2 Brief Story of a Clinical Risk Manager

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2.1 Introduction

This chapter briefly recounts the story of someone who worked as a clinical risk manager of a regional health service for 16 years since his appointment as director of a regional center for clinical risk management and patient safety.

The purpose of this chapter is to provide a testimony of one of the first international experiences of safety management in a public health service. It does not claim to speak to a particular type of profession but aims to relate an experience in which some will recognize themselves, others will be able to find advice, and others will be able to understand the differences with the health reality in which they operate. It may also be useful in order to define the "clinical risk manager," a new professional figure that has now entered the scene in our hospitals.

This story takes place in Italy, a country that, according to international indicators [1] and the World Health Organization (WHO) [2], has a fairly good health service but with very strong variability between the northern and southern regions.

Unfortunately, the economic crisis has worsened the situation and, in terms of quality of care, Italian services no longer occupy the top positions [3].

In the current Italian context, Tuscany is one of the regions with the best indicators of quality of care, along with some northern regions.

Let us briefly describe the context in which the story takes place. Tuscany is located in the center of Italy and covers an area of approximately 23,000 km^2, 67% of which is hilly. It is home to about 3.7 million inhabitants and a health service with 33 acute care hospitals of which three are university hospitals in Florence, Pisa, and Siena. Every year about 550,000 people are admitted to public hospitals in Tuscany. Of them, 1500 patients annually claim compensation for alleged harm resulting from treatment received, but only 40% of these citizens will be awarded compensation, amounting to a total of about 40–50 million euros a year.

Healthcare is mainly public and adopts the tax-financed Beveridge model. The cost of public health service is around 7.4 billion euros a year, with a per capita quota of 1981 euros, compared to a national average of 1888 euros per capita [4].

2.2 The Start

In 1989, Scally and Donaldson [5] promoted clinical risk management in the field of clinical governance and, in 1999, the "To err is human" report was published [6]. At the same time, James

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Reason travelled the world making his "Swiss Cheese model" known globally [7], while Charles Vincent published "Clinical risk management: enhancing patient safety" in 2001 [8].

It was precisely in 2001 when the medical director of my hospital brought me the book by Charles Vincent and asked me to take charge of health safety. The reason he proposed this role to me stemmed from my position as manager of a structure that dealt with ergonomics and the human factor in the field of occupational safety, a relevant issue for clinical risk management.

I started working on this topic with some young people from my unit and we grew passionate about it. I was the only doctor, a specialist in occupational health and public health, surrounded by an industrial designer and experts in communication sciences and sociology. The medical director was highly interested in patient safety. We no longer dealt with the latter, except for aspects related to occupational stress and burnout.

We started presenting the Swiss Cheese Model to fellow doctors and nurses, inviting them to promote incident reporting. We stressed the importance of a "no blame" culture to the directors of units, doctors, and nurses, with the support of health management, but our moment of fame came in 2002 when we invited James Reason to Florence. In an auditorium full of doctors and nurses, people began to talk about medical errors, a subject that up until then was untouchable, almost unthinkable. Since forensic medicine was dominant at that time, we wanted to make it clear that our aim was not the pursuit of professional responsibility (i.e., negligence, inexperience, and imprudence), but to learn from error.

Reason concluded his presentation by stating that "we cannot change the human being which by nature is fallible, but we can change working conditions in an attempt to prevent and intercept errors before they cause an adverse event." He also told us that we would still have accidents and that we should learn to manage them, even from the point of view of communication.

A journalist from the most important national television network heard about our Florentine experience and made a report for an important television program in which she showed how doctors discussed their mistakes. In the broadcast, you are presented with a slightly darkened hospital room in which a group of doctors, almost like some secret sect, was discussing adverse events. I believe it was the first significant event audit or confessional meeting filmed for television in Italy.

At that time, the alderman of the Regional Health Service, who participated in the James Reason conference, understood the importance of the subject and launched the establishment of a regional center that would coordinate all the activities for the management of clinical risk and patient safety in Tuscan hospitals. The aim of this center would have been the promotion of a culture of safety, the reporting of adverse events, and learning from adverse events—in a word, our mission. It was announced publicly that one million euros had been raised for the establishment of a regional patient safety center.

2.3 The Evolution of the Patient Safety System

After the James Reason conference, the Tuscany region decided to invest one million euros to organize a center for clinical risk management in an Italian region of 3.7 million inhabitants and 33 acute care hospitals.

I was then in charge of running this center with a budget of only around 600,000 euros for personnel management (the announced investment was therefore somewhat reduced). I of course turned to the operators I already had in my old ergonomic group, 8 young and brilliant technicians chosen on the basis of multidisciplinary skills, and overcame numerous bureaucratic problems that represented the greatest initial operational difficulty—bureaucracy is the greatest enemy of safety.

It is difficult for many to understand the importance of other professional figures in healthcare than traditional doctors, nurses, obstetricians, etc. In Italian healthcare, according to an ancient and outdated conception of professional

skills, there is a health area (i.e., traditional health professions) and a technical-administrative area (i.e., statisticians, computer scientists, sociologists, communicators, jurists, engineers). These areas rarely interact and are often separated both physically (e.g., across different buildings) and intellectually. Teamwork is exclusively linked to common interest in a few topics and to the networking skills of individual operators.

In my opinion, the acquisition of knowledge is difficult when people do not work together. This also applies to primary care and hospital professionals. Opportunities and moments for exchange are needed at least weekly.

I must say that in recent years clinical risk management has brought many professionals closer to each other, due to its multidisciplinary approach. For example, IT professionals are now involved in the ergonomics and usability of computerized medical records, which are frequently sources of error, while psychologists and communication experts are involved in the analysis of adverse events. Each of my collaborators had solid training in ergonomics and the human factor, acquired through master degree programs and academic courses, and therefore skills in accident analysis, communication, highly reliable organization, and resilience. If I had immediately opted for a team of doctors and nurses, the budget would probably not have been enough and we would have spent much more time recruiting new staff. Furthermore, for a healthcare organization, a doctor *contractually* costs more than a sociologist or industrial designer.

As a matter of fact, over time the skills available to the team proved both useful and valid for our work. A center that deals with clinical risk and the complexity of the causes of accidents must include professionals that come from various disciplinary areas besides health [9]. With regard to communication problems (which often cause accidents), organizational problems, and problems associated with the interactions with biomedical, ergonomic, and legal equipment, the professionals in our team were much better prepared than other professionals in their own discipline, precisely thanks to the specific training in human factor and risk management.

A scientific committee consisting of the best medical specialists and nurses in the health service had the function of supporting the center in all the more strictly clinical assistance-related aspects which we would encounter during significant events audit, mortality and morbidity meetings, and the promotion of safety practices.

Working in this multidisciplinary context has been culturally enriching for clinicians and nurses as well as other professional figures, resulting in a continual exchange of knowledge that has favored professional growth.

The headquarters were planned to reside in a building of the most important Tuscan hospital.

2.4 The Network of Clinical Risk Manager

After implementing staff training, a network of professionals (one in each hospital) was needed in order to organize the activity, develop a reporting and learning system, and create a risk management system.

We asked the general managers of each hospital to designate a point person for clinical risk and patient safety. In the beginning, we did not expect specifically trained professional figures but professionals from biomedical, psychosocial, and technical fields with good reputation, credibility, and standing among other clinicians and health professionals. Some choices proved to be right and others not, which is normal.

Over time, I noticed a certain vulnerability of this new professional figure. Although safety is the duty of every healthcare worker and cannot be delegated to a single professional, the risk manager often becomes a scapegoat for many problems. For this reason, they are sometimes replaced not on the basis of professional ability and merit but of loyalty to the general manager.

The selected professionals followed a mandatory university course involving over one hundred hours of training and a 1-week internship in a hospital risk management service. Subsequently, in almost all hospitals, the professionals obtained a risk management unit with collaborators.

For each hospital unit, other doctors or nurses, usually one or two, were then identified as facilitators.

The facilitators were expected to be professionals, usually doctors and nurses, who, in addition to performing their daily work, should have had hours dedicated to promoting clinical audits and mortality and morbidity meetings following adverse events, unsafe actions, and missed accidents.

2.5 Training and Instruction

The training of our gladiators, numbering about 30, took place in collaboration with one of the most prestigious Italian universities, the Sant'Anna School of Advanced Studies in Pisa. The course was very hands-on, including lectures by experts on the subject and many exercises on clinical cases of adverse events and the implementation of safety practices. However, the most beautiful experience of this course was the 1-week internship at various international hospitals.

We took our gladiators to numerous hospitals to show them what actions could be taken to improve patient safety. We visited the hospitals of many cities (such as Berlin, London, Boston, Chicago, Copenhagen, Paris, Valencia, and Amsterdam), comparing the different risk management models adopted. This experience was very useful for the planning of our work [10].

What stood out was that, in most of the hospitals we visited, clinical risk management was entrusted to nurses. The doctors were mainly involved in mortality and morbidity meetings and in research projects almost always conducted in multidisciplinary teams.

In our country, risk management is entrusted to medical personnel with the support of senior nurses, albeit with some rare exceptions. I believe that with regard to competences, it is always necessary to evaluate the context of reference and the functions of units, research, or clinical health. The training topics have gradually changed over time, adapting to emerging needs and to the transformation of the role of the professional.

After the risk managers' first year of work, we realized that the professionals coming from the clinical side performed better than those who had worked in health departments. The reason was essentially that the clinical professionals had a closer relationship with the structures we sought to improve.

Furthermore, the managers of quality and accreditation structures and the managers of clinical risk continued to exist as separate entities. The two roles coincided only in rare cases. For this reason, we identified in each hospital a clinical risk manager (CRM) and a patient safety manager (PSM), thus differentiating the functions [11].

In Italy as well as internationally, care safety and quality management and accreditation have had different stories. While clinical risk management was born in more recent times and has attracted the immediate interest of professionals, quality management and accreditation have never fascinated clinicians because of the excessive bureaucracy and the occasional distance of the procedures proposed by clinical practice from real problems.

Regarding our two professional roles, the CRM is a professional who works on the clinical side and is entrusted with risk management in a department, while the PSM is a doctor, nurse, or non-healthcare professional who operates among the health management staff. Figure 2.1 summarizes the differences between these two lines of operation and the professional figures involved.

Today, following specific training and experience, we can provide a professional certification

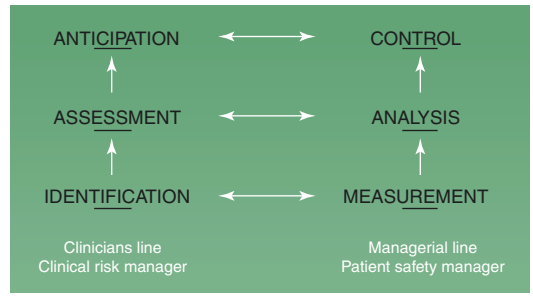

Fig. 2.1 Activities of clinical risk manager and patient safety manager

for this role (clinical risk manager/patient safety manager) in order to enhance their skills and offer more guarantees to insurance system.

The training has substantially contributed to the definition of a risk management model that we have theorized and put into practice over about 15 years.

2.6 Adverse Events

Some of the studies we have conducted in our regional health service [12, 13] did not show higher rates of adverse events compared to other research carried out with similar methodology. Similarly, the claims rate is average compared with other Italian regions.

Our reporting and learning system has clearly lowered the levels of confidentiality thus exposing our health service to the media. Where there is no transparency, it is difficult for serious accidents to emerge as everything is managed confidentially. If significant event audits or mortality and morbidity meetings are organized, news leaks out more easily. Nevertheless, the number of adverse events reported by our operators through our reporting system is always much lower than expected. The expected amount, which is at least 4–5 times higher, was determined from the comparisons we have made with colleagues from other countries where reporting systems have been operating for a longer time.

Under-reporting had been attributable to the fear of judicial consequences until the first of April, 2017, when the law on patient safety and professional liability was instituted. However, in our experience the main cause of under-reporting was the absence of a safety culture (i.e., "I'm not used to reporting, it's just not the way things are done") [14].

The law introduced in 2017 has protected reporting and learning systems from legal action since documents produced within these systems cannot be used for judicial purposes [15]. The development of a clinical risk management system did not completely shelter us from serious accidents but it helped to deepen our understanding of clinical cases with an unexpected outcome.

On February 20, 2007, about 2 years after we started implementing our risk management system, the first important event happened. We had a serious sentinel event that had great media coverage at the national and international levels. It happened in the field of transplant surgery, an area that we mistakenly thought to be fairly safe because it was under the control of national supervisory bodies. Furthermore, it involved an analytical laboratory in which the attention to the procedures of the accreditation and quality system is very high. The case involved the transplantation of two kidneys and a liver from an HIV-positive donor to three patients awaiting transplantation [16].

The event had great resonance but the center, at least in the initial phase, was absolutely not involved in the analysis of what happened. The case was managed by political leaders only and exclusively at a communicative level. It was announced that the cause was human error of an operator who had erroneously transcribed the machine data for serological examinations in the report.

Instead of a culture of learning based on the discussion of organizational problems that can determine the occurrence of significant events, a culture of guilt had prevailed. A culprit was immediately found; the rotten apple was removed from the bunch.

Subsequent analyses conducted by various national and regional committees have shown that in those working conditions any human being could have made mistakes. In this case, that human being was a good and honest biologist, the only one to bear the blame for what had happened. In organizing the task, the human factor had not been taken into account. A "traditional" way of working continued to prevail in which a human being rather than a machine had to perform a monotonous and repetitive job, reporting serological examination results.

It was therefore decided that each of these patients would be rewarded with a very high compensation. It was a decision that served to stop the controversy around the event: the news disappeared from the media in a few days.

As head of clinical risk management, I was determined to resign. After this serious event, I felt it was my duty, even if we had not yet intervened in the transplant system precisely because it was a sector with its own autonomy. I was asked to investigate what had happened. The results of the investigation we conducted brought about many changes, highlighting several critical issues in the transplant system. Donations had increased too quickly compared to the system's ability to meet operational needs.

It was one of the many cases in which I realized that legal truth is not always consistent with "true truth."

With regard to sentinel events, the biggest problem was overcoming the strong desire of politicians and general managers to look for a culprit (culture of guilt) in order to focus their attention on preventing the recurrence of such an event (no-blame culture).

When a serious accident occurs, the citizens want a culprit even if the time taken by justice is much longer than that of the clinical risk manager, whose first goal is to secure the hospital and provide psychological support for the victims of event, both the first victim, the patient, and the second victim, the professional.

2.7 The First Results

We had our first results when we started disseminating all the good safety practices that research had developed in the meantime: introduction of hand hygiene gels, checklists for operating theaters, prevention of postpartum hemorrhage, prevention of thromboembolic complications, bundles for the prevention of CVC infections, etc. Since, more than 30 safety practices have been developed in collaboration with clinicians. The greatest difficulty was the differences in implementation capacity, which depend little on the clinical risk manager. Much depends on the environmental context and on how much importance the general manager gives to safety and quality of care. The best results concerned those hospitals in which management executives gave great importance to the patient safety.

Unfortunately, some general managers were very far removed from the basic principles of clinical risk management. They were only interested in the economic costs and the volume of activity, not value of care.

Obviously, politics has considerable weight and responsibility in imprinting certain behaviors in general managers. Although training has been introduced in management courses, it has never been enough to change the externally ingrained behaviors nor the behaviors guided by the nature of the employees themselves.

Overall, we can affirm that some important successes have been achieved. At an organizational level, we have been equipped for years with a reporting and learning system that is a credit to our organization. There has been a reduction in the number of accidents and falls in the hospital, the latter being the most frequent cause of damage reports. According to third-party data, we are the Italian region with the lowest rate of maternal mortality and mortality in intensive care. Attention to infections has increased even if their rate continues to be high. Much more could and should be done.

2.8 The Relationship with Politics and Managers

Politicians, obviously with some exceptions, have rarely shown interest in the many national and international events we have organized. I realized over time that the topic of patient safety does not excite politicians. The reason is simple: talking about mistakes, the criticalities of a health system, and litigation has no electoral value. It is much more politically profitable to talk about robotic surgery, transplants, technological innovation, and opening up new health services. Even if it is clear from the data that in the last 15 years we have saved money and above all human lives thanks to clinical risk management, politics has always preferred other topics. On the other hand, it is true that patient safety is an electoral campaign theme that can be used to denigrate the political opponent. In fact, whenever elections approached, newspaper headlines about "mal-

practice" poured in to instrumentally demonstrate the inefficiency of the health service.

One of the critical issues that has arisen in recent years is the lack of autonomy of the center with respect to political apparatus and hospital managers. The regional bodies of clinical government that deal with the safety of care, such as the Tuscan GRC center, must have their own operational and budgetary autonomy. These are technical-scientific bodies that cannot depend directly on the political and administrative government. The model of government agencies should be adopted, guaranteeing these bodies a third-party nature and independence, precisely because of the importance of their role.

Despite the unanimous approval of a specific request by the regional council [17], the regional executive committee has never given autonomy to the center.

As operators, we have always remained administratively dependent on the hospital from which we came. This hospital was one of the structures subjected to evaluation by the regional apparatus and therefore by our center. This obviously led to a clear conflict of interests and consequent management difficulties due to the desire of some managers to influence the activities of the center.

Currently, the Italian law for safety of care foresees in every Italian region the presence of centers for the management of healthcare-associated risk and patient safety. However, the law does not provide precise indications on their administrative location and level of independence. None of these structures has total autonomy, being administrated by regional apparatuses or managed by personnel employed by hospitals.

Patient safety has never been a topic of pride for politicians even when the results were good. Politicians prefer to maintain an attitude of "understatement" on this issue. There is the awareness that at any time a serious accident can occur and this could be exploited by the opposition against the current administration. It is therefore preferable to promote the "positive" aspects of the health service such as the opening of a new structure, the purchase of new equipment, and the hiring of doctors. Although patient safety is one of the eight domains of healthcare risk management [18], its real importance has not yet been understood (Fig. 2.2).

Another crucial aspect involving the risk manager relates to the culture of guilt facilitated by hindsight bias. Those who do not subscribe to a culture of safety and sometimes even great clinicians often fall into this trap of judging the past based on new knowledge of the facts. In our country, in the event of a serious accident, people immediately want a culprit even when events may have complex causes. In some of the serious accidents in the health service that I investigated, the identification of a culprit and the communication to the public that the cause was due to human error generally reduced the clamor produced by the media. Stating that the problem is the responsibility of a single person and not a structural or organizational problem calms public opinion and is therefore a functional strategy for the system. Even before knowing the facts, we start to attribute the responsibility and the blame most often

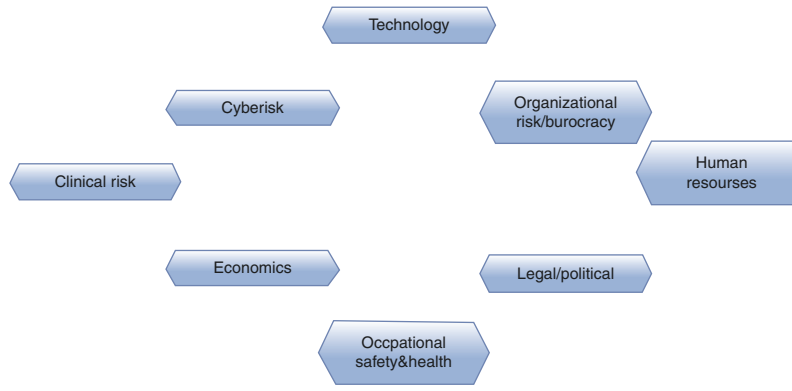

Fig. 2.2 Areas of risk in healthcare management

Table 2.1 Differences between human factors and forensic investigations

Type of investigation	Forensic	Human factors/ergonomics
Ownership	Judicial Authority	Clinical Governance Institution
Aim	Ascertain illegal actsFinding criminals	Redesign system interactions to improving safety
Approach	Focus on individual performance (contractual relationship)	Focus on system awareness (organizational context)
Investigation team	Police detectives, coroner, clinicians (team leader with expertise in forensics)	Experts in HF/E: clinicians, psychologists (team leader with expertise in HF/E)
Investigation methods and tools	Police interrogations, recorded interviews, surveillance	Meetings with healthcare professionals based on the systemic analysis
Outcomes	Preliminary investigation report with evidence of individual culpability	Confidential report of contributory factors and recommendation for improving patient safety
Time scale	In keeping with forensic procedures, investigation, debate, and court judgment (years)	In keeping with healthcare organization activities and needs (days/months)
Resulting actions	Judgment in a court of law and sentencing (individual-oriented)	Implementation of improvement actions and learning-focused patient safety measures (system-oriented)

to the individual, rarely to management, and hardly ever to politics.

I have noticed this attitude in numerous cases where even the most evident responsibilities of the political-administrative system were not brought under scrutiny (e.g., lack of personnel, technological criticalities, training criticalities).

Another important aspect is the general managers' understanding of the need to maintain the two lines of action separate in the management of sentinel events. We have repeatedly theorized that the first goal of a risk manager when an accident occurs is to analyze what has happened and quickly introduce prevention measures to secure the system. It is therefore necessary to initiate clinical audits, mortality and morbidity meetings, and root cause analysis.

The search for responsibility is generally the duty of the investigating judiciary or other administrative bodies whose purpose is to identify the judicial and administrative responsibilities.

It is therefore advisable that the risk manager is not involved in investigations aimed at identifying responsibilities. It is also advisable not to make the documentation produced within the reporting and learning systems available to lawyers or judges in order to identify the responsibilities. Exceptions are obviously cases involving malice, that is, intention to cause damage on the part of the professional.

In my experience, I have been in interesting situations in which we, as clinical risk operators, have investigated the same event together with the police. Table 2.1 shows some differences that emerged from a careful analysis of the facts [19].

As I once heard from John Ovretveit in his beautiful lecture in Florence, the successful improvement of patient safety depends only 10% on the clinical risk manager and slightly more (20%) on "safety practices" which must be based in strong scientific evidence. 40% of the success is derived from the cultural landscape in which the practices are disseminated but, above all, 60% is grounded in the climate created by the corporate establishment that favors the achievement of greater safety of care, rewarding and celebrating quality.

2.9 The Italian Law on the Safety of Care

Fourteen years after the birth of the center that I directed, the Italian law on the safety of care was promulgated. Some important international magazines have covered the contents [15, 20].

The law is due to two Italian medical parliamentarians, Federico Gelli and Amedeo Bianco and it is titled "Provisions for care safety and professional responsibility." It has introduced impor-

tant changes which have provided strength to all those working in the field of clinical risk management.

It has created specific clinical risk management centers in each Italian region with the aim of collecting data on adverse events and promoting best safety practices. It has also protected reporting and learning systems by preventing the use of the internally produced documents for judicial purposes. This law also provides specific training for those who decide to become clinical risk managers in hospitals. The professional certification system implemented in our country is giving further value to this professional role. Finally, it has provided regulation for scientific societies around the generation of guidelines and recommendations for safety of care. It is not yet clear whether hospitals can become "highly reliable organizations" [21] but this law could contribute thanks to the changes it produces.

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