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A Methodology Aimed to Guarantee Technology Continuity in Health Structures.

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Abstract— **In healthcare the importance of clinical continuity is essential for both patients life and health organization activity. Since technology continuity is having more and more importance for the service continuity, a correct management of medical devices must be guided by criteria that ensure its safe, appropriate and economical use through a well planned purchase, appropriate preventive and corrective maintenance**

Indeed, the aim of health technology managers is to optimize the integration of external interventions assistance and internal technical service to guarantee an efficient and cost-effective maintenance system. This paper proposes an innovative carefully thought methodology which is aimed to provide technological and procedural actions which offer support to decision makers in technology management regarding the implementation of continuity in medical services and response to technology failures and emergency events.

I. Introduction

THE British Standard BS 25999-2:2007 [1] defines "business continuity" as the "Strategic and tactical capability of the organization to plan for and respond to incidents and business disruptions in order to continue business operations at an acceptable predefined level."

The standard field application is wide and can be applied to every organization or institution type and size.

Hence, this paper proposes a methodology which is able to provide technological and procedural actions which offer support to decision makers in technology management regarding the guarantee of continuity in medical services and response to technical failures, by indicating specific assistance requests in the acquisition phase and procedures necessary for quick replacement of broken equipment with functioning ones.

The problematic regarded the linear accelerator in the Florence University Hospital of Careggi that broke down during the night time of a pre-festive day, resulting in a forced shutdown of all radio therapeutic activities for several days. Even if such technology is not a life saving device, the consequences were serious in that patients with critical problems, needing radio therapy, were unable to be treated creating delays also on the appointment lists. This is only one example of how technology is a fundamental aspect in providing continuity in clinical activities. Great importance has therefore been given to both the technical aspects which include maintenance contracts, technical activities and clinical engineering services and the procedural aspects of technology management [2] such as the presence of available back- up in other departments. The integration of these two components has direct bearing on economic aspects which in turn depend upon the total amount of financial investment required to guarantee service continuity.

A methodology validation which takes into consideration the clinical aspects is carried out together with the medical staff.

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II. Methods

The Florence University Hospital AOU Careggi is a specialized health structure with 1,670 beds and 6,000 employees and is a regional referral point for several clinical activities.

The methodology developed is composed of four main steps as follows:

1. Special Assistance Levels Definition
2. Technology Classification
3. Technology Levels Assignment
4. Clinical Validation

A. Special Assistance Levels Definition

All regular medical services are carried out during weekdays, with the exception of emergency departments (trauma and general care), intensive care units and special services such as radiotherapy and dialysis activities which are open 24 hours a day, seven days a week.

In case of failure, nights and holidays represent the most critical moments of technology management. Methodology development must confront the critical phase by providing support for efficient corrective maintenance [3,4] by providing fast technical functionality recovery without affecting non critical phase activities.

The first step is to define the type of interventions and actions that must be carried out in order to restore medical device functionality and consequently medical services as

indicated in Figure 1.

Level 0 represents regular assistance of medical equipment during the working day time in the week and concerns regular Clinical Engineering 'CE' activities provided by call center support and, if necessary, by technical interventions by CE technicians and external manufacturers. The cost for such assistance is included in the regular acquisition contracts. Levels 1- 4 respond to the first failure by restoring device functionality and are defined as "one action levels." In case of a second failure Levels 5-8 provide double interventions. They are defined as "double action levels." Finally, level 9 defined as "3-action level."' aims at giving 100% repair possibility by responding to a possible third failure. Furthermore, level 1 provides continuous technical remote assistance while level 2 relies upon external intervention by designated companies. Level 3 permits internal borrowing of available "twin devices" from other departments, considering the fact that, during the night or on holidays, not all hospital activities are in function. Level 4 includes a back up device while Level 5 combines remote assistance and external intervention. Level 6 includes

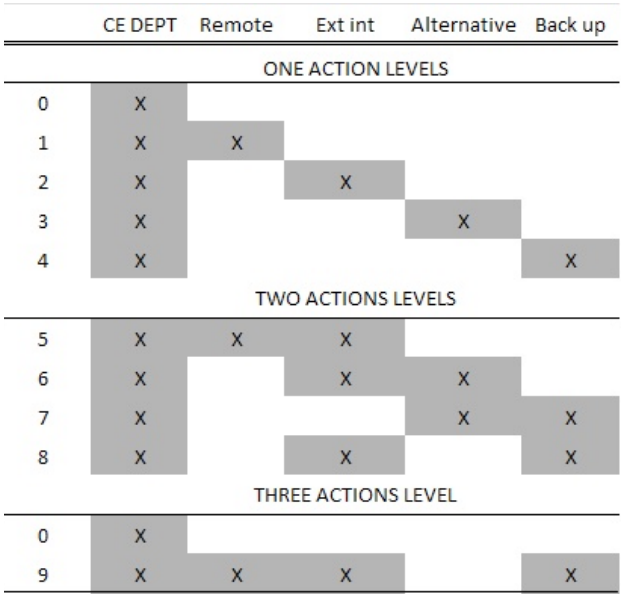

Fig. 1. Special Assistance Levels according to technical service types [5].

alternative and external intervention and Level 7 is composed of alternative and back-up device availability. Level 8 provides back-up and eventually any external intervention whereas Level 9 offers remote assistance, external intervention and back-up.

B. Technology Classification

We must consider repair difficulty in terms of time and type and the immediate clinical necessity to restore the functionality of the medical device [6,7] itself when dealing with the restitution of functionality of medical equipment.

These elements are defined in the Priority Index for each technology as indicated in Table I along with those devices

TABLE I
PRIORITY INDEX DEFINITION

Priority Index	Life Support	Clinical Support	Diagnostic	Therapeutic
High	ok	ok	ok	ok
Medium	ok	ok	ok	no
Low	ok	ok	no	no
Limited	ok	ok	no	no

designated to Special Assistance Levels analysis and those which are not. Technology levels High, Medium, Low and Limited are considered when estimating repair readiness. Given the importance of Life Support, Therapy, Diagnostic and Clinical Support devices and the potentially negative impact of technology failure on medical services, an initial evaluation is provided regarding functionality restoration priority. Life Support and Clinical Support regard all technology levels in Special Assistance analysis while Medium and High technology is considered in the Diagnostic area. Therapy areas refer only to high technology. This analysis does not take into consideration laboratory devices as they are not directly managed by the hospital CE departments but by individual service contracts.

C. Technology Levels Assignment

Once the Priority Index analysis is defined, Special Assistance Levels are assigned to different technologies by specialists and personnel from the Clinical Engineering department.

Level 1 is suggested for high tech devices and for surgery and emergency services equipment which is difficult to transport while Level 2 is applicable to those devices belonging to high-repair difficulty and pertain to Medium, Low and Limited technologies. Level 3 provides organizational procedures for the use and borrowing of other available devices taken from other departments. This option is suggested for both stand- alone and non software technology given that intervention is designated to medical personnel rather than technical. Level 4 is suggested for devices which are easy to store (medium or small sized equipment), to transport (not fixed or heavy pieces) and to install while Level 5 includes very high and complex level technologies such as radiotherapy systems. Level 6 aims at solving the problem instantly whereas in non critical phases external intervention resolves the problem especially if it occurs during the night. Level 7 is suggested for very necessary equipment without an alternative available in the ward and Level 8 Involves immediate response to emergency medical needs and at the same time works to provide functionality for regular activities during the non critical phase. Level 9 aims at immediately solving the problem by using the fastest, possible actions together with

remote, back-up and external intervention.

D. Clinical Validation

The final step of the methodology regards clinical validation through periodic meetings with the medical personnel that allows to analyze the clinical needs related to technology management [8] through the confirmation of the special levels assigned .

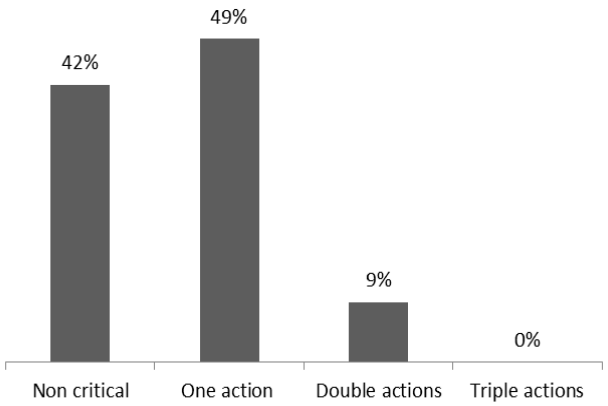

Fig. 2. Methodology results based upon type of action level (Florence University Hospital).

III. Results

The situation regarding study pilot at the Florence's hospital Careggi is reported in fig. 2. 42% of the devices are not considered critical and have no need of any special technical assistance. 49% of the equipment requires 'one action level' and only 9% of total devices are considered 'double action level'. No devices have been designated for '3-action level' assistance.

Fig. 3 indicates Special Assistance Levels distribution according to number of devices. The alternative Level 3, represents the highest option within the special levels including the 2911 devices (32%). Level 7 presents the highest percentage of double action levels with 604 devices especially regarding Life Support which emphasizes the importance of back up devices in this particular area such as respiratory technology, ventilators, defibrillators and portable scialitic lamps. Level 8 which includes 108 devices, is necessary for intensive care unit monitoring systems, central system monitoring and patient monitors and for dialysis systems. Level 6 includes 52 devices and deals with autoclaves requiring extraction of surgical instruments, hyperbaric chambers and linear accelerators. The alternative might result as being different in the last two categories among the various hospitals in the metropolitan/regional health system.

The operating theatre is an autonomous, one technology system and is designated to Level 3 in the eventuality of technology failures. Level 2 includes equipment used for non emergency therapies but important for scheduled clinical activities such as radio- and cobalt- therapies. Level 1 includes equipment that is fundamental in storing clinical data such as software systems for ECG data management.

TABLE I
SPECIAL ASSISTANCE LEVELS AND MACHINE DESIGNATION.

ONE ACTION LEVELS	
0	60%
1	-
2	-
3	32%
4	-
TWO ACTIONS LEVELS	
5	-
6	1%
7	6%
8	1%
THREE ACTIONS LEVELS	
9	-

IV. Discussion and Conclusion

Appropriate technology management is essential for the continuity of medical care activities especially in critical phases (holidays and nights).

Furthermore, the clinical validation modifies the percentage of level 0 passing from 9.41% to 9.58 % and identifies more precisely priority technologies. This is a result of the various contributions given to the Priority Index analysis by a multidisciplinary approach.

In conclusion, an integrated response involving several health structures would be desirable especially when dealing with the management of large equipment such as radiotherapy systems and hyperbaric chambers. This would contribute to a more optimized cost in Special Assistance Level requests.

Further developments require a more detailed procedure for the special assistance levels assignment and its validation including both the application to more hospitals and an economic analysis. The goal is obtaining an automatic system which could take into consideration also the specific clinical area where the device is used. For instance, an ultrasound device in ICU would require more special assistance than the one used in ambulatory.

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