The role of bioengineer in hospital upkeep and development.

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Abstract— **In Italy, hospitals of different dimensions have been equipped, in the last years, with a clinical engineering structure that is leaded by a bioengineer whose main role is management of bioinstrumentation in terms of planning for purchases and maintenance. Nevertheless, if we think that hospital structures, particularly those with considerable dimensions, are subject to a nearly continuous upkeep process, we can locate a new crucial role for bioengineers: being the main referents of upkeep process together with hospital's CEO. The process of upkeep and development of a hospital is always a complex multi-project that involves many steps starting from a deep planning effort. In this process, we maintain, the bioengineer should be involved starting from scratch.**

Keywords— **bioengineering role, risk analysis, failure, methods**

I. Introduction

The development of a hospital and the whole process that this development has to start is always a complex multi-project that involves many steps starting from a deep planning effort. In this process, we maintain, the bioengineer should be involved starting from scratch. Indeed, his competences range from buildings to ICT, from medical processes to patients' movement, to knowledge about bioinstrumentation. What's more, he should have the right background to deal with architects and construction firms as well as with clinicians and users. He should be therefore the right man to lead and manage the whole process.

Actually, many bioengineering course of studies are mainly focused to aspects like electronics and biomedical technologies and tend to leave bioengineers under-prepared in fields like buildings, project management, legislation knowledge. On the other side, their capacity in analyzing, decomposing and solving complex problems together with their knowledge about ICT tools, partially make up for cited lacks.

In this evolving environment, the position of bioengineer in hospital's life should be widened more and more from mere role of bioinstrumentation manager towards a position of team leader, particularly where there are plans of upkeep and development of the whole hospital structure.

II. The role

A. The evolving role of hospital management

Continuous legislative changing and development, together with a growing requirement of managing capabilities of health services actors are key features for understanding the role of bioengineers in the process.

Due to this logic the figure of a manager accept a responsibility of combining both operative and strategic direction aspects; this brings everyone to meet the challenge in the three spheres that distinguish the directional function:

- structure organization responsibility,
- process management responsibility,
- project planning responsibility.

Manager has therefore the necessity of scanning and understanding the needs that are the basis of planning and strategic development of services.

To answer to this need we have also to remember that a proper analysis must comprehend at the same time cost, time and quality aspects: technology management is one of the main cross connection between these aspects and target achievement. The background is obviously a framework based upon multidisciplinary and multi-professional team.

The role of an engineer that works inside an health service must be defined starting right from this point of view.

B. Educational programs and life-long training of a bioengineer

To be ready for this "evolutional" challenge the educational program of a bioengineer, beyond classical concepts of functioning and classification of biomedical instrumentation and equipment, must be completed with following topics.

General features of Clinical Engineering and Technology Management, particularly concerning technology assessment, performance evaluation and technological renewal of processes.
Safety basic concepts and essential requirements: Italian law D.Lgs. 626/94 and Risk Evaluation content.
Standard features: European directives and related health standards and regulation (ISO, IEC, CEN, CENELEC, CEI, UNI).

Hospital systems: standards and regulation.
Critical features regarding health structure management and organization and related law (L. 109/94; D.Lgs.157/95; D.Lgs.158/95; D.Lgs.358/92; D.P.R.554/99).
Project Management and related tools. Working Breakdown Structure (WBS) and critical path analysis.
RAD application for process management.
Imaging and signal processing instrumentation (RX, TC RM, PET, ECO).
Electro cardiography and cardiac stimulation instrumentation (e.g.: pacemaker and defibrillator).
Clinical Laboratory: clinical and managing features and main working methods.

C. Necessary tools

We often see that to realize complex structures, provided with advanced and expansive technology, a project is affected by a number of subjects that do not collaborate in an effective way. 'Project Management' specific techniques lie outside this discussion, but one comment is useful: project are often handled as a "black box" from inside of health structure till the final trial, but this lead to a situation impossible to supervise, with increase of costs and delay. After this consideration comes out to avail some tools, able to assess the effective agreement of the project to functional requirements of the underlying process, and feasible for different phases of project work.

This deal with a detailed study a process/service project quality, that could conjugate all spheres of directional function (structure, process management and project planning responsibility).

To achieve these goals we need a method capable of integration of characteristics and demand.

In the following, we itemize some of those methodological tools, but before is important to underline some concepts about clinical error management. The reason is that in a multidisciplinary environment, in which the first common goal is to deliver an effective service to a patient, human and system errors have to be well known and managed as well as good clinical practice.

Human error concept has been studied for a long time and incident prevention is almost joined to system design as a whole. [1]

The need to prevent human error lead to considerate the "mistake" under a new point of view: we have therefore to distinguish "active failure", that lead to immediate consequences, from "latent error", that conversely remain "silent" in the system until a "triggering event" is able to make them clear with all their latent power.

Human operator is the closest "actor" to this event, but we have to look for actual cause ("root cause") mainly among organizational sphere: these organizational faults are what we often refer to as "latent error", and is now shared their decisive role in the process.

If we think that not every "latent error" yields to an injury we have also to think that is necessary, for a fault to became an incident, to overcome all the technical and organizational safety barriers.

So, patient safety becomes a matter of organization, in which technical aspects are strongly presents and related to organizational/directional aspects: strict collaboration among clinicians and technicians (e.g. bioengineers) is the bridge to a under control (e.g. safety and affective) process.

To face this problem we can use two different kind of approach:

- Re-active analysis
- Pro-active analysis

Re-active analysis reckons on a "a posteriori" study of an incident and aims at identify all the causes that have lead to the incident. So, in this case we have a reconstruction that, from "active errors", lead to "latent errors".

Pro-active analysis approach, on the contrary reckons on a "a priori" study of the process to detect and eliminate (or strongly reduce) system critical points before incident event.

As an extreme synthesis of this universe of methodological tools we think that some examples could be useful to complete the discussion. In the following we spend some words about mainly exploited tools for health processes analysis. [2]

In the field of Re-active analysis the basic concept is the review of what happened to understand errors and/or critical points from en actual incident; in this area we can remember

- Incident reporting.
- Review.
- Sign research.
- RCA (Root Causes Analysis).

Pro-active analysis area instead, is based on the fundamental idea that is possible to prevent errors and, hence, that is a constructive attitude to develop, detail and apply a method for each phase of the process; the goal is to identify both criticality in the system and their connected "cures".

Here we have some of mainly used and meaningful pro-active analysis methods.

QFD (Quality Function Deployment),
FTA (Fault Tree Analysis),
HFMEA/HFMECA (Health systems Failure Mode and Effect Analysis/ Health systems Failure Mode Effects and Criticality Analysis).

Quality Function Deployment

An useful tool for project and process analysis, derived from quality management approach, is Quality Function Deployment (Q.F.D.), that allows to relate settled requirements for the service with features of the process underlying the service itself, using a simple matrix-based method. The method arise from the growing industry need to shift the care of design from "quality by inspection", crossing productive process by means of "quality by control", to achieve "quality by design".

The result is a sort of list of features made by dimensional specifications, installation equipment and instrumentation, guide lines and so on. All these features are weighted and linked to a "satisfaction parameter" that take into account of substantial agreement between design and production.

A further aspect to deal with is the opportunity fo a non-stop integration in the matrices of the tool of data and information taken from continuous increasing in knowledge of the activity under control/design.

Main different steps in QFD implementation are:

Identification of priority from "clients" of the study.
Evaluation of significance factors and related features in final product/service.
Definition of design characteristics, particularly in consideration of service links with other process.
Definition of "what" items are related to "how" items in final product/service.
Comparative evaluation of each design feature.

Once the team has defined all these connections, control systems and key feature in planning are determinate.

HFMEA/HFMECA (Health systems Failure Mode and Effect Analysis/ Health systems Failure Mode Effects and Criticality Analysis).

This is a prevention technique that comes from industry model FME(C)A ("Failure Mode and Effect (Critically) Analysis"): maybe one of the three fundamental technique for "a priori" improvement of a system, together with "functional analysis" and "problem solving".

The method starts from exploring hypothesis regarding all possible drawbacks of the system under examination (e.g. errors, faults, bugs, …). Conjecture can spurt from a simple brainstorming or other more complex medium. For each apprehended event, defined as *critical point*, a criticality level has to be defined. This level depends upon three main factors: probability of the event, graveness of the possible consequence of the event, and capability to detect the event itself, meaning the opportunity to observe the fact and to measure it someway.

If we apply this analysis to all revealed data, we can draw up a list of priority for prevention plan. Possible choices are: minimize by specific interventions the probability of the event, contain the graveness of the possible consequence, insert in the process control points centered on the peculiar capability to detect the event in each phase of the process. Countermeasures that can derive from the analysis could be synthesized in two kind of interventions: modification and/or adjustment in the design; runtime control of the process.

JCAHO standards are often taken as referring regulation system. [3]

The "H" letter of HFMECA means the particular use of the more general method to processes inside health services.

In this case HFMECA improve traditional steps by means of the integration of an algorithm used to define prevention actions after usual risk analysis; furthermore the calculation of the RPN (Risk Priority Number) is substituted by an "Hazard matrix" on which you can read directly the final risk level.

An HFMECA analysis can be briefly described in a series of logical steps:

1. Defining the subject of the HFMECA analysis.
2. Assembling the team.
3. Describing (often is used a graphical representation) the process: more complex cases can be usefully divided in more simpler processes by means of a diagram.
4. Driving a risk analysis.
5. Defining actions and organizational measures.

D. The experience

The experience we have conducted in applying these methods represents a synergic work of researchers called MonLAB. As a result of this work, a Monitoring System, wanted by Careggi Hospital (Florence, Italy) together with University of Florence, has been developed and is currently supervising the process of deep rethinking of the hospital itself, started in 1999 and scheduled to end in 2010.

To do this, methods of risk analysis, procedures and ICT tools have been developed to achieve these main goals: time and cost monitoring, critical moments prevision and alerts generation, real-time control of hospital evolving estate in terms of beds, ambulatories, deposits, clinicians rooms, technologies and more.

III. CONCLUSIONS

In the process of designing and development of health services, the figure of a manager accept a responsibility of combining both operative and strategic direction aspects. The three spheres that distinguish the directional function (e.g. structure organization responsibility, process management responsibility, project planning responsibility) force the manager to understand all critical points that are the basis of planning and strategic development of these services.

Bioengineer should be involved starting from scratch, due to his competences range from buildings to ICT and to the right background to deal with different technical actors as well as with clinicians and users.

The software developed in our research activity and the methodological techniques underlying the information system can be seen as the multidisciplinary and multi-professional approach to the construction of team that could efficiently support the function of the Direction in the "design of changing and improvement of services".

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