure induced by use (i.e. abuse, accident, environment conditions)	CM
UPF	Unpreventable failure, caused by normal wear and tear	CM
PPF	Predictable and Preventable failure	CM
SIF	Induced by service (i.e. caused by a technical intervention not properly completed or premature failure of a part just replaced)	CM
EF	Evident failure (i.e. evident to user but not reported)	SM
PF	Potential failure (i.e. in process of occurring)	SM
HF	Hidden failure (i.e. not detectable by the user unless special test or measurement equipment)	SM

C. Comparison with MAUDE database

By consulting FDA website we identified the product code which corresponds to our 13 medical equipment classes. With these product codes, it is possible to analyse MAUDE database and also the TPLC (Total Product Life Cycle) of medical equipment. MAUDE is a database of thousands of medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers [7]. Reports are grouped in macro classes which we associated to failure codes of Table 2. For example, when we read “battery issue” we associated it to BATT.

D. KPIs

By a thorough literature review and according to information available at CE department and their needs, we individuated 3 groups of KPIs as reported in the following:

1. *Financial*, with the primary objective to assess if the performance is cost-effectiveness. For example, we used: total CE expense as a percentage of total cost of acquisition (cost of acquisition ratio); CM (and SM) expense as a percentage of total CE expense; In-house (and external contracts) expense as a percentage of total CE expense; spare parts (and supplies) costs; hourly cost of technicians (internal and external).
2. *Technological*, with the purpose to assess the operational performance of the equipment in term of availability (related to customer satisfaction) and reliability. For example, we used: Repair Time, Uptime, Downtime, Class failure rate, Age failure rate.
3. *Organizational*, related to internal process and staff productivity. For example, we used: number of technicians per number of capital devices; number of SM performed per number of capital devices; percentage of SM with problems (i.e. not coded as NPF); “delinquent work-orders” (i.e. not completed within 30 days).

We computed them for the 13 classes of medical equipment in order to obtain the trend of each KPI from 2012 to 2016.

III. Results

A. Distribution of classified failures

Figure 1 and 2 show the distribution of failure codes obtained from CM and SM work orders, respectively, related to defibrillators (the most complete among the analyzed classes).

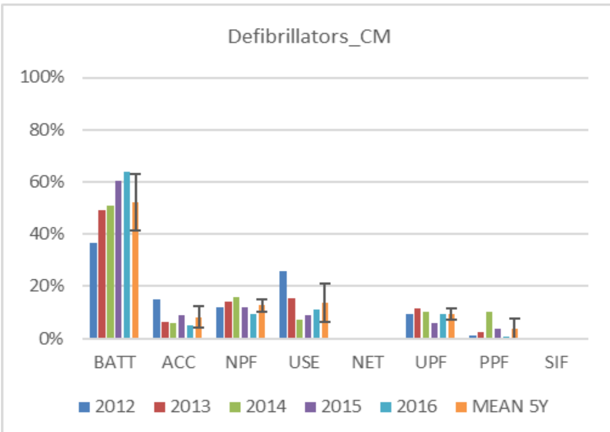

Figure 1 Defibrillators. CM failure codes distribution.

Within each type of failure, the first 5 bars of the histograms represent 5 years (from 2012 to 2016) while the rightmost bar is the average value with error bars of ±1 standard deviation (SD). The height of bars represents the percentage of failures found in CM or SM work orders. In figure 1 we can notice that in 2015 the 60.40% of CM work orders were related to battery failures, the 8.91% were related to use and the 5.94% were unpreventable failures.

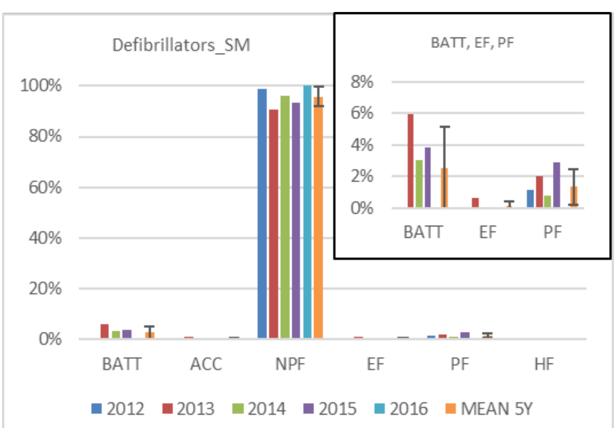

Figure 2 Defibrillators. SM failure codes distribution. The insert is an expanded scale of BATT, EF, PF to enhance their visibility.

We can read Figure 2 in a similar way: in 2016 SM work orders were 93.33% NPF, 3.81% BATT and 2.86% PF. CM values were corrected with the ETFR (Equipment Type Failure Rate, i.e. the percentage of units within a specific equipment type failed per year) [3]. This correction is necessary if we want to combine the CM and SM failure codes distribution and have a complete vision of the equipment fault history. In fact, CM are referred only to failed units and do not consider those which never broke. SM, instead, referred to all units. We did not show graphics with CM and SM combined because the great amount of NPF in the SM work orders did not permit to appreciate the trend of other categories of failures codes.

B. Comparison with MAUDE database

Figure 3 shows the comparison of distribution of failure codes of CM performed at Careggi in 5 years with the reports analyzed on MAUDE database. Notice that for Careggi's distribution there is a 12.33% of work orders classified as NPF which is not associable to MAUDE reports, therefore they are not shown in the graphic.

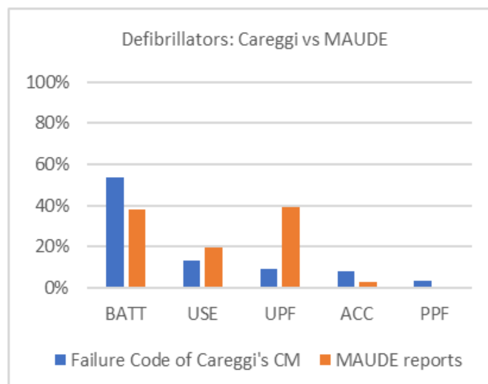

Figure 3 Defibrillators. Careggi CM vs MAUDE from 2012 to 2016.

IV. Conclusions

After the classification, we analysed the amount of the codified data looking for codes unusually high and for those related to potential maintenance omissions (i.e. PPF, SIF, PF, HF). Through the analysis of technical reports, we determined the causes of the failures to understand if they were individual errors or related to incorrect maintenance frequency and/or procedure. For each code, we associated a possible action that CE staff could perform, directly or indirectly, to enhance maintenance performance. For defibrillators we noticed high battery failures. CE could make indirect actions in order to purchase batteries with better longevity and improve training of users to correctly manage batteries to reduce risks of a premature depletion. For *use* related and *evident failures* it is necessary to train users to better manage the equipment and to report problems; for potential (and hidden) failures CE could make direct actions by increasing frequency of SM or add specific tests [5] on batteries in this case. By the combination of CM and SM distribution we can have a sort of signature of the equipment and, if we analyzed the whole inventory we can also have a signature of the entire hospital and use it to compare to other similar hospitals [3].

We used KPIs to compare results obtained from failures codes distribution. Defibrillators had an high percentage of BATT failure code so we analyzed KPIs related to defibrillators in order to have more detailed information about those failures. From the analysis of costs related to spare parts we effectively found an increase in battery expense (+48.6%) in comparison to the 5-years mean. By the analysis of AFR we found that 2016 is the year with most of units older than 10 years (51.14%) while the 5-years mean is 43.09%. Considering that units older than 10 years have a computed AFR of 60% it is possible that the high percentage of battery failures in 2016 was due to obsolescence. From SM performed in the last 5 years we found that only in 2016, when maintenance of defibrillators was outsourced to a service, there was a compliance in SM completion rate. But 2016 is also the year with most battery failures, so it is necessary adding specific instructions for technicians in order prevent BATT fault.

By performing a comparison with the MAUDE database, we could also have a wider vision of problems. For example, in accordance to the problem found in SM strategy, batteries failures are common in defibrillators. Despite USE category is the second highest after batteries failures in Careggi defibrillators, problems related to use are less than in MAUDE.

In conclusion, the assignation of these simple codes to the reports could become a regular practice of technician activity in order to use them in combination to KPIs. This is an objective method to monitor medical equipment maintenance at 360 degrees and to make a periodical cross-analysis of its performance.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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Corresponding author:
Author: Prof. Ernesto Iadanza
Institute: Department of Information Engineering
Street: via di Santa Marta, 3
City: Firenze
Country: Italy
Email: ernesto.iadanza@unifi.it