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# A human factors and reliability approach to clinical risk management: Evidence from Italian cases

Chiara Verbano *, Federica Turra

*Department of Management and Engineering, University of Padua, Str.lla San Nicola 3, 36100 Vicenza, Italy*

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ABSTRACT

Similarly to the industrial sector in the late 1980s, nowadays leading organizations in the healthcare sector acknowledge the fact that human errors, adverse events and system failures must be managed and controlled. Whilst Human Reliability Analysis (HRA) has been well-accepted and integrated into safety management processes in other industries, the application of such error techniques to the problem of managing the associated risks in healthcare is rare. The main purpose of this research is to analyse clinical risk management (CRM) and patient safety improvement in Italian healthcare organizations, through human factors and human reliability theories. In particular, the specific objectives are to explore the Italian state-of-the-art in CRM, with regard to organizational and managerial issues; to identify and verify the factors influencing the growth and sharing of the safety culture and to understand and describe the possibility of transferring human reliability methodologies and theories to the domain of healthcare.

Six case studies belonging to the Italian scenario have been performed, in order to describe the Italian healthcare system and to identify the key influencing factors of CRM policies.

Results obtained from within and cross-case analysis give an empirical contribution to the recent introduction of CRM in the Italian context and a theoretical contribution referring to the framework used to analyse CRM in healthcare organizations, and to the indications which emerged on the key factors influencing CRM.

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## 1. Introduction

Currently the theme of clinical error and risk is an issue of great interest for various healthcare sectors and it has a strong social impact. The healthcare system is a complex system in various respects, on a par with other contexts such as nuclear centres, aviation and military defence (Ministero della Salute, 2004). Since in every complex organization error and the possibility of accidents cannot be eliminated, all possible interventions must be used so that these are, at least, controllable.

Risk management in healthcare represents the group of various complex actions, implemented to improve the quality of the healthcare services and guarantee the safety of the patient (Walshe and Dineen, 1998), safety based therefore primarily on learning from error (learning organization). It is necessary to consider the error as an ineliminable component of the human reality. For this reason, if human error and the risk associated with it cannot be entirely eliminated, it is essential to encourage ideal working conditions: it is a question of implementing a group of actions that make it difficult for man to make a mistake and, secondly, implementing defences able to stem the consequences of any error which may occur. It is in this context that fundamental importance is given to the human factors theory and the human reliability theory, originating in the industrial context, and fruitfully applicable to complex socio-technical systems, such as healthcare systems (Stanhope et al., 1997).

Promoting the "learning from error" culture, and not hiding it, is a successful and rewarding strategy, as experiences matured in other contexts demonstrate (Spencer, 2000).

Clinical risk can be contained through risk management initiatives implemented at the level of the individual healthcare organization, at corporate and regional level. These initiatives, to be effective, must concern all the areas in which the risk can emerge during the patient's clinical care process.

Considering the social and scientific importance held by the knowledge of the risk in the healthcare field and its management methods, the purpose of this work is to understand its state-of-the-art in some of the best Italian healthcare organizations. In particular, the function of clinical risk management (CRM) will be analysed together with the process of risk management and management of patient safety in Italian healthcare organizations,

* Corresponding author. Tel.: +39 0444 998731; fax: +39 0444 998884.
*E-mail address:* chiara.verbano@unipd.it (C. Verbano).

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through the theory of human reliability and human factors methods. For this reason, a qualitative research, adopting the multiple case studies method (Yin, 2003) has been performed.

This article is organized as follows: Section 2 provides the main characteristics of the Italian healthcare system; Section 3 reports the theoretical framework resulting from the literature review; Section 4 defines the research questions and describes the data collection and analysis method used; Section 5 presents the results of the study; and Section 6 discusses the results and draws conclusions.

## 2. The Italian context

The Italian National Health Service is mainly composed of public health providers and a minor presence of private organizations. The overall national organization consists of three main institutional levels:

- the national level responsible for overall planning and control;
- the regional level responsible for territorial planning, organization and control; and
- the local level responsible for providing health care service.

Healthcare organizations have been undergoing years of great turbulence and rapid changes, but also years of great richness and potential for improvement.

Following the coming into force of the Legislative Decree (no. 502 of 30 December 1992), the concept of "*privatisation*" has been introduced into Italian healthcare organizations, aimed at researching a more effective and efficient management of healthcare firms and a greater satisfaction of patients' needs. The concept of "firm" implies first of all consistently making every level of the organization responsible and an adequate management by objectives and by processes, aimed at competition and continuous improvement. Therefore, the objective of the corporate approach to the management of the healthcare activity is the realisation of *controlled, competitive and integrated processes*, enabling it to react autonomously to the changes, by seeking to resist the intrinsic institutional resilience and to considerably contain the incidence of the costs, through the rationalization of the resources available (Carthey et al., 2001).

The Regional Agencies are very important actors in the development of CRM, patient safety and quality; they are the main structures whose mission is to facilitate innovation throughout healthcare systems and specifically to organise clinical risk management systems at regional level. The CRM regional centres have the task of promoting and coordinating initiatives for patient safety. From a practical point of view the RM programs are rather limited, but the general concern (both of managers and clinicians) has been increased. Unfortunately, there is as yet no systematic and comprehensive approach to safety in the medical domain.

## 3. Theoretical framework

From the analysis of the specific literature (Table 1), four subject areas emerge which, though of independent origin, interact profoundly each other: these are CRM, safety culture, the human reliability theory and human factors theory, and quality management.

The correct implementation of risk management in the clinical environment necessitates the contemporary development within the same environment of a safety culture, application of the principles of human reliability and human factors theory and the adoption of a quality management logic. Since these three aspects are tightly coupled they all participate in the process of implementation of clinical risk management.

These have been analyzed in-depth in order to characterize them and define their essential variables, and they constitute, together with CRM, the four constructs of reference for the empirical analysis which will be conducted (Fig. 1).

### 3.1. Clinical risk management

Clinical risk management can be defined as "an approach to improving quality in healthcare which places special emphasis on identifying circumstances which put patients at risk of harm, and then acting to prevent or control those risks. The aim is to both improve safety and quality of care for patients and to reduce the costs of such risks for health care providers" (Walshe and Dineen, 1998). From a more practical point of view, it has been defined as "the system of guidelines, protocols, steps, organizational and clinical procedures adopted by a hospital to reduce the probability that events and actions, that might potentially produce negative or unexpected effects on the health of patients, occur" (Floreani, 2005).

The subject of analysis of CRM is clinical risk, defined as the probability that a patient will be the victim of an adverse event, i.e. that he/she suffers from any type of loss or discomfort attributable, even in an involuntary way, to the medical care received during a stay in the hospital, which leads to an extended stay, worsening in the patient's health conditions or death (Kohn et al., 1999).

One possible classification of clinical risks divides them into the following categories (Ministero della Salute, 2004):

- *Errors* in the use of pharmaceuticals: prescription, preparation, transcription, distribution, administering, and monitoring.
- *Surgical errors*: foreign objects left inside a patient during surgery, surgery on the wrong part or side of the body, unnecessary surgery, incorrect management of the patient who has undergone or is going to undergo surgery.
- *Errors* in the use of equipment: malfunctioning caused by technical problems during manufacturing, malfunctioning caused by the person using the equipment, use in inappropriate conditions, inadequate maintenance, inadequate instructions, incorrect cleaning, use beyond the stated life cycle of the equipment.
- *Diagnostic* exams or procedures: not carried out, planned but not carried out, carried out in an inadequate or incorrect way, carried out in a correct way but on the wrong patients.
- *Timing errors*: delay in pharmaceutical treatment, delay in carrying out surgery, delay in diagnosis, other organizational, management, or logistical delays.

The process of risk management envisages, also in the clinical context, a first phase of identifying risks through the reconstruction of the corporate risk profile, a second phase of risk evaluation and quantification, and then the third phase of risk treatment in which the measurements and tools for management and mitigation are planned. The planning cycle closes with the setting up of the operational phase, which envisages the implementation of the set programme, control and then the analysis of the feedback from the activated process. Fig. 2 shows the stages of the CRM process detailed with the specific methods, theories and most significant models.

As far as the organizational positioning of CRM is concerned however, the activity of risk management, covering a strategic role between the various corporate functions, finds its natural allocation in the strategic management staff, since it does not mechanically intervene in a process with an administrative role, but acts as a support body to management decisions. This body programmes

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