

## *Past and present of risk management in healthcare*

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**Key words**      *Risk management, clinical, medical error*

**Summary**      The present article describes the history of risk management, how it was born and how it has evolved, with a specific focus on healthcare. Risk management was a strategy initially used primarily in the economic and business sector. We analysed how the continuous increase of medical malpractice lawsuits involving demands for compensation led to the adoption of risk management strategies in healthcare. The various clinical risk-management strategies adopted in different countries and in different historical periods are also described.

### Passato e presente del risk management in sanità

**Parole chiave**      *Risk management, clinical risk management, medical error*

**Riassunto**      Il presente lavoro ha ricostruito la storia del risk management come è nato e come si è evoluto con particolare attenzione all'ambito sanitario. Infatti il risk management nasce come strategia di gestione del rischio per essere applicato principalmente a livello economico e d'impresa. Successivamente abbiamo analizzato come il continuo aumento di denunce per errori medici con relative richieste di risarcimento, abbia condotto all'adozione delle strategie di risk management anche in ambito sanitario. Alla fine abbiamo analizzato le varie strategie clinical risk management nei diversi paesi del mondo e nei diversi periodi storici fino al modello attuale.

## Introduction

Risk management (RM) is the process by which you measure or estimate the risk and then develop strategies to manage it. Risk management began to be studied after World War II. Several sources date the origin of modern risk management to 1955-1964<sup>(1, 2, 3)</sup>. The evolutionary process has seen the transition from insurance coverage as the only possible solution for risk management, the adoption of techniques and methodologies that the view finder to the identification, evaluation and control of business risks.

With the process of corporatization of health, risk management has also expanded in this new sector. In fact, modern medicine led to increasingly complex forms of treatment and processes of care. These results in a range of opportunities for improved care, but also increases the risk of adverse events and patient harm.

Risks associated with patient care can never be completely eliminated, therefore, clinical risk management plays a crucial role in enabling hospitals to enhance patient safety. RM generally encompasses risks in the political, legal and business environments. Clinical risk management (CRM) is a specific form of RM focusing on clinical processes directly and indirectly related to the patient<sup>(4)</sup>.

## *Clinical Risk Management*

Historically, patient safety researchers investigating the impact of error in medicine have adopted outcome dependant definitions of medical error and its surrogate terms, and have limited their focus to patients experiencing adverse outcomes or injury as a consequence of medical care<sup>(5, 6)</sup>.

Perhaps, this tendency stems from a guiding principle of medical practice credited to Hippocrates, "primum non nocere", which translates to "First, do no cause harm"<sup>(7, 8)</sup>. Moreover, the manner in which patient safety has been defined promotes an outcome-dependant approach to defining medical error. Patient safety: the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of health care<sup>(9, 10)</sup>.

In the earliest studies on patient safety in the 1950s, medical errors were largely considered "diseases of medical progress"<sup>(11)</sup> and dismissed as "the price we pay for modern diagnosis and therapy". These reports tended to be limited to unusual patient reactions or those of magnitude and consequence<sup>(12)</sup>. In "Hazards of hospitalization," a pioneering investigation on error in medicine, Schimmel<sup>(13)</sup> maintained that "as-

assessment of all untoward reactions, regardless of severity, is essential to determine their total incidence and to indicate the cumulative risk assumed by the patient exposed to the many drugs and procedures used in his care.”

An emerging debate in the international context on the renewed interest in the issue of the safety and quality of health care. In recent years errors in medicine were brought to the attention of “clinical governance” of the health care system because of the economic implications and the damage they are causing disputes, not only for the ethical implications. The prospects for increased productivity and efficiency recovery, which had driven the attention of decision makers and companies since the late 1980s (in Italy, particularly with the process of corporatization of National Health System), are giving way to the themes related to the ‘quality’, looking for a balance as possible between the application of citizen-consumers increasingly demanding and economic-financial dynamics no longer dealt with short-sighted measures a single rationalization or containment of public expenditure.

For example in Italy, in addition to increased numbers of claims filed against doctors, the size of payments to allegedly injured patients has increased dramatically, moving from mere token amounts paid to victims of medical malpractice to the increasingly greater sums of money paid since the late 1980s. In part, this trend may reflect technological advances in healthcare and how judges view these advances.

While in the past, the physician had an obligation to use all available means to achieve the result without being legally obliged to actually achieve the result, now the physician is more frequently called to answer for any result falling short of patient expectations. In Italy today, more than 15,000 medical liability actions are filed per year against doctors, and hospitals (through their insurance companies) must spend over €10 billion (US\$ 15.5 billion) annually to compensate for therapeutic and diagnostic errors. Between 2000 and 2006, orthopaedics and traumatology were responsible for the highest number of cases filed relating to alleged malpractice, followed by obstetrics/gynecology. Estimates suggest a physician practicing in Italy for 20 years has an 80% chance of being named as a defendant in a medical malpractice suit, with an 80% chance of being exonerated for charges of negligence, imprudence, or unskillfulness<sup>(14)</sup>.

So if we are hit by a growing focus on clinical risk management, the reasons are to be found in the economic analyses that the ‘error’ or malpractice in medicine produces in terms of higher expenses for the health care system, particularly for

legal proceedings for professional responsibilities are constantly increasing. Today the insurance companies begin to waste oppose conclusion of insurance for doctors, due to the continued growth of compensation, dispute resolution, and lack of risk management and control. Just as said, currently the subject of clinical risk arises as a topic of significant severity which affects various sectors of health and has a strong social impact. Therefore, it is essential to know and analyse this aspect of health care, which is placed in the more general theme of quality of performance evaluation.

Also managing the unexpected is an essential everyday concern in high-risk organizations such as hospitals.

The issue of error in medicine and has had several security valences in history. The common practice that the doctor had always right and were effective and safe treatment, for which patients could not shirk. Insiders were of a completely different opinion: Gianbattista Morgagni, in his inaugural Speech at "Ordinary medical Theoretical" in 1712, saying: "I will say what are the first notions that would be the masters to give his disciples: reveal the deceptions of the senses and illustrate the most common and known errors to put against them for the future which is a shame for a man to admit that he cheated, but it is not to admit it when he is admonished by mistake". Also Augusto Murri, father of Italian Medicine, saying, "Err, Yes! is a word that makes the public scare. Wander at our expense? Err at the cost of our lives? Wonder seems justified, the prosecution seems very serious! Yet, or the danger of error or waive the benefits of knowledge. There is no other way: the man who does not err, no". More recently, the need for monitoring of medical error leads to the birth of the first US initiatives. Risk management was founded in the US in the 70's as a response to the crisis caused by the increase in malpractice issue and burden of refunds for errors in care, and the disproportionate increase of insurance taken. In 1971 President Nixon set a Government Committee that stated that the best way to reduce the frequency and severity of damage was the development of a system of prevention of error in all health facilities. Despite the recommendations of this Commission in the 70's he gave importance only to financial Risk management. This gave rise to a second crisis in malpractice 80's with high insurance losses, increased insurance premiums and claims. Finally the American Hospital Association formalized the creation of RM programs<sup>(15, 16)</sup>.

In 1985 more than 80% of American hospitals had a Risk management program. Things went forward more or less discretely until 1999 when the Institute of me-

dicine published “the report to err is human. Building a safer health care system”. The document estimated that medical errors were responsible for a dimension between the 44000 and 98000 deaths year in the United States, more than those due to accidents, breast cancer or AIDS. From an economic point of view the data were surprising: each year were spent about 38 billion dollars for errors and damage. Clinton and Bush Governments financed with 50 billion dollars, the AHRO Agency (The Agency for Healthcare Research and Quality) funded research to evaluate information technology systems and errors. Nevertheless, in 2002, a new crisis occurs: in Nevada closes the only trauma centre for the resignation of 56 to 58 for the disproportionate increase in orthopaedic of insurance; many insurance companies drop out of the health sector; many physicians go into early retirement due to increased insurance premiums. President Bush announces that would have taken legislative measures to reduce lawyers’ fees and limit complaints (in the USA the patient’s advocate is entitled to 30% of compensation in case of victory: a strong motivation to bring a lawsuit). But at a time when the United States realize that this is a mistake, in Italy the Bersani decree that introduced the so-called “Quota Lite Pact”. In essence, the victim of alleged malpractice, should not anticipate any plot to advocate and technical consultants. Only at the end will donate to the Attorney and experts a percentage of compensation <sup>(17, 18, 19)</sup>.

In other Nations is a whole succession of more or less precise studies. The document “An organisation with a memory (2006)” of the British Department of Health reported an incidence of adverse events in hospitalized patients of 10%, leading to an estimate of 850000 adverse events per year <sup>(20)</sup>.

### Conclusion

All patients are potentially vulnerable to errors. Therefore, medical errors are costly from a human, economic and social viewpoint and become a real public health problem as the oldest ones such as excessive use of antibiotics, occupational hazards, waste and the misuse of vaccines.

Key components in helping tomorrow’s doctors to discuss, cope with and commit fewer medical errors are team work, communication skills, evidence-based practice and strategies for managing uncertainty.

Lowering the costs of dispute resolution could lead to considerable savings for physicians and insurers, particularly in specialties with high mean defence costs.

We imagine a health care system in which those who provide assistance to be satisfied with their work and those who receive assistance will feel confident and have complete confidence that they receive assistance<sup>(15, 21, 22, 23, 24, 25)</sup>. With this thought by Donald M. Berwick, President of the Institute for Health Care Improvement, we want to finish this job that we hope both the greater awareness that emerged over the years and in different parts of the world, and that continues even at the very moment when we are writing this work, there was for the purpose of RM in the Health sector as a result of the awareness of the necessity of reducing errors in health care.

#### References

1. Crockford GN. The Bibliography and history of Risk Management: some preliminary observations. *The Geneva Papers on Risk and Insurance* 7, 1982: 169-79.
2. Harrington S, Niehaus GR. *Risk Management and Insurance*. USA: Irwin/McGraw-Hill, 2003.
3. Williams A, Heins MH. *Risk Management and Insurance*. New York: McGraw-Hill, 1995.
4. Briner M, Kessler O, Pfeiffer Y, Wehner T, Manser T. Assessing hospitals' clinical risk management: Development of a monitoring instrument. *BMC Health Serv Res* 2010; 10: 337. doi: 10.1186/1472-6963-10-337.
5. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. *N Engl J Med* 1991; 324:370-6.
6. Thomas EJ, Studdert DM, Burstin HR, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care* 1999; 38(3): 261-71.
7. Veatch RM. *Cross cultural perspectives in medical ethics readings*. Boston: Jones and Bartlett Publishers, 1989.
8. Nightingale F. *Notes on hospitals*. London: Longman; 1863.
9. National Patient Safety Foundation. *Agenda for research and development in patient safety*. Available on: [www.npsf.org](http://www.npsf.org) (accessed 2005 Jan 14).
10. Kohn LT, Corrigan JM, Donaldson MS. *To err is human: building a safer health system*. Washington: National Academy Press, 2000.
11. Moser RH. Diseases of medical progress. *N Engl J Med* 1956; 255: 606-14.
12. Barr DP. Hazards of modern diagnosis and therapy: the price we pay. *JAMA* 1955; 159: 1452-6.
13. Schimmel EM. The hazards of hospitalization. *Ann Intern Med* 1964; 60: 100-9.
14. Traina F. Medical malpractice: the experience in Italy. *Clin Orthop Relat Res* 2009; 467(2): 434-42.
15. La Pietra L, Calligaris L, Molendini L, Quattrin R, Brusaferrò S. Medical errors and clinical risk management: state of the art. *Acta Otorhinolaryngol Ital* 2005; 25(6): 339-46.

16. Millenson ML. Pushing the profession: how the news media turned patient safety into a priority. *Qual Saf Health Care* 2002; 11: 57-63.
17. Kohn L, Corrigan J, Donaldson M. *To err is human: building a safer health system*. Washington D.C.: National Academy Press, 1999.
18. Leape LL, Berwick DM. Reducing error in medicine: it's time to take this more seriously, *BMJ* 1999; 319: 136-7.
19. Italian Ministry of Health. Patient safety and clinical risk management. Quality Department, General Directorate of Health programming III 2008.
20. Reason J. Human errors: models and management. *BMJ* 2000; 320: 768-70.
21. Petti S, Messano GA, Scully C. Antibody level and immunity against Hepatitis B virus infection among general dental practitioners. *Acta Stomatol Naissi* 2013; 29(67): 1273-8.
22. Petti S, Messano GA, Polimeni A. Dentists' awareness toward vaccine preventable diseases. *Vaccine* 2011; 29(45): 8108-12.
23. Messano GA, Petti S. [Antibiotic resistance as a public health problem: the case of genital mycoplasmoses]. *Ig Sanita Pubbl* 2011; 67(6): 697-706.
24. Protano C, Nanni S, Giampaoli S, Romano Spica V, Vitali M. The municipal waste management: a comparison between Germany and Italy. *Ann Ig* 2013; 25(4): 343-51.
25. Millenson ML. Pushing the profession: how the news media turned patient safety into a priority.

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