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Enhancing the safety culture in Albanian healthcare institutions

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***ABSTRACT*:** *Being that the safety culture is still a novelty for Albanian healthcare institutions this article explores different experimental Enterprise Risk Management approaches appropriate to healthcare risk managers aiming to enhance the safety culture in them. First of all for, a precise definition related to risk incidents, errors in medicine and near-misses is given. And correspondently, healthcare risk managers are advised to establish a proactive risk management framework configured in gap analysis related to circumstances that generate errors and violations, human risks and technology to accurately organize the above mentioned process, make managerial decisions and create a business culture oriented toward safety through the exploitation of bottom-up service lines. Undoubtedly, that these framework is expensive not so much for the concept idea proposed than for staff hiring and continuous training, developing "system-wide" policies and procedures, internally managing the information received by offering also good opportunities in medical-tourism being that experience and costs become two key points for further development of these institutions in the near future.*

Keywords: *Healthcare Institutions, Risk Management.*

1. INTRODUCTION

For hospitals and other health institutions caring for patients, risk must be always in the top of mind because it can literally be a life-and-death business issue. As a result, most of health care institutions around the world have a long history of identifying, assessing and prioritizing risks although without achieving the expected results.

But the efforts made until now at risk quantification, especially outside the traditional clinical arena, have generally been dismissed as expensive, bureaucratic and overly compliance oriented, failing to deliver clear or measurable value that could be convincingly articulated toward a safe environment. Thus, only few of them regularly quantify their key risks or use analyzing metrics with the aim to make appropriate business decisions. Even fewer integrate risk metrics into their workforce budgeting and planning process, which is particularly surprising given that today, nearly half of the revenues of most hospital (by also considering the private health institutions) systems is budgeted to workforce-related costs, when this one has the greatest potential to manage risk and improve operating margins.

Consequently, risk has risen in the top of management's agenda especially due to the economic pressures with an increasing focus on the value rather than on the quantity of services performed by generating new risks and exacerbating the traditional ones. Increasingly, today, hospital executives and boards should recognize that the time has come for a more strategic and quantitative approach to health risk management by transforming it from an "ad hoc" activity into a core strategic business-planning process because the forces reshaping the healthcare industry aren't well documented by ushering in new challenges and risks, ranging from new payment mechanisms and quality standards to coordinated care delivery models and competition. In other words the implementation of health care reform legislation in Albania, in many of its significant measures-focused on quality, results and efficient care is expected to deal with employers, insurance companies and Medicare. In conformity with it, the hospitals now must start also with the hiring of physicians aiming to rethink both the duration and magnitude of their risk exposures. And in the mid of this change, hospital executives and boards should ask important questions like:

Are our risk management practices on a par with industry norms or those of specific competitors? or Do we need to address specific critical risks, such as nurse or physiotherapist recruiting and retention, leadership succession, patient privacy and pharmacy management?

Can we immediately comply with the new healthcare regulatory requirements affecting our industry? etc.

To appropriately answer to these and additional related questions requires an approach to risk management that goes well beyond a technical exercise in the framework and there isn't too much to look at risk management as a core business process with significant implications for hospital's strategy, financial health and growth

prospects. Where all these can be achieved as a combination of in-depth working experience in the health care industry and expertise in human resources as well as risk management to shape leading-edge risk management processes to the unique needs of the industry. To do this should be initiated with a comprehensive identification of the current

and emerging risks most relevant on behalf of hospital's ability to achieve the established near- and longer-term objectives. And then prioritize these risks from the standpoint of their probable impact on institution and their likelihood of occurrence. Which in turns provides a foundation for the organization's management team to determine how much risk it is willing to take on, and the risk mitigation strategies and tactics needed to be implemented in determined organization circumstances. In addition, it can be develop a risk/return framework for mitigation solutions tied to the hospital's strategic and financial goals, which enables hospital leadership by undertaking risk-adjusted decisions. Trying in a certain way, to bring specialized experience in developing hospital workforce programs, aiming to mitigate the new workforce risks that are emerging in the wake of an intensifying focus on primary and preventive care through the industry consolidation in the country handled from the aging workforce in supervision in order to enable:

- Risk management framework;
- Conduct a gap analysis and develop recommendations;
- Develop priorities for implementation;
- Implement.

2. THE ERRORS IN MEDICINE

The health system especially is very complex, independently from different variables involved, because the human being under fragile conditions may more frequently be at risk. Related to the latter, some examples can be represented by the specificity of individual patients, the technical difficulty of interventions as well as from multiple operators' professional experiences, and different management models. As other crucial human activities it has also a "business risk" proportional to the number of these variables and that's why there are many tools and shared norms undertaken to decrease the inherent risk.
However, there is almost a part of risk that could be defined as "pure risk", which in turns depends on variables less known such as by occasional circumstances, from the concatenation of situations that favor the occurrence of an adverse event. Precisely on the latter aspect, the boundaries of which are not always definable by the business risk, there are implemented in the recent policies of risk management aimed at reducing the avoidable errors. By this way, every single organization can be considered partially dominated by the culture of blame (serious incidents) as well as from safe culture (small risk and normal events).
Starting from the consideration that the error is an inevitable part of human reality, as stated by the title of a well known work in the field [1] "*To err is human*", it becomes critical to recognize that the system goes wrong by creating the conditions for the occurrence of errors (stress, little technology known ...), which remain latent until another operator error (active failure) does not make them manifest.

In fact, the adverse event is defined by [1] as "*damage or inconvenience caused, even unintentionally, to the medical care given during the period of hospitalization that causes an extension of the period of hospitalization, worsening health conditions or patient death*". From the other side, the error is specifically identified as the "*failure of a sequence of scheduled mental actions and activities to achieve the desired goal that cannot be attributed to the chance*".

And in the series of theories developed for the study of errors in medicine, Reason [2] distinguishes three different types of error, based on the Rasmussen's [3] behavior:

- Execution errors that occur at the level of skills (slips-representing actions that are performed differently than planned where the subject knows how should perform the task but inadvertently does not);
- Execution errors caused by the failure of memory (lapses-the action has a different result from that expected since the operator is not in capable of tracing the sequence correctly);
- Errors committed during the practical execution of actions (mistakes): meaning previous mistakes occurred during the planned processes/ strategies, as a consequence the target is not reached because the tactics and means implemented do not allow it. And here are distinguish two types of errors:

-*Ruled-based*: you chose to apply a rule or procedure, which does not allow the achievement of a specific goal;
- *Knowledge-based*: are errors that affect the knowledge, sometimes too poor, which also lead to the designation of inadequate actions. The goal will not be achieved, even if the above mentioned actions are correctly performed.

And a special case, that deserves to be mentioned given the importance of the phenomenon, is made up from the "*violations*" which are actions that are performed, although this is explicitly prevented by a regulation or a directive.
In the most recent classification of error, Reason (1992) goes beyond the human error theory embracing that which can be defined as system approach for the study of error, the also called "the theory of latent error".
Thus, Reason (1992) "proactive" key is presented through the following framework (see Fig.1):

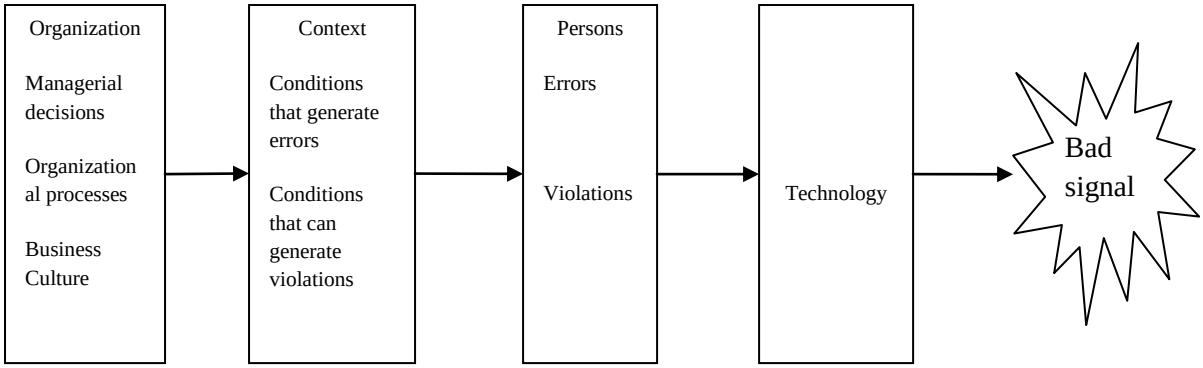

Fig.1: the proactive risk management framework

And the premises lie in the conviction that adverse events in reality match only in a small part with total errors as many accidents have not occurred only because the operator (or control) prevented that from happening. These events, are indicated as "*near-miss events*" from Nashef [4] in the same time are very worthy in their role as indicator compared to correctable health risk factors. In fact, now the modern systems of risk management provide right signals for every "sentinel event", defined as "unexpected event that involves death or serious injury or psychic activity or respective risk" referring to the definition of Joint Commission on Accreditation of Healthcare Organization (2001). From this systemic view is born the idea that the occurrence of an accident is the result of a chain of events that have passed all the defenses put in place meaning the famous model of "*Swiss Cheese*". By analogy, each slice of cheese represents a layer defensive organization, as the reliability of engineered systems, the "human reliability", and the presence of control elements or application of standardized procedures. Ideally each layer should be free of critical points, but in reality, each of them presents numerous. And they, like the holes in different slices of cheese, can open, close or move according to changing perspectives from which the above mentioned system is considered.
The presence of these holes in different layers itself against is not sufficient for the occurrence of the event, which takes place only in those special situations which allow the so-called "*trajectory of opportunity.*" The holes are represented simultaneously by execution errors (slips and lapses) and non execution errors (mistakes): being the first not completely eliminated, in order to increase the system security is necessary to act on the critical latent by consequently increasing the level of preparation through appropriate procedures.

3. Clinical risk management

The problem of error diffusion in health care has been frequently addressed and due to this there are many inquiries to which it may be refer such as Leape et al. [5], Wilson et al. [6], Davis P, Lay-Yee R, Briant R, et al. [7], Vincent et al. [8], etc.
Because the results of recent international studies reveal a considerable heterogeneity in the results related to the frequency of adverse events, concretely: the values range is between 3.7% and 16.7% of hospital admissions, but the data must be put into context before leading to extrapolations.

More constant instead proves to be the data of the studies (the two Americans, one Australian and one originated from UK), with regard to the predictability of adverse events where about 50% of them could be prevented. But by leaving aside the numerical value, is interesting to highlight the concept of "foreseeable error" because is needed to be focus on this direction. Under

this context, even Italy has begun in recent years to address the issue of "Risk Management in health ", as shown in" Technical Committee on Clinical Risk" on behalf of MD [9].
Correspondently, each health institution must try, together with the efficiency and effectiveness of services offered also its safety. It is clear that while a patient requiring assistance instead face a health damage, obviously a failure occurs, not only related to the individual performance of the operator/staff dealing but also to the entire system in its mission. In order to ensure the quality care, health institutions must implement systems for risk management, being by this way capable to alter or manage the conditions or potential events that can change the expected outcome of the process which results in losses or damages to the company and individuals involved.
Thus, the "Risk Management" represents the set of tools, methods and actions activated, by which is measured or estimated the risk and then are develop strategies that may govern it, alternatively said is a logical and systematic methodology that allows the identification, evaluation, communication, mitigation and elimination of the risks associated with any health activity.
The above mentioned risk methodology makes uses the one of the following analysis:
- the "reactive" one, which includes the incidents study "*a posteriori*" aimed at the identification of the causes that have allowed their occurrence;
- the "proactive" one, which aims at the identification of the criticality of the system before the incidents occurs and is based on the analysis of the processes and designation of secure systems by referring to Skill-Rule Knowledge (SRK) model proposed from Reason (1992) see Fig.2.

Fig.2: the SRK (1992) model

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While the also-called "SHELL model" proposed from Edwards [10] having the same scope with the Reason's (1992) human factors one act on the errors and violation's context according to the following diagram (Fig.3):

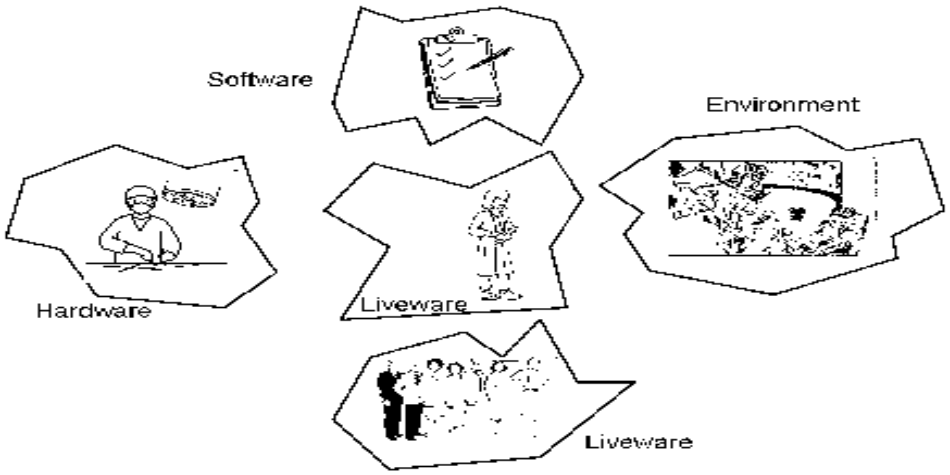

Fig.3: the SHELL (1988) model

From the other hand different tools are developed for such purposes by including:
-The disclosure of "error theory" and the classification of errors described in it;
-The introduction of systems "incident-reporting" free of negative consequences for anyone who reports the occurrence of the sentinel event;
-The promotion of doctor and sanitary professions lifelong learning;
-The development of business skills with the extensive use of realistic simulators.
Referring to the latter as example can be taken the field of anesthesiology, for the results achieved thanks to simulation, in the quality of a progressive model in favor of patient safety.
And the training based on the facts of Macrosimulation allows analyzing the operators' behavior under stress which reveals realistic and critical under certain clinical situations.

4. CRISIS RESOURCE MANAGEMENT

Historically it was believed that anesthesiologists were able to acquire skills regarding critical decision-making processes and behaviors "by osmosis", only through experience and by observing role models in possess of these qualities. Often the observation has clarified how these skills can represent loopholes without significant and specific teachings.
The study of rational behavior aimed at optimal management of resources in difficult situations is defined by the term "Crisis Resource Management" (CRM). While the CRM in Anesthesia (ACRM) aims to address these gaps: the emphasis is placed on the treatment of specific medical peri-operative high-risk situations, and the rest of attention is placed on the general principles of critical treatment and is applied to any situation with complex patients in care. However, the experiences in this regard have been developed and described as decisive in each context according to Stanford University School of Medicine study [11],despite the difficulty in assessing the fallout in terms of effective use of training.
By this way, Rall and Gaba [12] have statistically identified from the analysis of medical errors that have damaged the patients, some fundamental behavior points. It was found in fact that the errors are most often due to patterns of irrational behavior that from real medical professional ignorance. In details, the above mentioned points are:

1. Anticipate and plan;
2. Call for help as soon as possible;
3. Exercise leadership and fellowship skills;
4. Distribute the workload;
5. Mobilizes all available resources;
6. Communicate effectively;
7. Use all available information;
8. Prevent and manage the fixation errors;
9. Double check always;
10. Use all devices;
11. Reassess repeatedly;
12. Make a good team;
13. Wisely allocate the attention;
14. Dynamically establish the priorities.

Despite the records achieved, still remains a lot to be done especially since when the most important long-term strategy is constituted by a "change of culture" within the entire health system.

Also according to them the culture of blame, focused on individuals, should be replaced by the safety one which considers the mistakes and incidents as a problem of the whole institution. Therefore isn't useful to pursue a punitive approach, but instead to promote the in-depth analysis and research into the causes, with a "proactive" aim to predict the recurrence of the same risk conditions which caused, or could cause, the damage.

In other words the attention in these cases is oriented toward the institution in order to:

- identify the potential breaches in different levels;
- have a systemic vision;
- report the errors/incidents;
- proactively act for the creation of a safe business culture;

- improve the system on behalf of appropriate interventions;
- increase its safety.

Thus, a safe system means the:

- commitment of senior management to safety;
- improvement of self-observation between individuals and groups;
- institutional learning culture, sensitive to weak signals;
- "right" culture, the one that encourages the reporting and sharing of events;
- prompt response to weak signals;
- focus on the abnormally task and not on the person

achieved through precise procedures implementation.

5. HEALTH POLICIES MANAGEMENT

Referring to the survey organized from National Health Service [13] in England during 2006 for "Clinical Risk Management" purposes was revealed that:
-wards and clinics are untidy and chaotic;
-processes are unplanned and of byzantine complexity;
-professional tribes and departmental silos abound;
-physical layouts and "monoliths" prevent a smooth flow of work;
-queues are everywhere, etc.

While should be admitted that all these obstacles, given increasing financial pressures and the top-priority status that must be given to direct patient care, managers may find it difficult to find time to review or update respective policies and procedures. Because policies and procedures may become outdated, and the staff that adhere to outdated policies may carry out actions that are no longer consistent with industry-recognized practices leading to pure incidents. Under this context, healthcare risk managers are strongly encouraged to collaborate with other senior leaders in respective institutions in order to maximize the usefulness of policies and procedures and reduce potential associated risks by being:
-designated from a senior leader who also oversee the policy development, approval, and periodic review by the appropriate policy owner(s) such as: Legal and Compliance Department as well as Health Management Board, etc aiming concise health service guidance;
- reviewed on time and frequently;
-developed by offering training for managers;
-over sighted from a committee with multidisciplinary membership and representatives from all entities (nursing, pharmacy, biomedical engineering, physiotherapist, etc);
- oriented toward new-employees training programs;
-implemented on behalf of a feedback mechanism to staff that report situations to management that resulted in a near miss event;
- coordinated based on business units and services offered;
-electronically organized in the institution's intranet by greatly enhancing respective access.

6. CONCLUSIVE REMARKS

Clinical risk assessment and management includes important aspects such as legal-administrative governmental and insurance issues as well as economic aspects induced from incidents in terms of compensation and perceived quality of citizens' services.

The above mentioned process itself contemporary includes the clinical and managerial dimension through the implementation of different methods, instruments and actions that enable the:

-identification;

-analyses;

-valuation;

-and risk management. Leading to the understanding that clinical risk management is regarded as a system of : culture, politics, objectives, persons, resources, procedures and results.

By integrating various multi-professional skills such as: legal, technical; sanitarian, and administrative. Established through two parallel governmental bodies such as: clinical and litigation handled in turns from quality management and institutional accreditation systems.

Anyway for the cultivation of the culture of prevention and safety the concept of integrated network should be developed as it organizes the institutions in:

-business quality network;

-coordinators;

-safety responsible;

-directors;

-head of departments. Precisely, the above mentioned scheme increases risk management opportunity in healthcare institutions only through the implementation of:

-spontaneous reporting (incidents reporting and open access to health-incidents data pool) regulated with internal procedures;

- two additional forms of operational incident research (cross sectional and prevalence studies);

-Clinical Audit (including audit reason, criteria to be measured, planning, data analysis and summary);

-Root Causes Analysis (RCA- allows to the operators and organizations to learn about the causes and adverse events determination factors with the scope to raise the staff awareness on real causes for problem management and prevention);

-Failure Mode and Effect Analysis (FMEA or the also-called "Criticality Matrix" proactively and quantitatively assesses healthcare processes designed to indentify the critical point, analyze, monitor and estimate them).

Undoubtedly, all this makes a clear orientation towards prevention and safety culture in the institutions in question involving all organizational levels, from management to frontline staff taking into account the commitment of the latter to invest in resources and security.

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