The Risk Management in Italian Healthcare Organizations: Threats become Opportunities

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Abstract

Italian healthcare organizations are shifting from the administrative approach to the problem of risk towards prevention logic which considers potential mistakes as valuable learning opportunities. The numerous advantages offered by the risk management system can have a positive impact on the quality of patient care, on the workers by protecting them from allegations of malpractice, and finally on the organizational image.

Keywords: healthcare system, risk, clinical governance

1. Introduction

"We can learn from our mistakes unless we tie ourselves to an ideology, and therefore we are persuaded that we know and that, if we know, we don't learn anything. This is certainly the most dangerous error" (Karl Popper, 1972).

In recent years there has been a significant attention to errors and accidents in the health care delivery, which arises in part from the increase of articles in scientific literature and media, and mainly from the new Italian cultural and jurisprudential orientation to increase biological and existential damages. There has been the crisis of the traditional role of health insurance organizations: more and more organizations withdraw from the market assurance products for medical professional liability; other organizations offer products only to less risky specializations; other organizations still refuse to assure professionals who have already incurred claims, or expose only limited ceilings.

The Italian Pact for Health 2013-2015 is based on quality and safety criteria of health care, in order to guarantee Essential Levels of Assistance in the whole Italian territory. A special Italian parliamentary commission of inquiry has as main task the identification of the critical issues in the field of organization and management, which can lead to error in the health field or waste of public financial funds.
For the realization of these activities, it's necessary to make investments and to rationalize health care spending. In Italy in 2011only the 7.1% of Gross Domestic Product is devoted to the health sector, less than the United States or other European countries did.

The management philosophy aimed at improving the quality requires the study of risks (Esposito, 2013). A health care organization could reduce the cost of "non-quality" through the clinical risk management, a set of actions to improve the quality of the health service and the patient safety. The knowledge and the classification of the typologies of errors is a prerequisite for subsequent actions of risk analysis and mitigation.

2. Human Errors

The error is defined as the lack of planned actions to achieve the objective or occasions in which a planned sequence of mental or physical activities can't achieve the desired outcome (Reason, 1990).

There are three different types of human errors as follows (Figure 1) (Reason, 1990):

- *Slips* (execution errors at the level of skills). This category includes all the actions carried out in a different way from what was planned, and the error is due to the lack of individual skills. It refers also to unintentional actions due to fatigue, emotional upset, worry, overwork.
- *Lapses* (execution errors by a memory failure). In this case the action has a different result than expected, due to a failure of memory. Unlike the slips, the lapses aren't directly observable.
- *Mistakes* (errors not committed during the practical execution). It deals with past errors developing during the strategic planning process, such as: ruled-based mistakes, when the application of a rule or procedure doesn't allow the achievement of the objective; and knowledge-based errors relating to the poor knowledge, leading to actions that don't achieve the desired objective. In this case, the plan itself is wrong, even if the actions are carried out properly.
- *Violations* or deviations from standards procedures and protocols.

It's important to consider also the latent errors or hidden errors in the organization, or potential accidents. This refers to the so-called near-miss events (Nashef, 2003). The consequences of latent errors can remain silent in the system also for a long time and become evident when they combine with other factors affecting the organizational system balance.

The medical error is a significant phenomenon in the Italian health system, with consequences both for the patient and his family when the damage is assessed, and for physicians when the judge sets that the event wasn't caused by the responsibility of health care workers. In Italy, about the 4% of the hospitalized people every year suffer damages or consequences (disease) as a result of mistakes of doctors or of inadequate organization of the health care. Eight of ten doctors, with over 20 years of professional seniority, were subjected at least once to an investigation for an alleged error. Two of three cases often conclude after a long process, with a full acquittal. This situation causes significant biological and professional damage for the physician, but also a serious danger for the patient, with a consequent waste for the Italian healthcare system.

The risk is the probability of occurrence of all the events that can result in loss or damage the organization and the involved people. The risk is defined as a measurable uncertainty, within the more general concept of uncertainty (about future events) and in contrast with the non-measurable uncertainty (Knight, 1971).

3. The Concept of Risk Management

The risk management has developed as a business discipline in the United States in the fifties, with the spread of the culture of total quality, in consideration of the fact that a potential risk can become an element of customer dissatisfaction.

The risk management is defined as follows:

- Holistic process that covers all risks and their relationships including all effects (Kloman, 1992);
- Mechanism to manage the risk exposure allowing to recognize events that could have harmful or unfortunate consequences in the future, and defining the procedures to monitor these events (Dickson, 1995);
- Organizational function to identify, assess, manage and monitor risks of the organization, such as events that can be a threat for the physical and human assets of the organization and its capabilities to income;
- Auto-protective activity aimed to prevent the actual or potential threat of financial losses due to accidents, injuries/damages or medical malpractice (Kraman & Hamm, 1999).

The risk management is an example of innovation relating to the management of adverse events of arson and accidental. The activities of risk management are structured in a sequential model, in which the final decisions are supported by the detection of the potential adverse reactions. They are divided into three basic steps:

- *Risk identification*, for the systematic assessment of threats;
- *Risk assessment*, which is the translation of the threats in terms of quantity, by determining the probability of occurrence and severity of the potential harm;
- *Risk management*, to define and introduce the most appropriate actions to reduce risks in relation to organizational objectives.

The organization has to identify its goals and necessarily to limit the possibility that future events generate negative events that can affect the achievement of objectives. There is a close relationship between risks and objectives, because the risk is related to every event, external or internal to the organization, which can impact on the achievement of objectives. The risk can be an opportunity or threat, and managers must be able to benefit from opportunities, and at the same time to minimize and deal with the threats. The risk management thus becomes an integral part of the organizational systems and processes. Risks are identified and evaluated for their impact and probability of occurrence. If the organization decides to manage them, it's necessary to design and implement a system of risks, in order to reduce at least them to the acceptable level.

In the health sector, the risk management is defined as the set of clinical and managerial activities to identify, assess and reduce the risks for patients, staff, customers, and the risk of economic loss and of organizational image. It represents the set of various complex actions implemented to improve the quality of health care and ensure patient safety, based on learning by error. Such a process requires the systematic analysis of current and potential risks and the implementation of control measures and overall risk reduction.

The risk has to be considered not as a burden to be endured, but as a generator of success. In health care organizations the risk system should be carried out by special managers through a systematic system that allows, through successive steps, to identify, analyze, evaluate, monitor and eliminate the risks associated with every activity, in order to minimize losses and maximize opportunities for the organization.

4. The Clinical Risk

The clinical risk is considered as the probability that the patient is the victim of an adverse event, and suffers damage or distress due to medical treatments prolonging hospital stays, and resulting in the deterioration of health or death (Kohn, Corrigan & Donaldson, 1999).

In the literature, there is no single definition of clinical risk. For Vincent & Bark (1995) the clinical risk is the organizational response to the need to reduce errors and their costs. The risk management includes the procedures necessary to reduce all potential risk factors, not just clinical factors. Clements (1995) associates the clinical risk to the reduction of damage to an organization by identifying and quickly eliminating the risk.

In a hospital environment, risk factors should be identified through a continuous process of analysis and internal control, to assess the possible consequences and to identify activities sectors that most are subject to these consequences, in order to prevent future risk.

The clinical risks are classified by:

- *Critical areas* (operating room, hospital stay, emergency, diagnostics);
- *Specialties* (cardiology, intensive care, orthopaedics, surgery);
- *Damage by drugs* (frequency of causes, medication of high clinical risk);
- *Hospital infections* (frequency of causes, localizations, preventive actions);
- *Diagnostic errors.*

The continuous search for adverse events and the correction of defects in the system, that caused them, contributes to improve the organization, reduce costs and waste. It's important to study adverse events to govern the clinical risk. Adverse events are important "hidden costs", composed by direct costs (lengthening of the duration of hospital stay, cost of care to reduce the damage, legal insurance costs) and indirect costs (image, effects on the responsible of damage), resulting in decreased quality and increased costs.

Only recently scientific articles on the management of clinical risk have been produced and made available to the international community.

The adoption of computerized systems for clinical documentation, in practice, isn't obvious or simple. The security concerns interpersonal relations and largely depends on the functioning of the team. A responsible non-punitive culture should be created and inappropriate behaviours shouldn't be tolerated (Leape et al., 1998). It's necessary in particular: to involve the patient; to communicate the adverse event; to measure and analyze the doctors' performance; to publish data on adverse events. The risk management is an essential tool for clinical governance.

5. The Risk Management as an Instrument of Clinical Governance

The clinical governance is the system through which health care organizations improve the quality of their services and keep high standards of care, by creating a work environment of clinical excellence (Scally & Donaldson, 1998).

The clinical governance is the capability of health care organization to stimulate clinicians' behaviours in diagnostic, therapeutic and rehabilitation choices, towards clear and tested scientific evidence and assessments of cost-effectiveness and cost-efficiency. Health care organizations should promote health services professional guidelines, providing organizational support through incentive and evaluation systems of managers. The medical director of an organization is responsible for the clinical governance, including four typical dimensions of quality: professional quality; perceived quality; efficiency; and risk management. The medical hospital direction, however, has to identify the most critical areas in the hospital for care outcomes, for professional categories, for care process, for costs, to manage the working groups to define organizational guidelines, and to assess effectiveness and efficiency of the health care.

Health care organizations are responsible for the overall performance, for the development of improvement quality systems and they have to make public and transparent the management results (accountability).
The clinical governance requires an integrated system of organizational control, which is considered as the base for clinical audit, risk management and, more generally, quality services promotion. The control system aims to create a solid organizational environment aimed to achieve quality services and to develop clinical excellence (De Simone, 2013).

The risk management system is the link between the clinical governance and the control assurance. The warranty, safety and quality are more and more a *condicio sine qua non*: an obligation that no organization can escape. That's why it's necessary to create the organizational culture of safety based on a comprehensive reporting system. The clinical governance has to replace clinical negligence.

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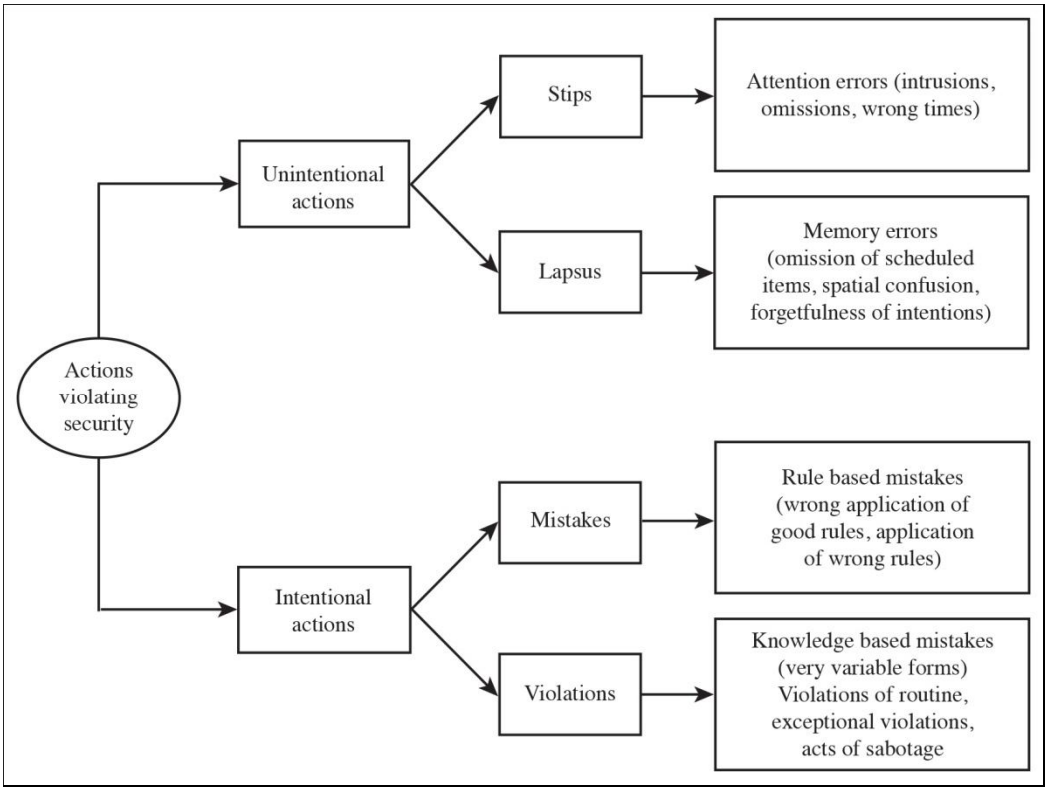
Figure 1: Typologies of Human Errors



Source: Adapted from Reason (1990)