The Instruments of Risk Management as an Opportunity for the Healthcare Organizations

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Abstract
The purpose of this paper is to review literature and instruments concerning the risk prevention in the healthcare system.
After explaining the clinical risk and the degrees of riskiness, the focus of the article is to highlight the approach and the instruments to manage the risk.
Deployment of healthcare risk management has traditionally focused on the important role of patient safety and the reduction of errors that jeopardize an organization's ability to achieve its mission and protect against financial liability; therefore it is vital for the organizations being able to expand their risk management programs from ones that are primarily reactive and promote patient safety and prevent legal/economic exposure, to ones that are increasingly proactive and view risk through the much broader lens of the entire healthcare.

Keywords: Risk Management, Risk, Healthcare

Introduction
The risk management system, according to some research, was established around the 1950s within the enterprises of the manufacturing sector in the United States, in order to support the owners of the factories to ensure the health protection of workers and the safety of the working environment. According to others, its origin is earlier, i.e. in the early twentieth century, within the economic and financial sector; while others assign its first skills to the aeronautical industry.
We can state that risk management has emerged only recently, becoming really more central both regionally and in the individual business environments, while strengthening healthcare quality and safety standards, in order to promote the patients’ safety and to reduce the organizations’ exposure.

The clinical risk
Dealing with the clinical risk, it is important to know some basic definitions.

**Damage:**
Alteration or impairment, temporary or permanent, of a body part or of a physical or mental function.

**Error:**
Failure in planning and/or in performing a sequence of actions that determines the failure to achieve the desired objective and that cannot be attributed to chance.

**Incident:**
An occurrence which gave or had the potential to give rise to unintended damage and/or not required in respect of a patient

**Adverse event:**
Unexpected event related to the process of care and involving damage for the patient, unintentional and undesirable

**Near miss or close call:**
The error that has the potential to cause an adverse event that does not occur by accident or because intercepted or because it has no adverse consequences for the patient

**Sentinel event:**
Severe adverse event potentially indicative of serious system failure, that may result in death or serious damage to the patient and which leads to a loss of public trust against the health service.
Due to their gravity, it is enough that one of these events occurs once in order to be necessary for the organization 1. to actuate an immediate investigation to establish which factors have caused the event or have contributed to the event and 2. to implement appropriate corrective actions

**Clinical governance:**
The system through which healthcare organizations are responsible for continuous improvement of the quality of their services and guarantee high welfare standards thus creating optimal conditions which favored clinical excellence

**Risk:**
Potential event or condition, Intrinsic or extrinsic to the process, which can change the expected outcome of the process itself. It is measured in terms of probabilities and consequences, such as the product between the probability that could occur a specific event (P) and the severity of the damage resulting (D); When calculating the risk it is also necessary to consider the ability of the human factor to identify in advance a risk and to contain the consequences of a potentially damaging event (K-factor).

Therefore we can define the clinical risk as to the possibility that a patient suffers damage or an involuntary inconvenience as a result of the health care, causing a prolongation of the period of hospitalization or deteriorating health or death.

First of all, it is important to make an important distinction between active and latent errors. The main feature of active error is the spatial and temporal proximity to the adverse event. Furthermore, it is easily identifiable and often is due to or an incident or a wrong action/decision of an operator.

On the contrary, latent errors represent mostly organizational and managerial lacks of the system, creating the right conditions for the occurrence of an active fault.

It is important to analyze and identify the causes of errors in order to verify if these are active or latent errors, and then try to redesign the processes in order to reduce the probability that the same mistake could happen again.

Usually detecting an active fault is simpler, but it becomes more complicated to identify all the latent deficiencies in the system.

We can state that the healthcare system, as a complex organization, should take into account, analyzing the errors, that they that can be generated by the interaction between various components of the system itself (i.e. human, organizational and technological).

Using the "Swiss Cheese Model" (figure 1) created at the beginning of the Nineties, by the psychologist James Reason, we can understand the complexity of the system on which we could take preventive actions. This template uses some slices of cheese with holes that represent the latent deficiencies that exist in healthcare processes. Editing multiple factors that normally act as protective barriers, the possibility to line up holes occurs, allowing the concatenation of conditions that lead to the occurrence of an adverse event.

Figure 1

Reason’s Swiss Cheese Model
Analyzing the risk in the healthcare environment, we must considerer that there are two types of risks:
An entrepreneurial risk, intrinsic to the technologies, and to the mechanisms of a healthcare organization and proportional to the complexity of the system;
A pure risk, which is not related to the complexity of the production system and depends on the chain of circumstances that favour the occurrence of an adverse event (that is not predictable or quantifiable).

**The degree of riskiness**
The degree of riskiness of healthcare system consists of many factors and it can be summed up in the following scheme:

**Structural factors**
- the building's characteristic features and facilities (design and maintenance);
- security and logistics of the environment;
- equipment and Instruments (operation, maintenance, renewal);
- infrastructure, network, digitalization, automatization.

**Organizational and managerial factors and working conditions**
- organizational structure (roles, responsibilities, work distribution);
- policy and human resources management: organization, leadership styles, reward system, supervision and control, training, workload and shifts (which contribute to fatigue and stress);
- organizational communication system;
- stakeholders’ involvement;
- ergonomic aspects (including workstation, monitors, alarms, noises, lights);
- policies for the promotion of patient safety: guidelines, diagnostic and therapeutic paths, error reporting system.

**Human factors (individual and team):**
- personal: individual characteristics (perception, attention, memory, decision making, responsibility, mental and physical conditions, psychomotor performance) and professional competence;
- interpersonal and group dynamics and the resulting level of cooperation.

**Users’ Characteristics**
- epidemiology and socio-cultural aspects (demography, ethnicity, socio-economic background, education, management skills, complexity and presence of acute and/or chronic diseases);
- social networks.

**External factors**
- legislation and legal obligations;
- financial constraints;
- cultural and socio-economic environment;
- influences of the public opinion, of the media, of the professional associations and of the public protection association;
- insurances.

**Risk prevention and risk management**
In order to analyze and investigate adverse events or possible unfavorable events, it is necessary to identify the causes that can generate the fact and to learn from these errors, preventing them from happening again.

Recently, different methods and tools (mainly coming from Anglo-Saxon countries) of analyzing the clinical risk management have been developed and have been increasingly used in many health realities.

To achieve the result, which is both to identify the lacks in the system that may contribute to generate an adverse event and to design effective and protective barriers, we could use two approaches: a proactive approach and a reactive approach.

The proactive approach means analyzing and reviewing existing processes and procedures, trying to identify critical points in each stage.

Here are some tools for the identification of the risk taken from clinical literature:

a) Reporting system. It is a structured way to gather information regarding the occurrence of adverse events and/or possible undesirable events, useful to intervene with appropriate preventive measures and, more generally, to spread specific knowledge and promote research in areas of greatest criticality. There are various types of reporting (mail, telephone, electronic/paper submission ...) using a preset template or free template. Some systems, as well as involving the health personnel, may also allow family members, patients, and citizens to report the events.

b) Safety Briefings. They consist of a meeting that can be made at the beginning of the work shift, with the participation of all stakeholders involved in the care of the patients. During these briefings, in fact, a brief assessment or a colloquial discussion, about the potential risks for the patients in the operational unit. At the end of the shift, a debriefing must be carried out, in order to investigate if potentially risky situations have occurred in the course of activities or if there are questions of the patients or of their family members.

Therefore, the safety briefing represents a simple, economical, and easy to use the instrument, useful to assure a safety culture and a shared approach to safety in the healthcare facilities.

c) Safety walks around. These instruments consist of performing, by a group of safety referees, a visit with the operators along the corridors and rooms of the operational units. During this tour, the group starts a conversation with one or more interviews with individual or group actors (patients, practitioners, volunteers), aiming to identify existing or potential hazards that may result in adverse events for patients. Depending on what emerges during this “walk-around”, the clinical team could develop possible solutions to share with all the staff involved.

d) Focus group. It represents a qualitative technique, used by human and social sciences, where a group of people (8 – 12) is invited, by one or more moderators to talk, discuss and debate about a problem, starting from the experiences and perceptions of people involved the same problem. These group may be composed either by each individual professional, by a team, by patients, by family members and by other stakeholders.

e) Review of medical records. A medical record represents a reflection of what the practitioner does, but especially of how the professional does it. Reviewing medical records, represented a milestone in the studies about errors in the healthcare; they represent, in fact, the method used longer in order to assess the quality, allowing investigations about decision-making and outcome observations, analyzing the adherence to guidelines and protocols.

f) Screening. With this technique, it is possible to evaluate computer databases (or paper files), to analyzing in real time or retrospectively adverse events, avoided adverse events or sentinel events, in order to create intervention plans based on historical and real data.
g) Observation. Through an outside observer, it will be possible to evaluate a potential discrepancy between the process of care, put into place, and the expected results (i.e. comments on the administration of medicines).

The *active approach*, instead, consists in a technique starting from an adverse event reconstruction, following the sequence of events backward and trying to identify all the factors that caused/contributed to the occurrence of the event.

The main analysis methods are called FMEA - Failure Mode and Effect Analysis and RCA - Root Cause Analysis.

Briefly, the Failure Mode and Effect Analysis represent a qualitative analysis useful to define what might happen if an experience a fault omission or an error may occur. The FMECA resumes the previous analysis by adding a quantitative path oriented to take operational decisions that are coherent. Therefore, we can state that this method is simply a forecast type technique, that aims, through various questions, to lower the risk of errors, due to a lack of evaluation or to an incorrect consideration during the planning phase. The questions that are posed by applying this technique are as follows:

- Which are the weaknesses of the project?
- In which stage of the process is more likely to occur in an error?
- Which of the possible failures could be eliminated (or its possibility of occurrence could be reduced) by modifying the project?
- What damage could be caused to the user or to the company if there is a fault in the process? or in the
- Which is the most urgent change required?
- Which is the cheapest change required?

The second method is named Root Cause Analysis; it represents a technique of investigation that will examine what happened, searching the deeper reasons why it happened. It studies the causal factors of an accident by focusing its attention on the system and on the process that generated it, looking for improvement. Normally the RCA is used in cases involving accidents or that could result in damage for the patient (e.g. errors in transfusion practice, drug dosing, anesthetic complications, attempted suicide ...).

All these techniques are used to implement changes in the healthcare organization, in order to improve the safety. We can state, therefore, that to improve patient safety it is essential to create an organizational model that includes a clear identification of the objectives to be achieved, responsibilities, tasks, resources, and skills.

In particular, Sexton and Thomas (2004) suggest:

- identify the strengths and weaknesses of the organization;
- assess the effects of organizational changes;
- improve communication among staff;
- assess the organizational aspects such as absenteeism and turnover;
- establish coherent development goals and interventions.

Furthermore, it is vital that any facility, providing healthcare, prepares a plan to promote safety as an integral part of the company overall plan of clinical risk management. It is also important to create an adequate safety culture "educating" the operators to take charge of their responsibilities.

**Conclusions**

The clinical risk management plan is the set of actions that are undertaken by an organization for the prevention and protection against error.

The purpose of this paper, in fact, is to find a common thread that leads the reader to understand the importance of good management of risk management for the healthcare organizations.
The clinical risk, if handled properly, does not represent a simple cost for the healthcare business, but it could be also considered as an opportunity for the company; in fact, it emerges that for all age groups, people's health choices are always influenced by reasons that reflect quality and safety. Positive references, quality of service, and forefront equipment (38.6%) are results strongly dominant in choices of the single verse the service to which to turn, while the price affects fewer people's choices about their health. We can, therefore, state that healthcare organizations might use company policies about quality and safety in order to encourage people in choosing the right service, instead of using an approach focused on prices. Anyway, although trying to make the best possible planning, we should also take into account that markets are always affected by uncontrollable forces, but through an appropriate marketing and communication plan, a good understanding of the planning process and a good knowledge of the healthcare market, it will be possible, for the organizations, to adapt their weakness and mostly their strengthens to the changing competitive conditions of the healthcare system.

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