A systemic methodology for risk management in healthcare sector

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ABSTRACT

The recent biomedical, technological, and normative changes have led healthcare organizations to the implementation of clinical governance as a way to ensure the best quality of care in an increasingly complex environment. Risk management is one of the most relevant aspects of clinical governance and approaches put forward in literature highlight the necessity to perform comprehensive analyses intended to uncover root causes of adverse events.

Contributing to this field, the present paper applies Reason's theory of failures to work out a systemic methodology to study risks impacting not only directly but also indirectly on patients. Also, the steps of such approach are organized around Human Reliability Assessment phases, in order to take into account the human component of healthcare systems. This framework is able to foster effective decision making about reducing failures and waste and to improve healthcare organizations' maturity towards risk management.

The developed methodology is applied to the pharmacy department of a large Italian hospital. An extensive validation in different healthcare settings is required to fully prove benefits and limitations.

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1. Introduction

In recent years healthcare systems have been involved in a number of different changes, ranging from technological to normative ones, all asking for increased efficiency. In addition, the biomedical progress in the last decades has contributed to raise the level of organizational complexity in hospitals, which is given by many different factors, such as multiple professional experiences, non-uniform management models, patient specificity, surgery complexity, reduced inpatient days, and a growing number of healthcare service users due to an increase in average lifetime. As a result, medicine complexity, driven by innovations in both science and technology, stresses the need for new managerial models (Bridges, 2006). Thus, this context highlights the necessity to develop systemic approaches able to detect waste and errors and to suggest organizational and/or technological solutions for continuous improvement.

To this end, following the success of the application of Kaizen principles to the manufacturing sector (Liker, 2004; Liker and Hoseus, 2008), international healthcare organizations, such as The Joint Commission on Accreditation of Healthcare Organizations and The World Health Organization, have developed and adopted the concept of clinical governance. Clinical governance aims to ensure that patients receive the best quality of care. It includes systems and processes for monitoring and improving services, risk management, clinical audit, clinical effectiveness programs, staff management, education training and continuous personal development, and the use of information to support healthcare delivery (Sale, 2005). Among the different aspects of clinical governance, risk management is crucial since it addresses the clinical risk impacting on patients. Literature shows that clinical risk management does not always take a systemic perspective. Moreover, it does often not rely on the understanding of people acting in the investigated processes, nor gives it a valuable support to decision making.

This paper operationalizes Reason's theory of failures by developing a methodology to investigate healthcare processes and related risks impacting either directly or indirectly on patients.

The work provides a systemic approach based on expert knowledge and able to sustain continuous improvement. With the purpose of explaining how it works, the methodology is applied to the pharmacy department of a large hospital. However, more case studies are needed to completely assess the relevance of the framework to the healthcare sector.

The paper is organized as follows: Section 2 highlights the need for a systemic perspective on healthcare risk and presents Reason's theory of latent failures. Section 3 discusses the importance of errors to clinical risk, as well as the features characterizing a successful methodology for managing it. The proposed methodology and its application are presented in Section 4 and Section 5

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respectively. Benefits and limitations of the approach, together with future research lines, are discussed in Section 6.

2. Healthcare risk: need for a systemic perspective

Similarly to any other complex system, the complexity of healthcare systems generates adverse events if not controlled (Vincent, 2006). An adverse event may be defined as an unintended injury or complication resulting in disability, death or prolonged hospital stay that is caused by healthcare management rather than by the patient's underlying disease process (Ross Baker et al., 2004). An intrinsic characteristic of medical care is the fact that, whenever it is delivered, patients run the risk to suffer from a disease as an unwilling consequence of treatments (Thomas et al., 2000). Thus, the probability of errors and adverse events in general cannot be eliminated in healthcare organizations. However, it can be controlled by the application to risk management phases of a recursive process of continuous improvement inspired by the Plan, Do, Check, Act (PDCA) paradigm (Tonneau, 1997). According to The Project Management Institute, risk management includes the processes concerned with risk management planning, identification, analysis, response, monitoring, and control. The aim is to increase the probabilities and impacts of positive events and to decrease the probabilities and impacts related to adverse events (Project Management Institute, 2004). Risk management has been adopted to cover all healthcare risks, both clinical and non clinical ones.

The present work focuses on clinical risk, which has been defined by different authors. Wilson and Tingle refer to clinical risk as clinical error to be at variance from intended treatment, care, therapeutic intervention or diagnostic result (Sale, 2005). Kohn et al. (1999) define clinical risk as the probability that a patient is affected by an adverse event voluntarily or involuntarily caused by medical treatments. However, clinical risk is not only due to medical activities directly impacting on patients but it is reliant on a larger set of activities and professionals. It can be determined by many factors relating to the system, the environment, and the interplay of individuals operating in the processes connected to the delivery of care (Kohn et al., 1999). This research takes such broader perspective on clinical risk, including all events that may affect patients' safety both directly and indirectly.

Within clinical risk, medical errors are particularly important since they may occur during multiple hospital processes, from therapy prescription, thorough preparation, distribution, and administration (Vincent, 2001). Several studies performed in US, Australia, New Zealand, and Europe (Davis et al., 2001; Leape et al., 1991; Vincent et al., 2001; Wilson et al., 1995) reveal that about fifty percent of adverse events taking place in healthcare systems may be prevented. This highlights a strong need for understanding the triggering events of medical errors as well as their correlations in order to decrease the probability of occurrence of these errors by working on all their possible causes.

The theory of latent failures put forward by Reason is relevant to this end (Reason, 2002). According to such author, adverse events are seldom determined by a single error, being it either human or technological, but more often they are the result of a chain of errors and events where the person responsible for the final error is only the last causal link. In other words, adverse events are produced by many factors, such as organizational, professional, personal, and technical ones. Reason's model defines an adverse event as an unexpected release of energy that may be prevented by erecting barriers between the source of energy and the person or the object to be protected (Fig. 1). In this situation, the word "barrier" refers to a wide range of preventive/protective measures including protection devices, security systems, working procedures, training, supervision, and emergency plans
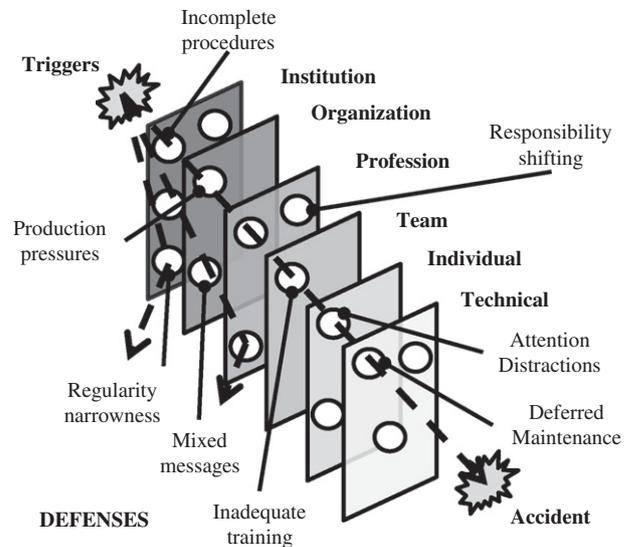

Fig. 1. Reason's model (adapted from Barach (2002)).

(Harms-Ringdahl, 2009). When there are deficiencies in these barriers, they are not able to block the unexpected flow of energy and originate an adverse event that may be classified as a "near miss" (almost an event), an "incident" (event without damage), or an "accident" (event with damage) according to its severity (Hollnagel, 2004). Deficiencies are represented by latent and active failures (Reason, 2001). On the one hand, latent failures alone are not able to cause full-blown symptoms, only if connected to other factors and under facilitating conditions they originate adverse events. On the other hand, active failures represent immediate triggering events, they are related to people acting in a system and their detection often implies the identification of an individual responsibility.

The existence of both direct and indirect causes for adverse events in any social–technological complex system, as highlighted by Reason's theory, stresses the need for taking a systemic perspective to risk, in order to have a global view on how the interrelations among technical, human, and organizational factors cause or prevent negative events. This necessity is even more evident for clinical risk, since healthcare systems are human intensive and their ultimate goal is providing a medical service ensuring the safety of the entire population.

3. Managing clinical risk by working on errors

A systemic perspective is not the only feature characterizing a successful methodology for managing clinical risk. Preventing risk requires to understand how to strengthen those procedural, administrative, physical, and individual barriers intercepting and blocking the energy flow responsible for deviations. To this end, it is useful to work on what constitutes such energy flow, that is, according to Reason's theory, on errors.

Error taxonomies put forward in literature provide relevant insights on how to cope with adverse events occurring in the healthcare sector. Several classifications of errors have been developed (Baysari et al., 2008; Baysari et al., 2009; Cosby, 2003; Shorrock, 2002; Wieman and Wieman, 2004). Among them, Predictive Human Error Analysis (PHEA) is one of the most detailed (Embrey, 1992; Hollnagel, 1998). PHEA groups error modes according to the following activities: planning, execution, control, information retrieval, communication, and selection. For example, in a healthcare setting, prescription errors may be related to planning, if the