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# A New Failure Analysis for Maintenance Management in Complex Hospitals

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Abstract—management of medical devices in hospitals includes the planning of medical equipment acquisition and maintenance. The presence of critical and non-critical areas together with technological proliferation render the management of medical devices very complex. This study creates an easy and objective methodology for the analysis of medical equipment maintenance, that makes the management of medical devices more feasible. The study has been carried out at Florence Hospital Careggi and it aims to help the clinical engineering department to manage medical equipment by clarifying the hospital situation through a characterization of the different areas, technologies and fault typologies.

**Keywords**—Clinical Engineering, Maintenance, Medical Devices Management, Key Performance Indicators.

### I. INTRODUCTION

ANALYSIS of medical devices management is necessary for replacement plan in hospital because it depends on the area where the device is used (destination of use of devices), the user's experience and training, the technological level of the equipment and finally on whether the devices are acquired or in service. Because the situation is different for each hospital, it is necessary to develop a methodological analysis that uses objective and easy criteria to support decision makers (e.g. the clinical engineering department in hospitals) during the main phases of technology management such as the acquisition and maintenance planning.

The analysis has been developed at Florence University Hospital of Careggi, a third level hospital with 1,670 beds and 6,000 employees. The Clinical Engineering department is responsible for the management of 15,000 medical equipment devices directly managed or controlled through external suppliers assistance and services. The first step is the

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classification of medical devices according to their technological level and their destination of use. The second step is to individuate the correct Key Performance Indicators (KPI) for analysis: the Failure Rate per Category (FRC) and the Number of Technical Interventions (NTI).

### II. METHODOLOGY

### A. Medical Devices Classification

All devices according their own technology have been classified by "technological complexity [1]." Criteria for the classification are reported in Table I.

## TABLE I DEVICE COMPLEXITY CRITERIA

### DEVICES COMPLEXITY LEVEL

TECHNOLOGICAL ASPECTS
TECHNOLOGY INTEGRATION LEVEL
SOFTWARE PRESENCE
MINIATURIZATION LEVEL

NON-TECHNOLOGICAL ASPECTS ERGONOMICS USABILITY

- USER EXPERIENCE
- YEARS OF DEVICE USAGE

Only technological aspects are considered for classification even if device complexity also includes non-technological aspects such as usability, ergonomics and user experience.

Further, all devices have been classified according to their "Destination of Use" in healthcare [2].

### B. KPI Analysis

Quantitative KPIs have been applied to previous classifications. The Failure Rate Category (FRC) indicator is the Global Failure Rate index that takes into account the specific category of the failure [3]. Six categories of failure have been considered and classified by analyzing all technician reports present in the Database: "Software (FRC-SW)," "Electronic/Electric (FRC-ELE)," "Mechanic (FRC-MEC)," "Accessories (FRC-ACC)," "False Alarm (FRC-FA)" and "Unclassifiable (FRC-UN)".

The NTI indicator takes into consideration the number of technical interventions by considering whether the technicians come from the internal Clinical Engineering department, from an external private company or from suppliers assistance.

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### III. RESULTS

The analysis makes use of the Clinical Engineering Database of the hospital by including all the maintenance data from the Cardiovascular department from year 2001 of 2,000 medical devices. This department has been chosen for the analysis because it includes a large number of medical equipment that uses many different technologies.

In the "Technological" classification four categories are considered: "High-Tech," "Medium-Tech," "Low-Tech" and "Limited-Tech," see Fig. 1. The Limited-Tech classification aims to eliminate possible degradation of data during the KPI analysis because of the presence of improper clinical and technological devices (e.g. lamps and beds).

# N° Devices 1200 1000 800 400 200 Hi-Tech Medium-Tech Low-Tech Limited-Tech Technological Level

Fig. 1 Distribution of medical devices according to their Technological complexity level

In the "Destination of Use" classification five categories are considered: "Life Support," "Diagnostic," "Therapeutic," "Laboratory" and "Activity Support" (see Fig. 2). Clinical Support devices as well as the Limited-Tech category in the previous classification are considered separately so as to not contaminate data with improper medical devices (e.g. autoclave or television system).

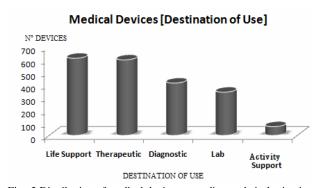


Fig. 2 Distribution of medical devices according to their destination of use and application

The KPI analysis has showed a correlation between technological classes and FRC, see Fig. 3. The sum of all the FRC types is proportional to the technological level of the devices.

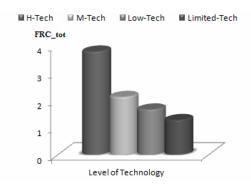


Fig. 3 Number of Total Failure Rate Categories according to "technological complexity" classification

Therefore, High-Tech is the category that needs more for continuous controls and interventions. Attention to Service Level Agreements here is necessary because hospitals may not be completely independent of external suppliers assistance for the management of these devices.

By analyzing Fig. 4, it is possible to see that FRC-ELE and FRC-SW are typical for High-tech. FRC-MEC is equally distributed over all classes. It is interesting to observe that Limited-Tech doesn't present any FRC-False Alarm. It is also important to note that FRC-UN characterizes mostly Highand Medium-Tech.

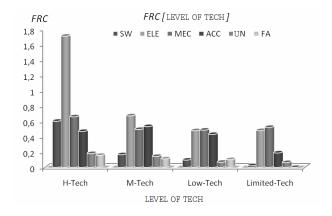


Fig. 4 Number of Failures per Category per n° of devices classified according the technological complexity classification

The FRC analysis on destination of use classification is reported in Fig. 5. FRC-SW characterizes Therapeutic destination of use. Activity Support does not have FRC-FA; further, FRC-FA is low for Diagnostic and Lab areas. It is also interesting to note as FRC-ACC is low for Lab.

NTI application on destination of use classification is reported in Fig. 6. Diagnostic and Lab areas are the exceptions of the general trend of NTI[destination of use], that normally has the highest values for all uses of internal NTI. Both Diagnostic and Lab present higher values for external technical interventions than internal ones. Lab and Diagnostic are characterized by High-Tech medical devices.

ISSN: 2517-9438 Vol:2, No:8, 2008

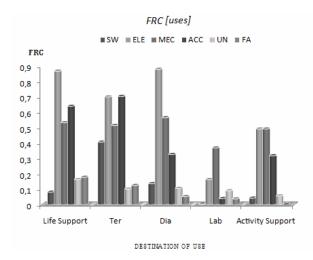


Fig. 5 Number of Failures per Category per n° of devices classified according the "destination of use" classification

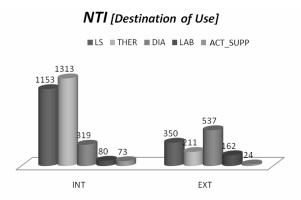


Fig. 6 Number of Technical Interventions according to "destination of use" classification and to technician provenience

Further, Diagnostic area represents the destination of use with the highest NTI-External with respect to all external interventions.

Finally, NTI have been classified according to failure typology, see Fig. 7.

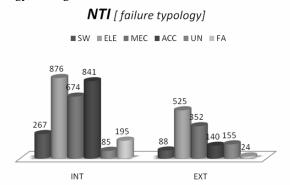


Fig. 7 Number of Technical Interventions belonging according to Failure Typology and to technician provenience

It is interesting to observe that Unclassified failures represent the only typology with more NTI-EXT than internal

ones. No clear reports for external interventions have been common during the analysis. Finally, False Alarms result much higher in NTI-INT than in the -EXT ones.

### IV. DISCUSSIONS AND CONCLUSION

High-Tech devices represent the most critical class in maintenance management because they have the highest values of FRC provided.

FRC-MEC and FRC-ELE are very high for Limited-Tech (See Fig. 3); maybe mistakes in devices classification have been made. With further analysis, it becomes clear that most Electric/Electronic and mechanic failures belong to scialitic lamps and patient lifting respectively. Both technologies must be re-classified as Low-Tech devices.

Further, for better classification a semi-quantitative checklist is distributed to users in order to evaluate nontechnological aspects of medical devices such as usability and personal experience with them.

It is interesting to note that after observing FRC-FA both Medium- and Low-Tech present high values of this indicator (see Fig. 3). Thus, in the acquisition phase it is important to consider these aspects as well as to ask for user training with lower technological devices.

Another essential aspect of the acquisition phase is demonstrated in Fig. 7: asking technicians of external private companies to leave a formal, pre-prepared report of their work after every maintenance would create a much more efficient control. This would help the Clinical Engineering Department to better control important Hospital areas such as Lab and Diagnostic that present high NTI-EXT and a high concentration of High-Tech equipment.

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