ERROR AND RISK ANTECEDENT STATISTICAL MONITORING IN HEALTHCARE

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TOPICS – Organization, Clinical risk management and medical performances

This study describes ERASMO, a statistical process control method intended to monitor the antecedents of errors and to foster patient safety and quality improvement in healthcare; it is applied with success, still in experimental way, at San Gerardo Hospital, Monza (Italy).

KEYWORDS

Patient safety – Clinical risk management – Risk factors – Healthcare statistical process control – – Adverse drug events.

1. INTRODUCTION

Since the publication of the "To Err Is Human" report[6], that was able to show both the complexity and the vulnerability of the current health care systems, health professionals and managers have focused their interest in the theories of human error and the methods for risk assessment; that is also because of the relevant growth of the insurance fees and of the claims on clinical negligence[6]. A difficult, even if necessary, cultural changing is occurring in Italy as well, trying to foster an effective improvement of the patient safety[17], leaving behind the claim-compensation mechanism.

As a result, on one side more and more robust techniques have been developed to prevent the occurrence of the adverse events and to assess the clinical risk in healthcare organizations, and on the other side it has pointed out the need for a wider and continuous involvement of the "frontline" personnel, promoting the sense of responsibility, awareness and self-learning.

The event-based approach is one of the most frequently adopted to disseminate safety culture and risk management programs in healthcare organizations. However, some recent surveys proved how the implementation of incident reporting systems on voluntary bases encountered many difficulties in delivering effective results[9]. Specifically, there are three main shortcomings that characterize such systems:

- generally, they offer a limited statistical basis, insufficient to carry out a quantitative risk analysis; consequently, the higher is the safety level achieved by the hospital, the wider is lack of data (apart of the consideration that also a single error is ethically unacceptable);
- like every event-based system of investigation (for example, the Root Cause Analysis), they focus on the contingent factors of specific occurrences, while the systemic factors influencing several incident scenarios are put in second order;
- they are in a more or less accentuate hostile relationship with the need to overcome the "blame culture" in favor of organizational learning processes; in accordance with the Italian laws and its more common jurisprudential interpretation, an error reporting assumes a shape of knowledge or even an admission of direct responsibility.

It was then acknowledged the importance to focus not only on the observed adverse events (that characterize any event-based evaluation system), but also to extend the analysis to the systemic factors that may act in different occurrences of incidents[5,8,15,18,19]. That means, in other words, to move the observations backwards in the process that gives birth to the adverse event, reaching the fields of the human behavior and of the technological and organizational systemic factors. In a complex working environment (as the hospital is), some weak conditions may have no effects unless an unsafe action combines with an intrinsically dangerous systemic situation, thus generating an adverse event that causes consequences for the patient that unfortunately are not always negligible (see Figure 1).

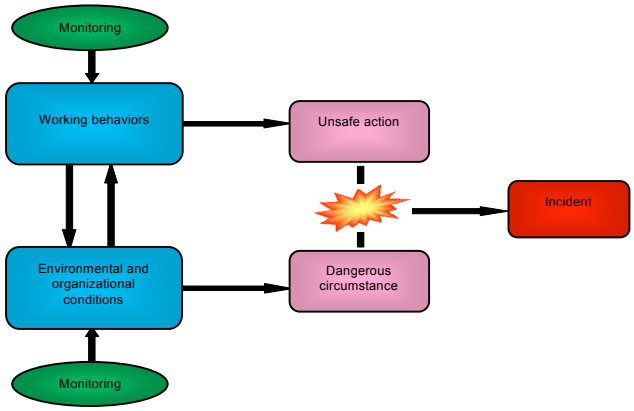

Figure 1: Anatomy of an incident

2. METHODOLOGY

The use of statistical control charts in healthcare is well documented for investigations on research areas that are purely clinical[2,13,14,16].

The present work is intended to apply that kind of tools to the observation of behavioral and systemic factors as a basis for the clinical risk monitoring in a generic care process. The peculiarity of the proposed approach has to be found in the use of the error antecedents survey instead of the error or near misses monitoring, thus ensuring bigger samples together with a wider acceptance among the operators than traditional error reporting systems. Error and Risk Antecedent Statistical Monitoring (ERASMO) method allows the direct participation of clinicians and nurses since the early design of the monitoring forms on which control charts will be constructed. Such an approach is derived from some concepts of the Behavior Based Safety Process (BBSP[7]), that is applied for the continuous improvement of workplace safety of industrial operations[10].

The main requirement for the use of ERASMO is a previous quantitative risk assessment on the care process that has to be put under observation. The experimentation of the method has been conducted on the drug administration process in three wards of San Gerardo Hospital in Monza (Italy).

The use of a proper method for risk assessment allows to link all possible error modes and the quantitative estimate of their risk level to each phase of the process. Such an estimate was obtained by using Clinical Risk and Error Analysis (CREA[17]) method, which identifies the error modes through the application of techniques such as Cognitive Task Analysis[12] and Human HAZOP[11] and computes statistical data available in scientific literature in order to plot risk levels for the most critical error modes and activities. The choice of the activities to be monitored is driven by the contribution to the total risk amount, as shown in the cumulative risk charts (see figure 2).

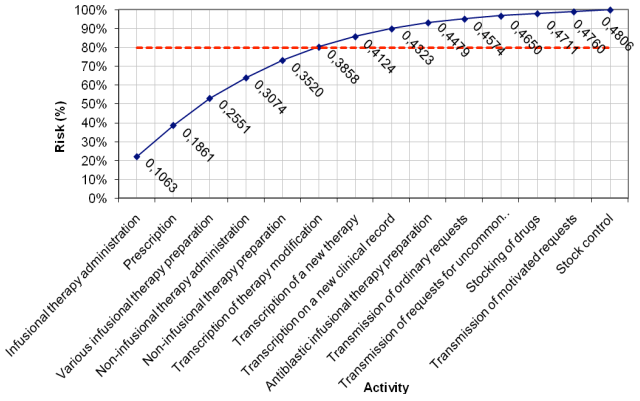

Figure 2: Example of a cumulative risk plot

On the basis of a previous risk assessment study, clinicians and nurses have been requested to identify possible critical conditions during the accomplishment of their duties, together with the causes that are most likely to happen. To that aim, Vincent's classification of influencing factors[19] was used (table 1). Clinicians and nurses have also been requested to estimate the conditional probability of such factors to happen, given the occurrence of a specific error mode (for all activities under analysis). The information gathered that way represents the qualitative and quantitative pattern for the definition of the error antecedents monitoring forms, which are to be daily filled in along each ward. It is also possible to define one specific form for nurses (that have to be filled in at each turn) and one for clinicians (that have to be filled in once a day), because of the differences between their respective profiles and tasks in care processes.

The forms are made of several statements, derived from experts' suggestions regarding error causes, that operators mark as "true" if observed during the accomplishment of their duties, or "false" otherwise. Operators' anonymity is guaranteed, because it is not necessary to identify who executes observations; it is instead required for the forms to be recorded in chronological order, so that time tracking of risk conditions is allowed.

Factors Type	Contributory factors	Example of problems that contribute to errors
Institutional context (not considered in the study)	• Economic and regulatory context • National health service executive • Clinical negligence scheme for trusts • Social attitude to risk	Insufficient priority given by regulators to safety issues; legal pressures against open discussion, preventing the opportunity to learn from adverse events
Organizational and management factors	• Financial resources and constraints • Organizational structure • Policy standards and goals • Safety culture and priorities	Lack of awareness of safety issues on the part of senior management; policies leading to inadequate staffing levels
Work environment factors	• Staffing levels and mix of skills • Patterns in workload and shift • Design, availability and maintenance of equipment • Administrative and managerial support	Heavy workload, lending to fatigue; limited access to essential equipment; inadequate administrative support, leading to reduced time with patients
Team factors	• Vertical communication • Written communication • Supervision and willingness to seek help • Team structure (consistency, leadership, etc)	Poor supervision of junior staff, poor communication among different professions; unwillingness of junior staff to seek assistance

Table 1: Factors influencing clinical practice and contributing to adverse event[19]

(continue)

Factors Type	Contributory factors	Example of problems that contribute to errors
Individual (staff) member	• Knowledge and skills • Motivation and attitude • Physical and mental health • Competence	Lack of knowledge or experience; long-term fatigue and stress
Task factors	• Task design and clarity of process • Availability and use of protocols • Availability and accuracy of test results	Unavailability of test results or delay in obtaining them; lack of clear protocols and guidelines
Patient factors	• Complexity and seriousness of condition • Language and communication • Personality and social factors	Distress; language barriers between patients and caregivers

The turnover of the personnel involved in the monitoring is an important organizational aspect, because it gives several benefits:

- the approach could thus be characterized as a tool for self-control and self-teaching at a teamwork level, instead of a hierarchical control (so inverting the trend of error reporting systems);
- all the operators are involved in a monitoring and a critical evaluation process of potential at risk conditions (non conformities) at the operational and organizational levels;
- working overload due to monitoring is better distributed, thus making it more acceptable to all personnel.

Because of the properties of the object of the monitoring, the control chart "for non conformity fraction" (or *p* control chart[1,3,4]), that belongs to the family of the control charts by attributes, was considered the most appropriate. The observations are in fact supposed to behave as a binomial variable with p probability and Bernoullian distribution, assuming just the values true or false, once the independence among experiments is assured. If there was a dependence among the observations, a multinomial distribution should be considered.

Specifically, the aim of the control chart is to show the trend of the risk level in each ward, related to the presence of factors that could foster the occurrence of errors in a fixed instant. The observed non conformities are then weighted with the risk value related to each j^{th} statement, following the results of a former quantitative risk assessment (in the present case, CREA[17] method had been used). Such an approach allows to calculate the risk value for each sample unit, represented by the i^{th} monitoring form, following the equation:

$$R_i = \sum_{j=1}^{N} x_{ji} \cdot R_j$$

where x_{ji} is equal to 1 if the factor has been observed, 0 otherwise; i=1…M are the monitoring forms and j=1…N are the statements in the i^{th} monitoring form.

The total risk of a form, given by the sum of the risk values of the observed factors, represents the clinical risk to which patients are exposed at the monitoring date. The use of control charts allows to assess if the clinical risk in the ward is kept into an acceptable range, showing the samples that exceed the bounds.

Statistical theory indicates how to calculate upper and lower control bounds, in respect to the central tendency line. So, if M forms made of N statements each are gathered, the central tendency line of the p control chart is equal to:

$$CEN = \bar{p} = \frac{\sum_{i=1}^{M} R_i}{M \cdot N}$$

while upper and lower control limits are, respectively:

$$UCL(Upper\ Control\ Limit) = \bar{p} + 3 \cdot \sqrt{\frac{\bar{p} \cdot (1 - \bar{p})}{N}}$$

$$LCL(Lower\ Control\ Limit) = \bar{p} - 3 \cdot \sqrt{\frac{\bar{p} \cdot (1 - \bar{p})}{N}}$$

However, control limits for the exposure of patients to risk have to be related to the threshold that was defined in the previous risk evaluation; in the specific case, CREA iso-risk curves were considered (see Figure 3): as a consequence, zero risk was identified to be the lower control limit, while the upper limit was fixed at R=0.01, which identifies the area of acceptable residual risk or planned improvement interventions. It is anyway allowed for the analyst to extend or to cut the control area, by choosing in advance the values of the iso-risk curves that identify different priorities of intervention (for a more detailed description of the adopted risk calculations, please refer to [17]).

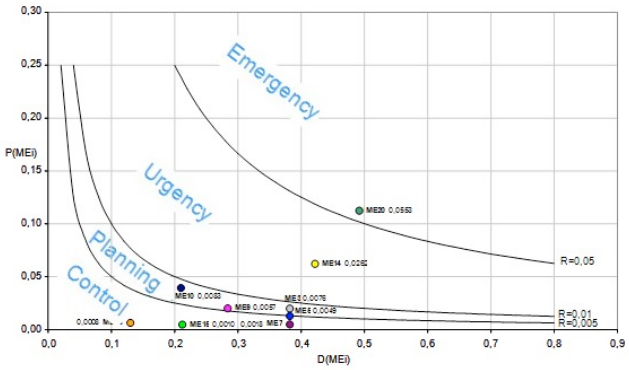

Figure 3: Example of a risk chart

3. RESULTS

The experimentation was carried on in three sessions (in 2004, 2005 and 2007), that lasted four weeks each and involved an increasing number of wards, that is 3 in the first, 8 in the second and 15 in the last year. During the first year, the 80% of the observations made by physicians in Cardiology and the 63% of those in Adult Hematology were related to the temporary interruption of the clinical activities to answer to different solicitations (by colleagues, patients, nurses etc.). Team and work environment related factors were the most frequently observed by physicians in Cardiology, while personnel related factors were evidenced in Adult Hematology. In this last ward, many observations were related to the lack of use of standard form-filling (e.g. to write in capital letters), whereas such problem is absent in Cardiology, that uses electronic prescriptions. Both Adult Hematology and Pulmonology nurses underline the criticality of the interruption of activities, the execution of different tasks at the same time and the therapy forms not filled in capital letters. Pulmonology is characterized by a significant influence of team factors, that in Adult Hematology have to be summed to duties and personnel related factors.

Analyzing the results in those "historical" wards along the three sessions, it can be seen that the observations made by physicians regarding the temporary interruption of the clinical activities decreased in Adult Hematology to the 52% in 2007, while in Cardiology grew to the 89% in 2007 after a reduction to the 68% in 2005. The observations related to the lack of use of standard form-filling in Adult Hematology almost disappeared in 2007. The incidence of team related factors was confirmed in Cardiology both in 2005 and in 2007, even if with a significant reduction, while environment factors substantially decreased and were substituted by factors connected with the duties of the operators (see Figures 4 and 5), that were confirmed as the most relevant in Adult Hematology.

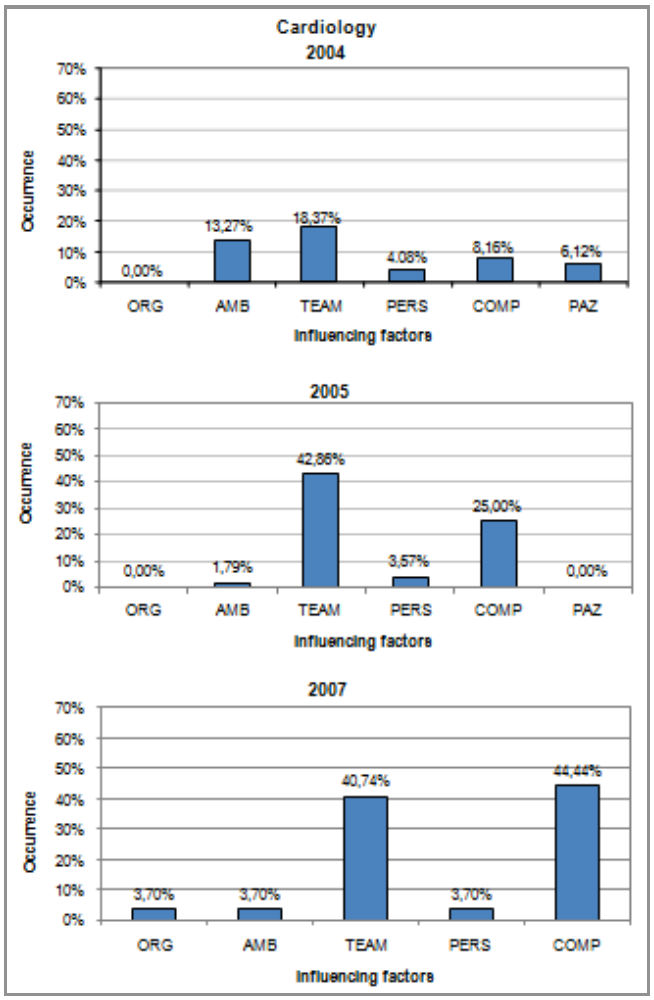

Figure 4: Influencing factors observed by physicians in Cardiology in the three sessions (2004 – 2005 – 2007)

The interruption of activities for the nurses in Pulmonology (see Figures 6 and 7) and Cardiology was the error antecedent that was most frequently observed in all the three sessions, together with the execution of many activities at the same time.

The error antecedents that revealed to be the most relevant in those three wards generally had a significant incidence in all the other wards that were involved in the second and third sessions. Another criticality that was proved to be widespread in all the wards is the poor monitoring of the activities carried on by the new hired or specializing personnel.

It has to be said that the relevance of the monitored error antecedents in terms of risk is strongly influenced by the estimates of the former quantitative risk assessment, that showed different values among the wards, and by the care and the constancy in filling the forms, that is generally higher for the operators that are more confident with the ERASMO method, even if a minimum of 90% of complete filled forms were achieved in all the wards.

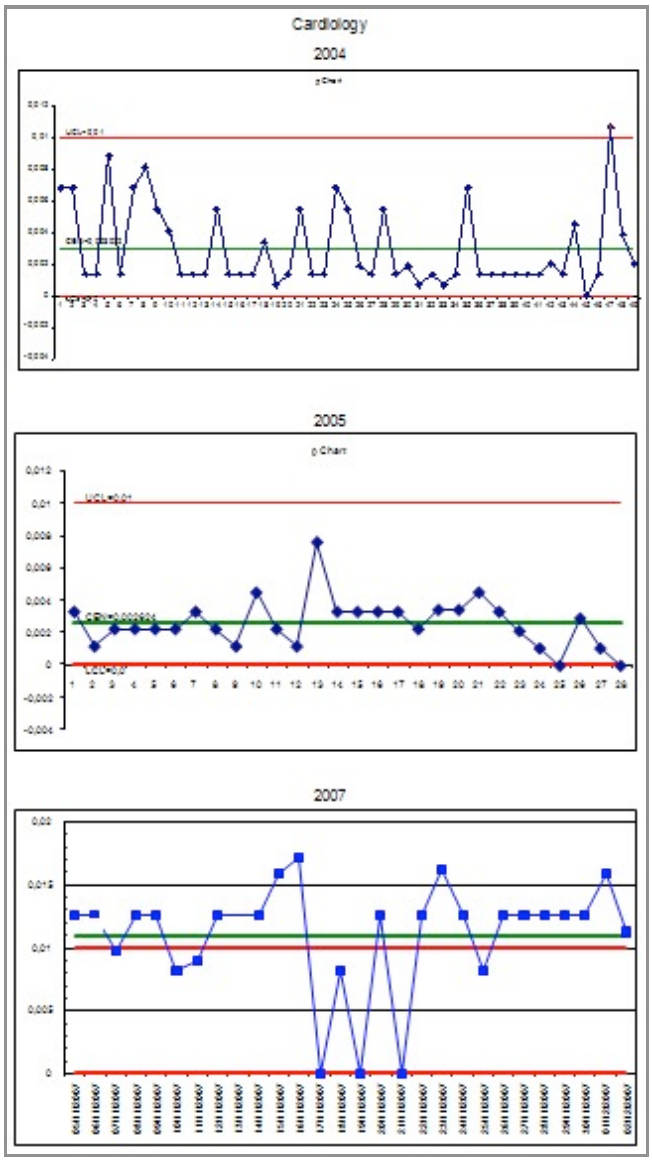

Figure 5: Control charts for the physicians in Cardiology in the three sessions (2004 – 2005 – 2007)

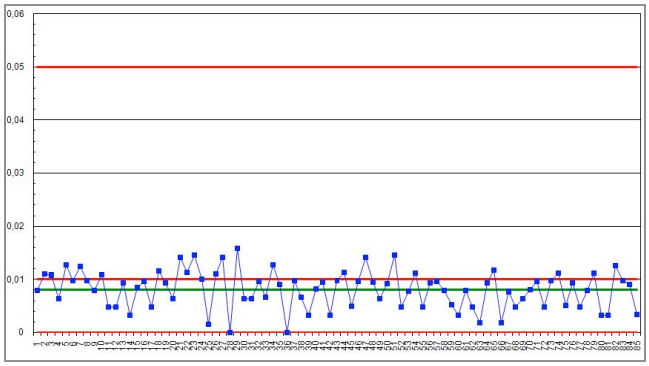

Figure 6: Control chart for the nurses in Pulmonology, third session (2007)

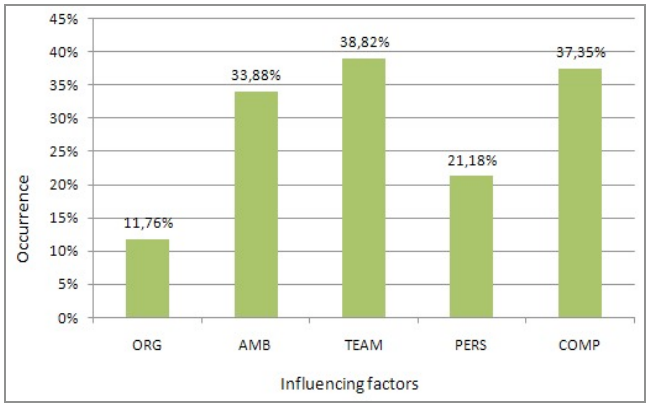

Figure 7: Influencing factors observed by the nurses in Pulmonology in the third session (2007)

4. CONCLUSIONS

According to the classification made by Thor et al.[16], ERASMO is a statistical process control (SPC) method, the study of which had the following characterizing features:

- hospital wards study setting;
- it was applied on the drug therapies in many fields of healthcare: Emergency medicine, Cardiology, Internal medicine, Surgery, Urology, Hematology, Urology, Geriatrics, Nephrology, Pediatrics, Pulmonology, Obstetrics, Gynaecology;
- the unit of analysis was any single ward;
- the variables of interest were in the area of the "clinical management – number of defects/events or occurrences in a clinical process", specifically the number of error antecedents that are observed during a work shift.

The experimentation confirmed the usability of statistical control charts as a risk monitoring tool in the healthcare field. There are two kind of information that can be brought on: on one side, it is shown the trend of the safety status of the ward during the time of the monitoring, while on the other side the conditions that are out of control are reported, thus allowing to evaluate the stability of the safety conditions that are granted in the ward.

However, control charts are as much meaningful as the monitoring is constant all over the period of observation, then a continuous collaboration by both physicians and nurses is requested, even if the daily workload could be increased. In the described experimentation, such a continuity was partially permitted by a group of young specializing physicians (but just for the 2004 and 2005 sessions). The success in the implementation of the tool is strictly related to the individual commitment to error prevention, together with the willingness to participate in activities that are collateral to the normal ward duties. In some cases, the effort that was requested had been too high, if there was an overload in the duties of the personnel.

Other benefits, limitations, barriers and facilitating factors or conditions have been found in the application of ERASMO as an SPC method, are reported as follows still referring to the work made by Thor et al.[16]:

- benefits: it helped in the assessment of the impact of changes to the process, in the identification of the areas for improvement and in distinguishing special from common cause variations in the process. Moreover, it enabled a better informed decision making by giving useful information on the process and empowered the

operators in suggesting possible improvements to be taken;
- limitations are related to the fact that cause-effect relationships are not always obvious, even if identified with statistical confidence, and to the ability of the stakeholders to apply correctly the method, together with the problems in the data collection, especially when paper forms were used, as in 2004 and 2005 sessions;
- barriers rose because in the first experimentations ERASMO represented for all the personnel a new way of thinking of their duties, and it was seen as both time consuming and of uncertain helpfulness, particularly when the data were gathered manually;
- the main facilitating factors or conditions consisted in the introduction of an experimental MS-Access based software for data collection, in the redundancy of the training, both in classroom and "on field", and in the timely delivering of the results, involving as much operators as possible in the analysis of the control charts.

From the results, it is possible to derive some conclusions that not only regard empirical aspects of the experimental application, but also immaterial factors. Such an adjective is related to aspects that are not measurable, but anyhow perceived by several informal interviews with both the personnel and the hospital management. It is then possible to find further positive outcomes of the experimentation, at different levels:

- practical demonstration of the capability to overtake the "error – punishment – cover up" mentality, introducing a path that starts from the comprehension of the deep reasons of the error, passes through the development of the improvement strategies and arrives to the systematic observation of the reduction of the root causes in any specific activity. Such an approach allows both to deliver a better statistical assessment of the causes and to carry out a better management of the Root Cause Analysis in the case of an actual accident;
- the development of the attitude to the critical revision of the professional behaviors;
- transparency and willingness towards an integrated hospital risk management process;
- the training and cultural value for the people involved in the experimental study.

From the experimentation it can be clearly deducted that tools for the risk evaluation and monitoring, such as ERASMO, can foster the dissemination and consolidation of safety culture and the capability of the personnel to self correct working behaviors, by substituting the blame logic with the promotion of continuous improvement processes within the entire organization.

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