The Clinical Risk Management in a Hospital Ward: a Case-Study adopting System Dynamics Approach

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1. Introduction

In recent years, the attention to medical errors increasing due to a higher patients awareness about their rights and the importance attributed by health care companies to the quality of their services. In the context this growing importance it became essential to define patient safety. Even though the Institute of Medicine IOM defined patient safety as "the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare" there is not yet a full acceptance of this definition by all healthcare organizations because of the strong distinction, implemented in healthcare organizations, between quality and safety. To overcome this barrier it is useful to adopt the patient safety definition provided by Emanuel and Berwick[1]: "patient safety is a discipline in the healthcare sector that applies safety science methods toward the goal of achieving a trustworthy system of healthcare delivery. Patient safety is also an attribute of healthcare systems; it minimizes the incidence and impact of, and maximizes recovery from, adverse events."

In Italy, as happened in the rest of the world, the attention to the problem of error in medicine shown a renewed interest after the publication of the report "To Err Is Human" by the Institute of Medicine (Kohn et al. 1999). After this important document, the scientific research in the field started to expand and new frontiers in the study of clinical errors have been opened. The change of vision generated by this research has "humanized" the professionals working in the health care system, and has changed the concept of medical errors being no longer considered as a reason for punishing the guilty yet as a reason for learning from the errors at the level of the whole organization.

The clinical risk refers to the probability that a patient suffers damage during the delivery of healthcare services. In order to allow a clear understanding of the phenomenon, it is useful to define some Clinical risk management (CRM) key-concepts on the base of the indication provided by the Joint Commission[2]:

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[1] K. Henriksen, et al., Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 1: Assessment). Rockville (MD): Agency for Healthcare Research and Quality, 2008.

[2] The Joint Commission is an independent not-for-profit organization that accredits and certifies more than 20,000 healthcare organizations and programs in the United States. It is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards. The stated mission is: "To continuously improve healthcare for the public, in collaboration with other stakeholders, by evaluating healthcare organizations and inspiring them to excel in providing safe and effective care of the highest quality and value"[2]. Joint Commission International is also one of the most important organization providing international healthcare accreditation services to hospitals around the world.

- **sentinel event** is any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient, not related to the natural course of the patient's illness. Such events are called “sentinel” because they signal the need for immediate investigation and response. The terms “sentinel event” and “error” are not synonymous; not all sentinel events occur because of an error, and not all errors result in sentinel events. Sentinel events are 16 and they were been defined by the Joint Commission (table 1).
- **adverse event** is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.
- **near miss** is a situation which could cause an adverse event for the patient (for example, a fall avoided by the intervention of a nurse).
- **no harm event** is an event that had the potential to result in harm to the patient (such as falling without patient outcomes).

	Different types of sentinel events
1	Procedure on wrong patient
2	Procedure on wrong site
3	Wrong procedure in correct patient
4	Unintended retention of foreign object in a patient
5	Hemolytic blood transfusion reaction resulting from ABO incompatibility
6	Medication error leading to the death of patient reasonably believed to be due to incorrect drugs administration
7	Maternal death or serious morbidity associated with labor or delivery
8	Death or permanent disability in healthy newborn weight more than 2500g
9	Death or serious injury as a result of patient fall
10	Suicide or attempted suicide of a patient
11	Rape or assault of patient
12	Rape or assault of staff member
13	Death or serious injury as a result of intra-and extra-hospital carriage
14	Death or serious injury due to improper triage assignment
15	Death or serious injury as a result of surgery
16	Any other adverse event that cause death or serious injury

Table 1. Sentinel events

2. Literature Review

Thirty years ago medical errors weren’t even mentioned in medical literature. In 1994 Leape published a paper about the question of medical errors[3]. In this work, the author underlined that error rates in medicine were particularly high and that the healthcare companies had not take into account it properly, as other safety critical industries had. He argued that the solution to the medical errors’ problems did not lie in medicine but in different field as a psychology and human factors. Many errors are beyond the human’s conscious control so error prevention that relies

[3] Leape LL. (1994). Error in medicine. Journal of the American Medical Association, 272(23):1851-7

exclusively on discipline and training is doomed to failure. For this reason he focused his attention on the way to change or improve the work condition than the personnel training.
In the year 2000[4] Reason re-published a paper of 1990[5] about error management, which addressed the medical error's issue from a new perspective. Following the theoretical framework of Reason (2000), the human error problem can be viewed in two ways: the person approach and the system approach. Each model of error refers to different views of error's etiology and management. The person approach focuses on the unsafe acts (errors and procedural violations) of people at the sharp end, arising from deviant mental processes (forgetfulness, inattention, poor motivation etc.). Their management is aimed at reducing undesired variability in human behavior. According to Reason, "followers of this approach tend to treat errors as moral issues, assuming that bad things happen to bad people" (Reason, 2000). The system approach refers to the concept that errors can occur even in the best organizations because of the fallibility of people. The errors management is based on the assumption that although "we cannot change the human condition, we can change the conditions under which humans work" (Reason, 2000).

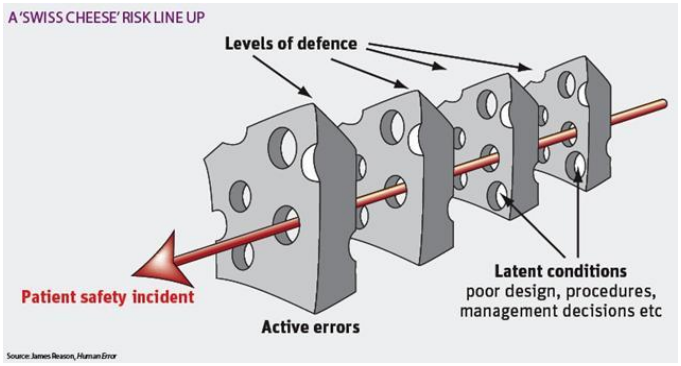


Figure 1. The "*Swiss cheese"* model, Reason The human error, 2000.

A central role, in the system approach, is occupied by defenses and barriers of the organization. In an ideal and desired condition, each defensive barrier would be intact, however, in real life, they were more likely to be slices of "*Swiss cheese"* (figure 1) with many holes constantly moving, opening and shutting. As Reason said: "the presence of holes in any one "slice" does not normally cause a bad outcome. Usually, this can happen only when the holes in many layers momentarily line up to permit a trajectory of accident opportunity bringing hazards into damaging contact with victims" (Reason, 2000). The Swiss cheese model represents a metaphor of the trajectory of an accident which gives us the sense of hazard being ever present and occasionally breaking through when all the holes in the Swiss Cheese line up. In the light of these studies, a healthcare organization can be considered as a complex system, inside which it is possible to trace the various interconnected sub-systems.

[4] Reason, J. (2000). Human error: models and management. *BMJ , 320*, 768-770.
[5] *Reason, James (1990): Human Error. New York, NY, Cambridge University Press.*

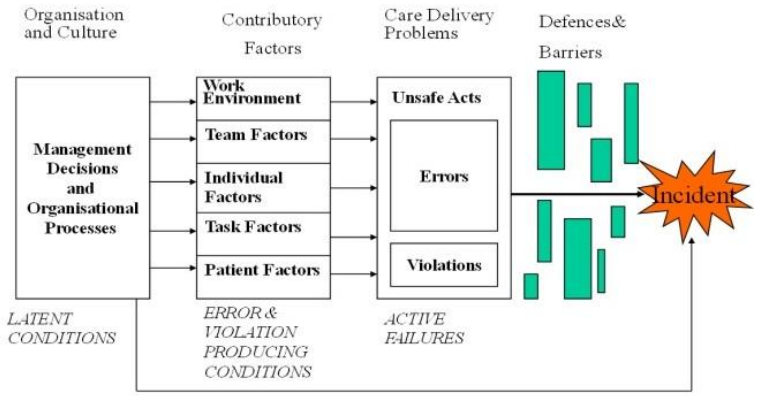


Figure 2. Organizational accident model (Reason 2000)

Through the work of Reason, the evolution of error has gone from an individual perspective to a system view. In the individual perspective, the efforts to reduce the errors are centered on people and are based on the encouragement to "do better" (upgrading or adding new rules or procedures). The prevailing culture is the “blame culture”. In the systemic perspective, errors and human behavior cannot be understood in isolation, but only in relation to the context in which people work. Many of the errors need to be considered from this broad system approach to be managed and Reason provides an efficient organizational accident model (figure 2) to describe the immediate errors and problems and the background latent conditions.

Vincent (1998), by using the system approach provided by Reason (1990), has studied the role of human factors in the generation of an adverse outcome in healthcare. The term human factors can be defined in several ways but, a widely accepted definition is that of the Health and Safety Executive: “Human factors refer to environmental, organizational and job factors, and human and individual characteristics which influence behavior at work in a way which can affect health and safety. A simple way to view human factors is to think about three aspects: the job, the individual and the organization and how they impact on people’s health and safety-related behavior.” (HSE, 1999).

In reference to the human factors that can influence clinical practice and can contribute to the generation of the adverse outcome, Vincent (1998) identifies 7 main framework and their relative contributory factors (table 2).

Framework	Contributory Factors	Examples of Problems That Contribute to Errors
Institutional	Regulatory context Medico-legal environment National Health Service Executive	Insufficient priority given by regulators to safety issues; Legal pressures against open discussion, preventing the opportunity to learn from adverse events
Organization and management	Financial resources and constraints Policy standards and goals Safety culture and priorities	Lack of awareness of safety issues on the part of senior management; Policies leading to inadequate staffing levels

Work environment	Staffing levels and mix of skills Patterns in workload and shift Design, availability, and maintenance of equipment Administrative and managerial support	Heavy workloads, leading to fatigue; Limited access to essential equipment; Inadequate administrative support, leading to reduced time with patients
Team	Verbal communication Written communication Supervision and willingness to seek help Team leadership	Poor supervision of junior staff; Poor communication among different professions; Unwillingness of junior staff to seek assistance
Individual staff Member	Knowledge and skills Motivation and attitude Physical and mental health	Lack of knowledge or experience; Long-term fatigue and stress
Task	Availability and use of protocols Availability and accuracy of test results	Unavailability of test results or delay in obtaining them; Lack of clear protocols and guidelines
Patient	Complexity and seriousness of condition Language and communication Personality and social factors	Distress; Language barriers between patients and caregivers

Table 2. Framework of Factors Influencing Clinical Practice and Contributing to Adverse Events (Vincent et al., 1998)

In this hierarchy of factors, patients and staff as individuals are at the front-end (bottom) of the factors, team factors and working conditions in the middle, and organizational/institutional factors at the top.

- Patient framework: the patient's condition has the most direct influence on practice and outcome, moreover patients have a key role to play in helping to reach an accurate diagnosis, in deciding about appropriate treatment, in choosing an experienced and safe provider, in ensuring that treatment is appropriately administered, monitored and adhered to, and in identifying adverse events and taking appropriate action. Other patient factors that may influence the communication with the staff and hence the clinical practice are patient's language and personality.
- Task framework: this framework refers to the procedures to implement in order to ensure the correct dispensing of healthcare. We have to take into account the availability and use of protocols and their lack of clarity as key factors to affect the quality of care and in the generation of adverse outcome.
- Individual staff member framework: several individual factors may influence the clinical practice such as personality, knowledge, experience, and training. Other factors related to staff concern the physical and mental health. These last factors may be damaged by work stress and burn out, two problems strongly associated with healthcare contexts.
- Team framework: each member of the staff is part of a team, and his performance may be influenced by other members, and how they are organized, and how they support, supervise, monitor, and communicate with each other.
- Work environment framework: factors related to the work environment may include staffing levels and mix of skills, patterns in workload and shift, design, availability, and maintenance of equipment. There is a growing evidence base from healthcare architecture, interior design, and environmental and human factors engineering that supports the assertion that safety and quality of care can be designed into the physical construction of facilities.
- Organizational and management framework: organizational factors are omnipresent, but difficult to quantify (organizational climate, group norms, morale, authority gradients, local

practices) that often go unrecognized by individuals because they are so deeply immersed in them. However, over time these factors are sure to have their impact and the system performance. Management factors refer to the way in which the organization is handled such as financial resources and constraints and policy standards and goals.

- Institutional framework: the institutional framework influences patient safety and quality of care by shaping the context in which care is provided. It refers to the economic and regulatory context, and to the National Health Service Executive.

The seven levels framework has outlined the patient, task and technology, staff, team, working environment, organizational and institutional environmental factors that are revealed in analyses of incidents. These same factors also point to the means of intervention and to the different levels on which safety and quality must be addressed.

3. Traditional CRM's method and their pitfalls

CRM is an approach for improving the quality and safe delivery of healthcare. This can be accomplished by placing special emphasis on identifying conditions that put patients at risk, and by establishing mechanisms to minimize or prevent these risks.

In order to reduce the incidence of the clinical risk and to improve the quality of the cares, in the healthcare sector have been imported risk management methods successfully applied in other sectors. The most widespread methods are:

a) Root Cause Analysis,
b) Clinical Audit,
c) Incident Reporting.

All these methods, although useful in the identification of risk probability and assessing the potential effects of the occurrence of adverse events, do not support the management of healthcare organizations in the identification and evaluation of risk management policies because they are based on an linear analysis of the system and the relationships between business processes. In particular, the shortcomings of those methods are:

- They don't take into account the feedback structure of the net of causality that links each other the variables of the healthcare system;
- They are static**,** namely they ignore delays normally existing between the triggering of the cause and the occurrence of the related error and, consequently, they are not suitable to simulate future trends;
- They don't consider the interactions between the different risks;
- They are inadequate in helping healthcare companies in setting safety targets and evaluating safety performance improvement on a quantitative basis;
- They don't properly support the healthcare companies' management in the identification and assessment of policies aimed at improving the clinical risk profile.
- They don't take into consideration the costs and their effect on the organizations management.

For these reasons, all these methods are inadequate in helping healthcare companies in setting safety targets and evaluating safety performance improvements. Therefore, it is possible that a hospital does not invest in clinical risk reduction because of the costs and of "heaviness" of the operational procedures in such investment. This happens because of the lack of understanding and/or of 'inability to assess the benefits that investments in clinical risk reduction produce. In fact, where these methods have been considered often they have not had a real application, because healthcare organizations have been limited to a formal implementation of these procedures, but

this has resulted in a substantial improvement in the approach of clinical risk management. Therefore, it is necessary that healthcare companies perceive that an improvement in the risk profile often results in a considerable saving on insurance policies, on the cost for claims and on the costs of “non-quality” and “safety”. In addition, by reducing the clinical risk, the healthcare companies get a better image and, therefore, an increase in their competitiveness. Therefore, it is necessary to adopt a systemic and multi-dimensional approach that allows healthcare companies’ managements to properly evaluate the effects of CRM policies on organizations’ performance, both in the short and medium long term.

4. System dynamics as a new powerful method to deal with the clinical risk

Despite the relative newness of the adoption of the SD methodology in the CRM field different examples of applications of the system dynamics approach to the healthcare sector have been reported in the literature. The system dynamics literature on this topic can be classified into two groups: those that deal with specific diseases and those that deal with broader policy and management concerns. Literature focusing on diseases includes: Oral Health (Hirsch et al., 1975); Cardiovascular Disease (Hirsch and Myers,1975 & Luginbuhl et al., 1981); Diabetes (Homer et al., 2004 & Jones et al., 2006); Obesity (Homer et al., 2006); and chronic illnesses more generally (Hirsch and Immediato, 1999). Literature focusing on management includes: EHIR Adoption (Erdil & Emerson, 2008); Patient flow (Wolstenholme, 1999); Safe Design Capacity (Wolstenholme et al, 2007); and Waiting Lists (Van Ackere and Smith 1999)[6].
According to Homer and Hirsch “a central tenet of system dynamics is that the complex behaviors of organizational and social systems are the result of ongoing accumulations (of people, material or financial assets, information, or even biological or psychological states) and both balancing and reinforcing feedback mechanisms” (Homer and Hirsch 2006). System dynamics uniquely offers the practical application of these concepts in the form of computerized models in which alternative policies and scenarios can be tested in a systematic way that answer both "what if” and “why”. Such models support the healthcare management in properly evaluating the effects of CRM policies on organization performance, both in short and medium-long term.

5. Case-study: the ward of obstetrics and gynecology in Italian Hospital

The research was carried out in a public hospital placed in a little town near to Palermo (the capital of Sicily Region), which serves approximately a population of 35.000 people (some macro-variables of the hospital and the operational unit involved in the research are shown in the table3). The hospital is part of the ASP6 Palermo that represents the Provincial body for Health Services, an entity as provided by law that is responsible to manage and coordinate the services and public health activities for the whole province. In particular it was decided to concentrate the research in a specific operational unit: the ward of obstetrics and gynecology.

[6]Goldsmith D., Siegel M. (2011) Improving Health Care Management Through the Use of Dynamic Simulation Modeling and Health Information Systems. System Dynamics conferences 2011 proceed papers.

MACROVARIABLES	HOSPITAL	OBSTETRICS AND GYNECOLOGY WARD
BEDS	87 ORDINARY 18 DAY HOSPITAL	12 ORDINARY 2 DAY HOSPITAL
EMPLOYEES	291 (85 DOCTORS, 154 NURSES, 21 OSS, 2 OTA, 8 AUXILIARY, 21 TECNICS)	33 (10 DOCTORS, 10 OBSTETRICIANS, 12 NURSES, 1 OSS)
AVERAGE PATIENTS PER YEAR	4124 IN 2011 4238 IN 2012 4025 IN 2013	720 IN 2011 914 IN 2012 773 IN 2013
RISK MANAGER	YES	YES
SYSTEM OF COMPLAINS MANAGEMENT	YES	YES
INCIDENT REPORT	32 (2011) 29 (2012) 14 (2013)	16 (2011) 1 (2012) 1 (2013)
CLAIMS	11 (2011) 37 (2012) 23 (2013)	2 (2011) 4 (2012) 2 (2013)
SENTINEL EVENTS	1 (2011) 1 (2012) 0 (2013)	0 (2011) 1 (2012) 0 (2013)

Table3. Hospital and obstetrics and gynecology ward macro-variables

The choice is motivated by the high risk level of the operational unit at issue, and by the high emotional involvement that the ward of obstetrics and gynecology involves, activating social, ethical and emotional values, extremely important as they concern motherhood and the newborn. Moreover it was decided to focus just on the obstetric and gynecology ward and not on its outpatient clinic. The reason is primary the following: the possibility of errors occurrence in a outpatient clinic (sentinel, near miss or no harm event) is low because of the service characteristics (there are no drug administration, no surgery, no blood transfusions in a outpatient clinic and so on).

5.1 Objective of the study

The objective of the research is to investigate the relationship between the patient safety culture in the hospital's ward and various types of adverse outcome in the clinical practice. The hypothesis is that a safety culture assessment represents a tool for improving patient safety. While a variety of levers (clinical training and guidelines, information technology, organizational structures and industry regulations) are being pushed in healthcare organizations to improve patient safety, the belief is growing that an institution's ability to avoid harm will be realized only when it is able to create a culture of safety among its staff. Safety culture is a performance shaping factor that guides the many discretionary behaviors of healthcare professionals toward viewing patient safety as one of their highest priorities[7]. In order to transform culture it is important to first understand and confront it, to do this a questionnaire was administered to the whole ward's population. The choice questionnaire is the "*Hospital Survey on Patient Safety Culture*" (Nieva, Sorra, 2003).
By using a simulation model we want to test the weight that the patient safety culture has in the generation of adverse events in order to identify the best policy able to achieve the optimal trade-off between cost and benefit.

[7] Nieva V.F., Sorra J. (2003) Safety culture assessment: a tool for improving patient safety in healthcare organizations. Qual Saf Health Care2003;12(Suppl II):ii17–ii23

5.2 Research methodology

5.2.1 Exploring the CRM procedures in the hospital

In order to explore the CRM procedures in the hospital three semi-structured interviews were administered to the main hospital's key actors of risk management: the ASP risk manager, the operational unit referent for clinical risk, and the responsible of midwife's nursing care.
The hospital is part of the ASP6 Palermo that represents the Provincial body for Health Services, an entity as provided by law that is responsible to manage and coordinate the services and public health activities for the whole province. Inside ASP6 is planned a risk management operational unit aims to organize the hospitals clinical risk management according to the guidelines, it has implemented a system clinical risk management which requires the involvement of Hospitals and individual wards (1 ASP risk manager, 5 risk management medical directors one for each ASP hospital, 41 health workers one for each ward of the five ASP hospitals).
Over the past years three different training courses on the clinical risk management have been performed. The first training course was addressed to the 41 operational unit referents for clinical risk, the second was addressed to nurses. Both training courses focused about the diffusion of a patient safety culture in order to improve the staff participation in the clinical risk management. The third training course was addressed to nurses, it was about the management procedures and transmission of incident reporting and prevention of patient's falls.
The Ministry of Labor, Health and Social Policy in 2010 has set up a data stream, the Information System for Monitoring Errors in Healthcare SIMES, with the aim of detect information relating to sentinel events and claims. SIMES data stream it is composed of three different forms to be filled: form A, form B and form 3 claims. The health care worker involved in the adverse event, fills and submits the form A with the operational unit referents for clinical risk to the risk management medical directors of the hospital within three days. The risk management medical directors with the ASP risk manager immediately starts a preliminary analysis to determine if the event meets the criteria to be called a sentinel event. In the case where the event is defined sentinel event he transmits the data to the Ministry of Health. Within seven days from the date of the event is set up an internal committee shall carry out a Root Causes Analysis and defines any improvement measures. The risk management medical directors and the ASP risk manager in the light of the results of the committee fill out and submit, no later than forty-five days from the date of the event, the form B to the Ministry of Health.
In addition to the SIMES data stream other sources of data collecting were activated in the ASP6: spontaneous reporting of adverse events, near miss and no harm event (Incident Report), monitoring implementation of the Joint Commission International standards and Ministry recommendations. These streams are inserted in a database. However the Incident Reporting, just because spontaneous, it is not always able to keep track of all near misses and no harm events that occur in the organization. With regard to the third category of events reported by the incident report namely adverse events, they are usually associated with claims because they are related to events occurred and not to not happened events (near miss) or events with no harm for the patient (no harm events).
However this way to manage the clinical risk at ASP6 is quite new, it was introduced in 2011, for this reasons we have no data before 2011 and moreover, for this reason we have not a shared patient safety culture among the hospital staff, the culture needs time to become part of the work routine. Due to this recent CRM practice adoption we have no a complete track of error occurred, as we can see from hospital data just few events were reported to the management during this last three years (see table3).

5.2.2 Exploring the professional staff's CRM culture in the hospital

A questionnaire was administer to the whole personnel of the ward (10 doctors, 10 obstetricians, 12 nurses and 1 OSS), in order to explore the perception about the patient safety culture and clinical risk in the hospital. Responses were voluntary and no personal information was collected to avoid fear of respondents' identification. Twenty-seven of the thirty-three questionnaires administered were completed and returned. The chosen questionnaire is the "*Hospital Survey on Patient Safety Culture*" Nieva, Sorra, 2003 (see annex 2). The questionnaire is focused on patient safety issue and on error and event reporting. The dimensions investigated by the questionnaire are:

Seven unit-level aspects of safety culture:

- Supervisor/Manager Expectations & Actions Promoting Safety (4 items),
- Organizational Learning—Continuous Improvement (3 items),
- Teamwork Within Units (4 items),
- Communication Openness (3 items),
- Feedback and Communication About Error (3 items),
- Non-punitive Response to Error (3 items), and
- Staffing (4 items).

Three hospital-level aspects of safety culture:

- Hospital Management Support for Patient Safety (3 items),
- Teamwork Across Hospital Units (4 items), and
- Hospital Handoffs and Transitions (4 items).

Four outcome variables:

- Overall Perceptions of Safety (4 items),
- Frequency of Event Reporting (3 items),
- Patient Safety Grade (of the Hospital Unit) (1 item), and
- Number of Events Reported (1 item).

The Hospital Survey on Patient Safety Culture (Hospital SOPS) was originally developed, pilot-tested and revised in the USA and then released by the Agency of Healthcare Research and Quality (AHRQ). The survey was designed to assess opinions of hospital staff about patient safety issues, medical error and event reporting and includes 42 items measuring the above mentioned 12 dimensions of patient safety culture. Respondents are asked to rate each item of a dimension on a five-point likert scale of agreement (strongly disagree, disagree, neutral, agree and strongly agree) or frequency (never, rarely, sometimes, most of the time, always). The survey includes two questions asking respondents to provide an overall grade on patient safety for their work area/unit and to indicate the number of events they have reported over the past 12 months. Respondents are asked to provide limited background information about themselves.

5.2.3 Designing the causal loop diagram (CLD) and built the Stock and Flow Model

A section of group model building GMB with the three main hospital's key actors of risk management was used to collect data for the Causal Loop Diagram CLD. The GMB represents the first step in the system dynamics modeling process, allowing to create a shared view of the problem among the key stakeholders. Following Vennix et al. (1992), three main tasks were performed by modelers to generate the CLD: elicitation of information, exploring courses of action or convergent tasks, and evaluation. The main output of the GMB sessions is the CLD, a document

that describes the causal relationship between the key-variables of the healthcare company involved in this study, in order to understand their role in the etiology of the adverse event.
The CLD was the starting point to build a Stock and Flow Model, in order to test the impact of different policies on ward's performance. The model was built using Powersim Studio 7.0.

6. Results

6.1 Commentaries from questionnaire

The data collected in the questionnaire allowed to identify the perception of the personnel about the issue of clinical risk management. The data analysis was performed by SPSS 16.0, and it was analyzed the correlation (r di Pearson) between the different dimensions (annex1 correlations). Moreover the collected data have allowed to determine the overall patient safety index (66,54%) by calculating the scale means.

6.2 The causal loop diagram

The data collected with the group model building session allowed to identify some of the main cause-effect relationships characterizing the organizations system. As showed in the causal loop diagram (figure 3), the high number of *patients* is related to a high number of *treatments*. The law of large numbers tells us that a higher number of *treatments* determine a rise in the number of *adverse events* due to clinical errors. The high number of *adverse events* cause an increase in *claims* that are related to a loss of *image*. The loss of *image* has a return in term of loss of *patients* (loopB1).

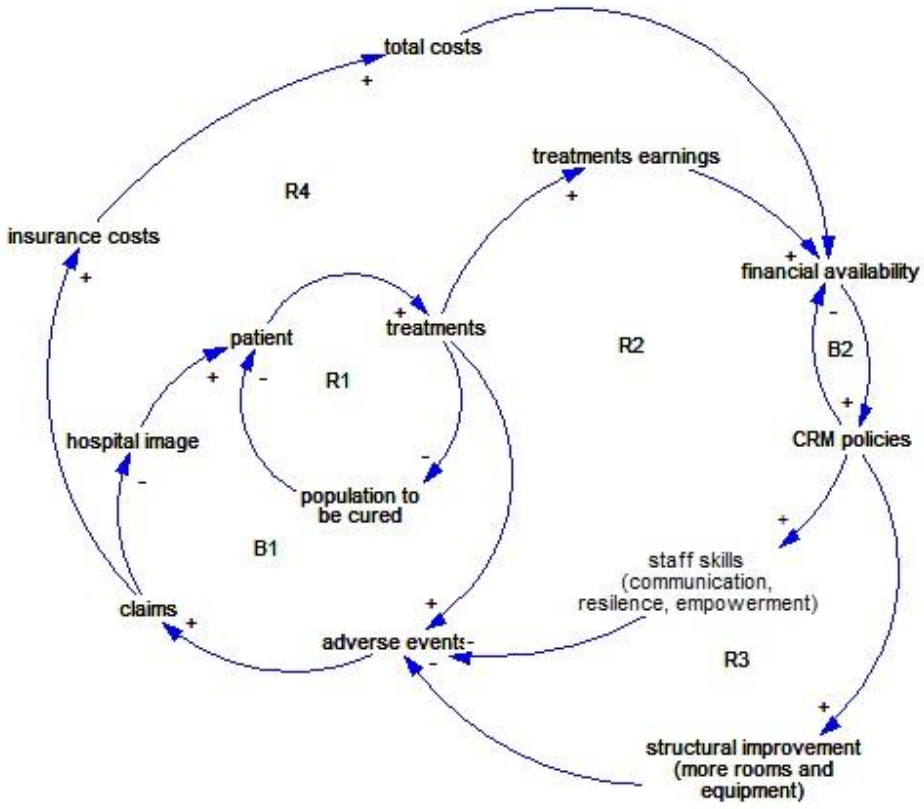


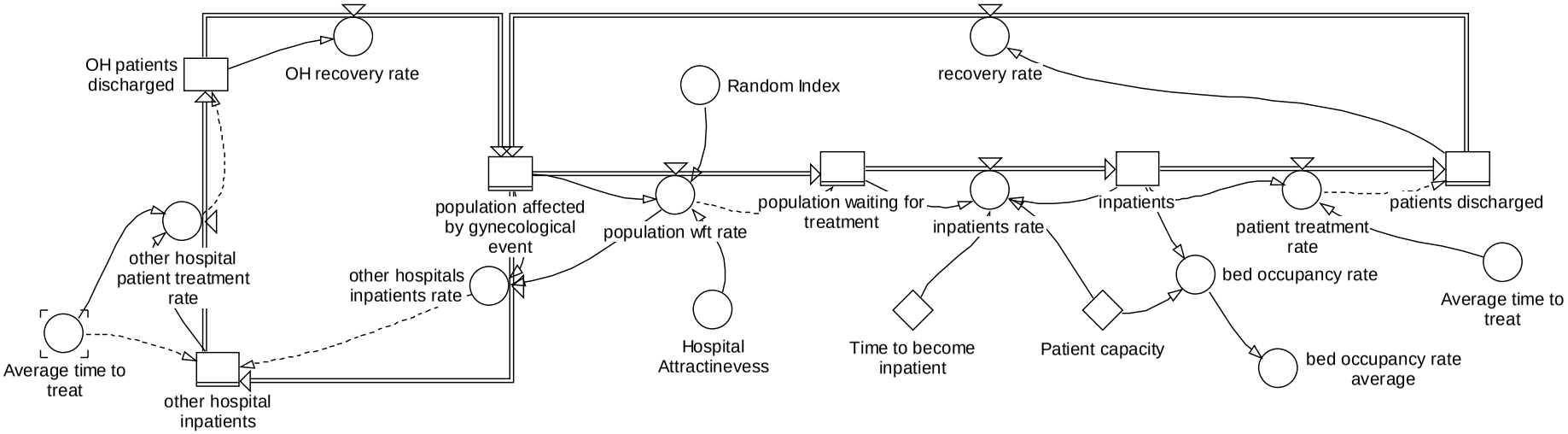
Figure 3. The Causal Loop Diagram

Nevertheless, when the number of *treatments* increases, there is an increase in *treatments earnings* and consequently in the *financial availability*. In this way the health care company has more money to invest in *CRM policies*. It is logical that the *CRM policies* reduce the *financial availability* (loopB2). However *CRM policies* should improve some *staff skills* (such as communication), or they should activate some *structural improvement* (more rooms and equipments, computerized medical records), in order to reduce the number of *adverse events* and the number of *claims*, with a positive effect on the *hospital image* and consequently in the number of *patients* and *treatments* (loopR2 and loopR3). A reduction in the number of *adverse events* causes a reduction of *claims*. In this way the *costs* related to insurance and compensations claims and hence the *total costs* are reduced. This reduction has a positive effect on the *financial availability* and so in the possibility to invest more *in CRM policies* with a further reduction of *adverse events* (loopR4).

6.3 The Stock and Flow Model

Based on the CLD described above a stock and flow structure has been developed in order to test the impact of different policies on ward's performance. Figure 4 shows a section of the stock and flow model describing the hospitalization process: subsystem1 patient.

Figure 4. Sunsystem1: stock and flow structure related to the hospitalization process



The central stock “population affected by gynecological event” represents the amount of people, served by the hospital and affected by gynecological events that require hospital treatments. As a consequence these people can become hospital inpatient or became other hospital inpatient due to the “hospital attractiveness”. For this reason, from the stock “population affected by gynecological event” we have to possible outflow: one is “other hospital inpatient rate” that conduct people to be treated in other hospital and then discharged and placed again in the main stock “population affected by gynecological event”; and the other one is “population waiting for treatment rate”.
This second flow is the beginning of patient chain: a patient passed from several stock and flow (“population waiting for treatment”, “inpatients rate”, “inpatients”, “patient treatment rate”, “patient discharged” and “recovery rate”) that represent the hospitalization and the recovery process. This process is affected by two indexes: “patient capacity” (number ward’s beds), and average time to treat (a means of different treatment timing of the ward over time).

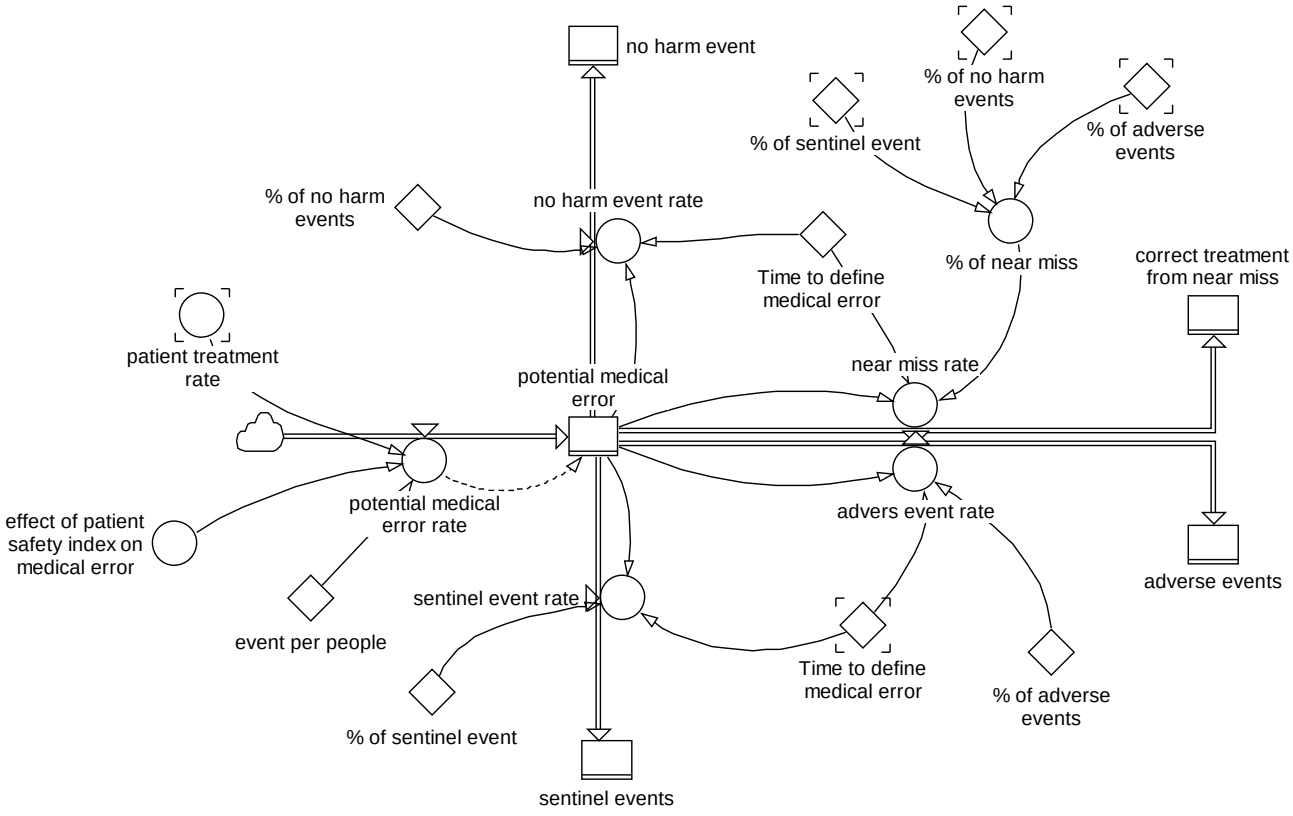


Figure5. Subsystem2: dynamics of errors

Figure 5 shows a section of the stock and flow structure, subsystem 2, describing the dynamics of errors in health care. The central stock “potential medical errors” change trough the inflow “potential medical error rate” that is the result of the amount of treatments of the year “patient treatment rate” and the “effect of patient safety index on medical error”. This last variable represents the weight of the patient safety culture in the generation of clinical errors. It depends by the stock “patient safety index”. We decided to create a graph function to explain the effect of the patient safety index on medical errors. We assume that when the value of patient safety index is at his maximum (100%) there are no medical errors, so the value of the “effect of patient safety index on medical error” is zero, it means zero error each treatment. When the value of patient safety index is at his minimum (0%) the value of the “effect of patient safety index on medical error” is 1, it

means one error each treatment. However we decided to limit the value of the graph output ("effect of patient safety index on medical error") in a range from 0,003 and 0,8 because the two extreme values do not represent the reality, we cannot have one error each treatment and furthermore we cannot exclude the small chance that an error may still occur because hospitals and health care are usually high-risk contexts, "errors can occur even in the best organizations because of the fallibility of people" (Reason, 2000).

The value of the stock "patient safety index" was measured in the ward on 2013 and it was 66,52% based on the scale means of the questionnaire's answers. However we assumed that this value was the result of the last 3 year CRM policies implement by the hospital, so the value of the stock at the time0 (01/01/2011) of the simulation was set at 43%. This value arises from some info about the CRM level before 2011collected during the interview with the CRM's hospital key actors. As a consequence of the last death occurred in the ward (24/12/2010), the last of nine deaths occurred in the ward over the three years2008,2009 and 2010, the Obstetric and Gynecology ward's activity were suspended (suspension did not affect emergencies cannot be postponed) for about a month, during which the hospital' management analyzed the "roots" causes of all the adverse events occurred in the ward in 2010. The critical factors highlighted by the analysis of the root causes have been the subject of planning by the Strategic Management. The Strategic Management, has scheduled a number of organizational interventions both structural (the delivery room and operating room were located on the same floor with the aim to optimize time, transfers and interventions) and functional (increase in staff, review of procedures relating to hospital and pre-hospitalization, improvements in staff availability). The launch of this innovative master plan in the beginning of 2011allowed to achieve the following results: Reorganization of human resources (mentoring activities through the establishment of a special team that has been focusing on the evaluation of staff employed by the ward in terms of skills and experience; training with regular meetings on specific CRM issues and the application of best practices; the improvement of the organizational wellness and the organizational culture in term of patient safety), Quality and clinical risk management (spontaneous reporting of near miss, no harm events and adverse events through the Incident Reporting protocol; systematic review of medical records; activation of the simes data stream; implementation of best practices, procedures, operational protocols, guidelines, etc.), Integration of hospital / territory (for this purpose, has been defined Birth Path Protocol, which provides the integrated management of pregnancy by: the management of low-risk pregnancy at the Family services until the 36th week; the activation of an outpatient clinic for high-risk pregnancy at the hospital; referrals to Family services for care of the mother and newborn after hospital discharge).

From the stock "potential medical errors" there are 4 outflow "sentinel event rate", adverse event rate", "near miss rate" and "no harm event rate" and the respective stock that represent the different kind of error in which a hospital can occur. Each flow is regulated by the frequency percentage of different errors in the medical routine (based on literature data analysis and the historical data analysis of the hospital: 0,2% sentinel events, 5% adverse events, 78,8% near miss and 16% no harm events).

Since our research scope is to test the weight of patient safety culture in the generation of clinical errors, the model boundaries are set to create a simple but sensible SD model. For limitations of the model see the section 7. "Conclusion, Implications, Limitations and further research".

6.4 Scenario Analysis

Based on the analysis of the system described in the previous section, four different policies have been tested and compared with the purpose to estimate the effect of such policies on hospital's performance. In effect, the amount of medical errors can be considered as a performance index for the hospital, it tells us how the hospital personnel and how the hospital management deal with patient safety. Indicators for performance and outcome measurement allow the quality of care and services to be measured. This assessment can be done by creating quality indicators that describe the performance including the occurring, for instance medical errors.

Scenario	***% of corrective action over clinical event***	***% of Investment in CRM policies***
Base run scenario	20	10
No policy run scenario	0	0
Medium policies run scenario	20 *(01/01/2011--31/12/2014)* 40 *(01/01/2015—01/01/2018)*	10 *(01/01/2011--31/12/2014)* 16 *(01/01/2015—01/01/2018)*
High policies run scenario	20 *(01/01/2011--31/12/2014)* 100 *(01/01/2015—01/01/2018)*	10 *(01/01/2011--31/12/2014)* 20 *(01/01/2015—01/01/2018)*

Table 4. Scenario analysis

As showed in table4, these policies differ by the percentage of corrective action over clinical event and by the percentage of investment in CRM policies. The percentage of corrective action over clinical event refers to the number of corrective action effectively implemented after a reporting (simes data stream or incident reporting), it ranges from 0 (no corrective action after reporting of clinical error) to 100 (a corrective action each event reported). The percentage of investment in CRM policies refers to the percentage of investment, respect the total amount of investment of the hospital, reserved to CRM. It ranges from 0 (no investment in CRM policies) to 20 (20% of investment in CRM policies). From the interrelation of these indexes four scenarios arise:

- In the "base run scenario", the hospital policy is aimed at maintaining the current level of CRM.
- In the "no policy scenario", it is assumed that the hospital decides to cut to zero the actual investment in CRM policies and as a consequence no corrective action will be implemented over clinical event.
- In the "medium policies run scenario", it is assumed that the hospital will increase the CRM policies investment by 6% (from 10% to 16%) with the respect of the current level by the beginning of 2015. The amount of corrective action implemented over clinical event will increase by 20% with the respect of the current level by the beginning of 2015 (form 20% to 40% of corrective action implemented after an event reported).
- In the "high policies scenario",), it is assumed that the hospital will increase the CRM policy investment by 10% with the respect of the current level, by the beginning of 2015 (from 10% to 20%), and the corrective action implemented over clinical event by 80% with the respect of the current level, by the beginning of 2015 (from 20% to 100%, it means a corrective action each single event reported).

For the scenario analysis a seven year time horizon is considered. The first three years of the simulation run (2011 - 2013) have the scope to replicate the past ward's performance. The last four years (2014 – 2017), are intended to forecast the potential effect of chosen policies on ward performance.

The following figures (fig. 6, 7 and 8) show the simulation results of the four different scenarios.
In the base run scenario, it is assumed that the hospital policy is aimed at maintaining the current level of CRM. This policy could imply some minor error that determines an increase in hospital attractiveness and in the patient safety index. Hospital attractiveness passed from 49,12% on 2011 to 55,60% on 2018, and patient safety index passed form 43% to 90%, as a result also the number of patient per year increase. Despite the increase of patients, however, sentinel event passed from 0,44 event per year to 0,09 event per year and adverse event passed from 11 event per year to 2,34 event per year, it means an improvement of the patient safety and the quality of the service delivered.

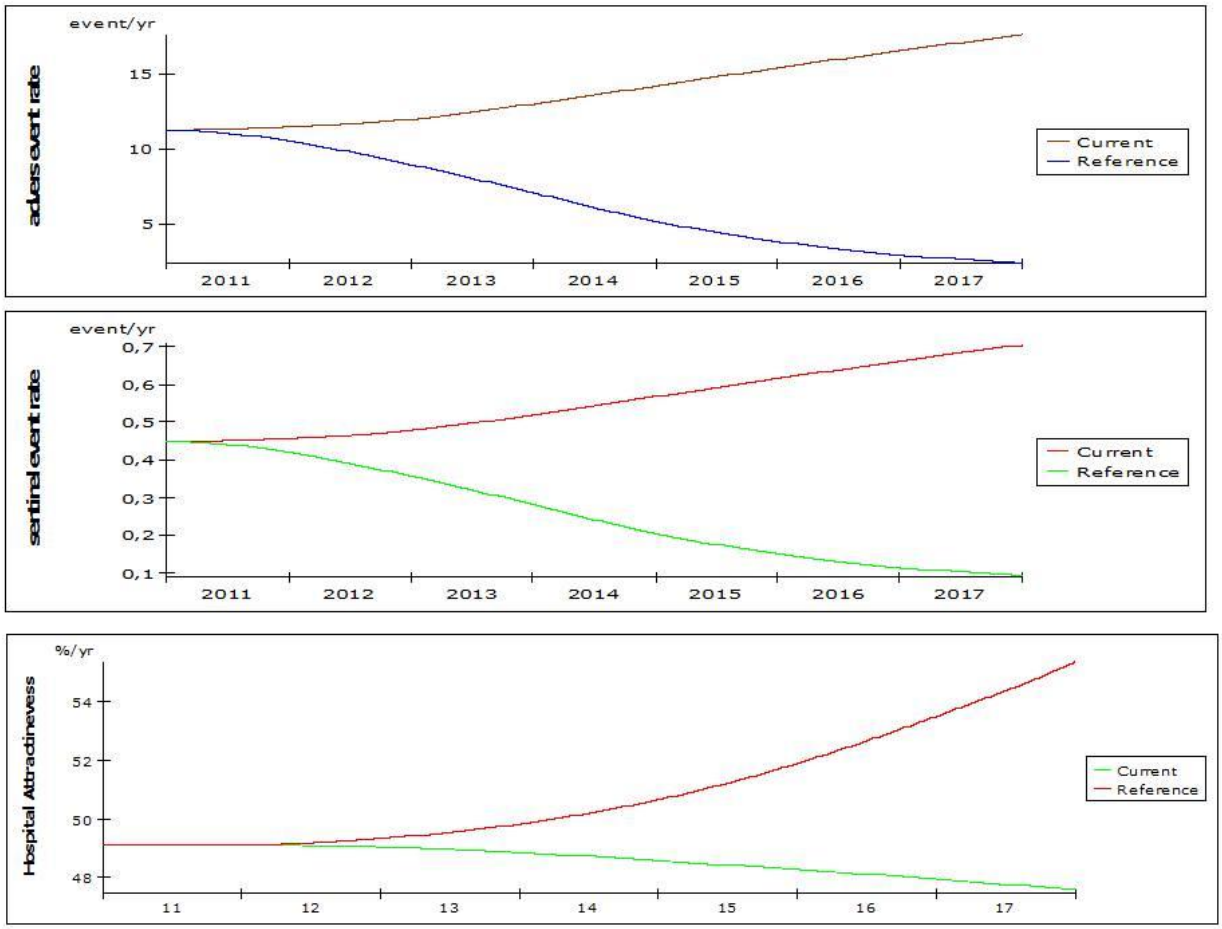


Figure 6. Base Run (Reference) & No CRM Policies Run (Current) for Hospital

In the no policy run scenario (figure6) we assume that starting from time0 (2011), the hospital decide, to cut to zero the actual investment in CRM policies and as a consequence no corrective action will be implemented over clinical event. This choice determine a gradual deterioration of patient safety quality, the patient safety index drops to 30,30% by the end of 2017. As a consequence the sentinel event increases till reaches 0,70 events per year and the adverse event increases till reaches 17,64 event per year. Due of this bad situation the hospital attractiveness drops to 47,59% by the end of 2017 resulting in a decline of patients per year. The analysis of this scenario is aimed to test the model robustness under extreme conditions.

In the medium policies run scenario (figure7), it is assumed that the hospital will increase the CRM policies investment by 6% (from 10% to 16%) with the respect of the current level by the beginning of 2015. As a consequence the amount of corrective action implemented over clinical event will increase by 20% with the respect of the current level by the beginning of 2015 (form 20% to 40% of corrective action implemented after an event reported).

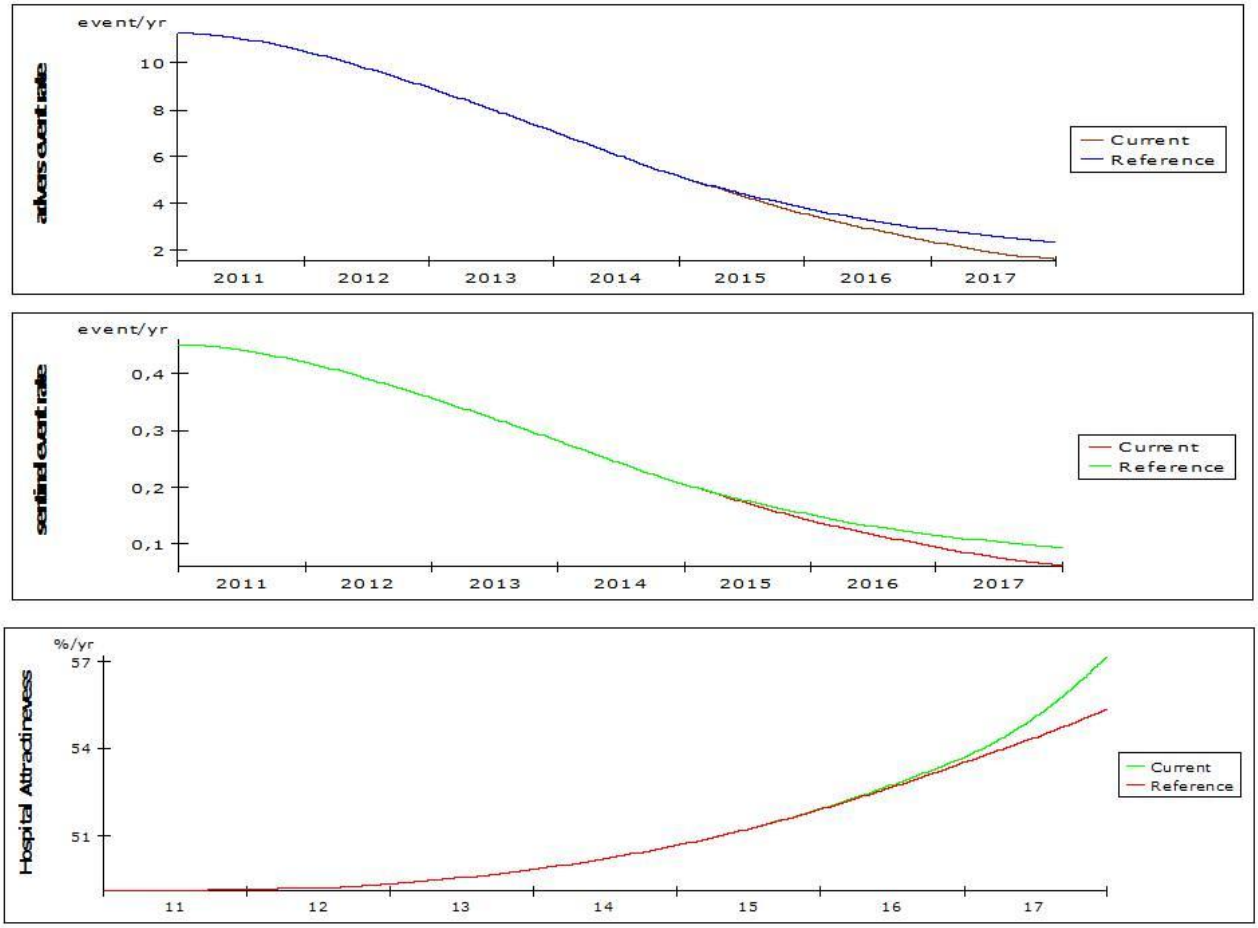


Figure 7. Base Run (Reference) & Medium CRM Policies Run (Current) for Hospital

As a result of adopting these policies a positive effect on all previously examined performance indicators is registered. The patient safety index increases till 99,9% by the end of 2017 with a decrease in sentinel event (0,06 event per year) and in adverse event (1,59 event per year). The increase in hospital attractiveness caused by the low number of potential error generates an increase in the patient inflow.

In the high policies run scenario (figure 8), it is assumed that the hospital will increase the CRM policy investment by 10% with the respect of the current level, by the beginning of 2015 (from 10% to 20%), and the corrective action implemented over clinical event by 80% with the respect of the current level, by the beginning of 2015 (from 20% to 100%, it means a corrective action each single event reported). As a result of this policy the patient safety index jumps to 100% by the end of 2016 and stabilize it-self to this value, sentinel event and adverse event reduce themselves till respectively 0, 05 and 1, 47 events per year. As a consequence hospital attractiveness increases till 58,35%. However if we compare this scenario with the medium policies run scenario, there is no a huge difference in term of performance, for this reason we can assume that the higher investment cost required by this policy would not be counterbalanced by the low difference, in term of performance, respect to the medium policies run scenario. Consequently, the management, could prefer medium policies run scenario in term of sustainability.

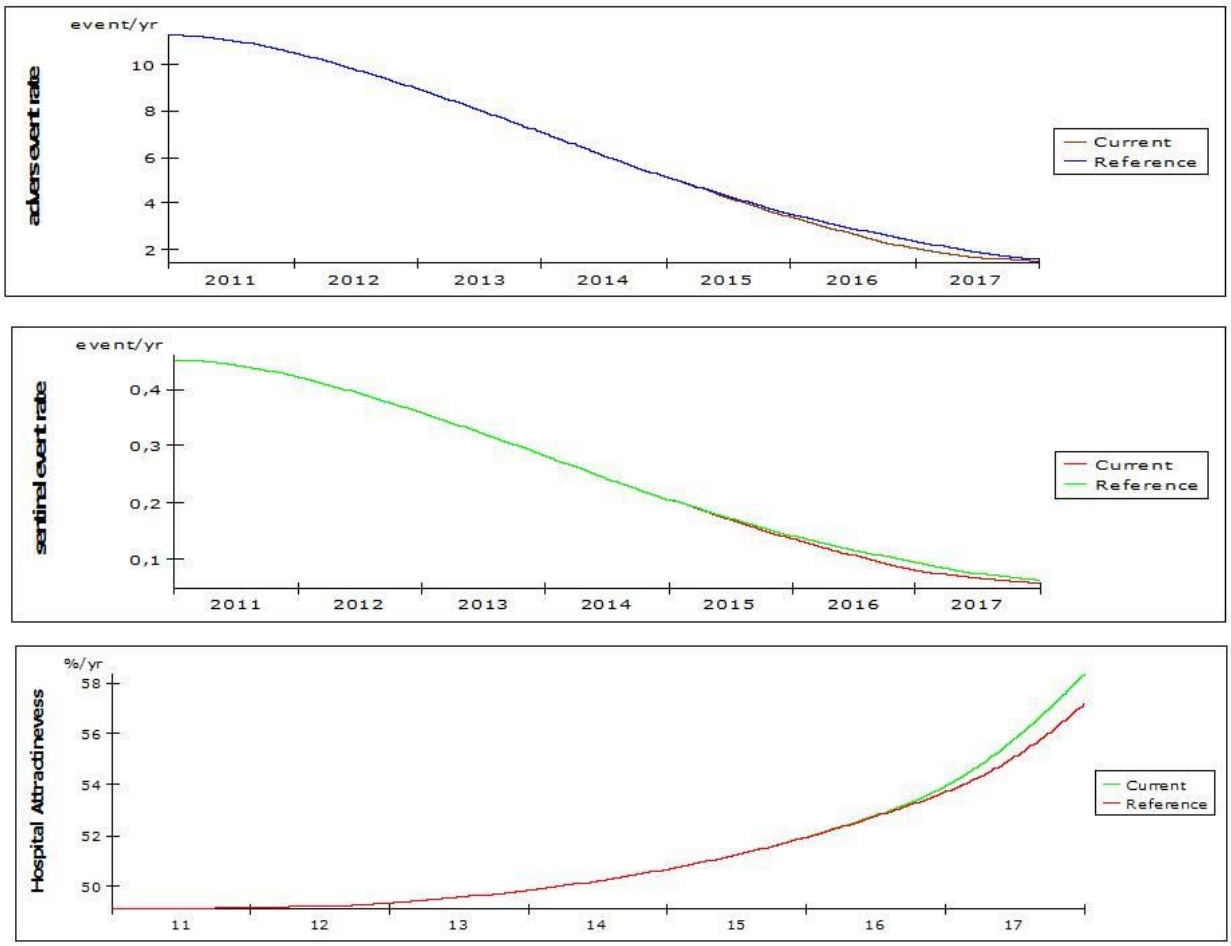


Figure 8. Medium CRM Policies Run (Reference) & High CRM Policies Run (Current) for Hospital

6.5 Can an organizational behavior be better captured by a simulation results than organizational historical data?

If we compare the behavior of the system during the first three years (2011, 2012, 2013) with the historical data collected from the hospital, we can see that the amount of medical events arise from the simulation is quite different from the number of events collected by the hospital (see table 5). The model reproduces a number of adverse, no harm and near miss events that fit only partially with the historical data collected from the hospital (tab. 5). More in detail, whereas we can observe that the number of sentinel events during the 2011 – 2013 time range and the number of adverse events of 2011 are the same, both in the simulation run and in the hospital historical data, the number of adverse, no harm and near miss events showed by simulation model are much higher than the ones collected from the hospital (tab. 5).

To explain this partially unfit of the model behaviors with the historical data, we can assume that:

a) the fit between simulation results and ward historical data (2011 – 2013 time horizon) about the number of sentinel events could be ascribed to the national current regulation that oblige the hospital staff to report a sentinel event, where the physicians and nurses always adhere to such a regulation since sentinel events are very often together with patient' claims;

b) the fit between simulation results and ward historical data (2011 time horizon) about the number of adverse events (and the unfit for no harms and near miss events), could be ascribed to the launch of a innovative master plan in the beginning of 2011, specifically set for the personnel of the

obstetric and gynecological ward, focused on the implementation of the incident reporting system and SIMES data stream. The fact that only the number of adverse events showed by the simulation model fits with the ward historical data could be explained exploring the ward's staff mental models about the role of the different typologies of events in generating medical errors, where the adverse events are worth considering since they are the only ones that could generate an observed medical error and, as consequence, a patient's claim.
So, we hypothesize that this partially data unfit is given by the high sensibility of the model to catch the causal relationship between the organizational behaviors of the ward's personnel and the underlying mental models that generate them. The poor attention to CRM practices showed by the ward's personnel can be confirmed also by the fact that during the questionnaire administration, they sometimes argued about the inutility to submit an incident report especially when a no harm event or a near miss have been occurred. As two ward's nurses said during the questionnaire administration: "At the end no one was hurt, so it doesn't matter…"; "Even the patient doesn't realize that he was been in trouble, so why I have to report something about it?".

Types of clinical adverse event	Base run simulation results	Hospital historical data
ADVERSE EVENTS	11 (2011) 9 (2012) 8 (2013)	10 (2011) 0 (2012) 1 (2013)
NO HARM EVENTS	35 (2011) 31 (2012) 26 (2013)	3 (2011) 1 (2012) 0 (2013)
NEAR MISS	173 (2011) 154 (2012) 126 (2013)	3 (2011) 0 (2012) 0 (2013)
SENTINELL EVENTS	0 (2011) 0 (2012) 1 (2013)	0 (2011) 1 (2012) 0 (2013)

Table 5. Comparison between base run simulation result and historical data of the first three years.

From the organizational psychology perspective, we can assume that the reason of this poor attention to CRM practices lies on the resistance to change, which could be defined as the act of opposing with modification or transformation of the organizational status quo. Resistance to change can occur when people don't really understand the reasons behind the change, when people know the reasons for the change, but they don't see how those reasons translate into benefits they value, when people are unclear about how the change will impact their job roles, what new expectations they will have to meet after the change and whether they will be able to meet those expectations, when people feel that change plans are being imposed on them by others, that they do not "own" the change.
This means that the first step in the organizational change process is the change of organizational culture, a change that is not yet fully realized in the analyzed ward. Actually, the prevalent organizational culture seems still to be the "blame culture", where the error is seen as a failure and not as something from which to learn.
Moreover, submit an incident report takes time, too much time for a nurse or a doctor, fully busy with his work. The Incident Report form is very detailed and no ever simply to fill with the info available, so often a staff member prefers to skip to submit a event without harm with the patient and concentrate on his work.

7. Conclusions, Limitations, and further research

We suppose that our study could have a broad appeal for researchers. Globally the healthcare cost increases due to the increase in aging population, total health care spending in the overall developed countries is expected to increase dramatically (for example, in US it will reach $4.8 trillion in 2021, up from $2.6 trillion in 2010 and $75 billion in 1970. To put it in context, this means that health care spending will account for nearly 20 percent of gross domestic product, or one-fifth of the U.S. economy, by 2021). The complexity of the profit maximization phenomenon at the expense of patient's safety has become a pressing issue requiring remedial action.

Our research findings suggest that it would be convenient for healthcare companies to invest in CRM policies in order to reduce the expenses resulting from ineffective errors management (claims, loss of image, loss of patient, insurance costs etc.).

Similar to other studies, our research has some limitations that can be addressed in the future research work. One limitation is given by the model boundaries. In the model there is a lack of financial indicators and some system variables that may influence the hospital's performance have not been considered (role of Regional Healthcare Administration, patient associations, Joint Commission International). A second limitation is given by the choice to represent the different patient safety index factors by a single variable that takes into account their average values.

Nevertheless, despite these limitations, this research delivers results with implications for the applications of system dynamics methodology to CRM. It would be advisable to develop CRM research at international level to undertake comparative research studies in cross cultural setting aimed at creating communities of practice where sharing best result and fostering organizational learning.

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ANNEX 1 correlations

Table3 correlations	Team Work	Staffing	Organizational Learning—Continuous improvement	Nonpunitive Response To Error	Overall Perceptions of Safety	Supervisor/manager expectations & actions promoting safety	Feedback and Communication About Error	Communication Openness	Frequency of Event Reporting	Hospital Management Support for Patient Safety	Teamwork Across Hospital Units	Hospital Handoffs & Transitions	Patient Safety Grade
Team Work	1 27	-,489** 0,01 27	0,222 0,265 27	0,015 0,941 27	0,055 0,784 27	0,078 0,701 27	-0,014 0,946 27	0,276 0,164 27	0,337 0,086 27	0,239 0,23 27	0,241 0,227 27	0,014 0,944 27	0,295 0,135 27
Staffing		1 27	-0,085 0,675 27	-0,178 0,375 27	0,279 0,159 27	0,135 0,502 27	-0,106 0,6 27	-0,091 0,651 27	-0,156 0,436 27	-0,145 0,471 27	0,022 0,912 27	0,024 0,907 27	0,108 0,592 27
Organizational Learning—Continuous improvement			1 27	0,147 0,464 27	0,338 0,085 27	0,094 0,641 27	,568** 0,002 27	-0,083 0,68 27	,584** 0,001 27	,507** 0,007 27	0,272 0,17 27	0,141 0,483 27	,597** 0,001 27
Nonpunitive Response To Error				1 27	0,366 0,061 27	0,115 0,567 27	0,345 0,078 27	0,146 0,467 27	0,306 0,121 27	,414* 0,032 27	0,362 0,064 27	0,104 0,605 27	0,249 0,21 27
Overall Perceptions of Safety					1 27	……...,508** 0,007 27	,549** 0,003 27	0,262 0,187 27	,473* 0,013 27	,551** 0,003 27	0,323 0,101 27	0,347 0,076 27	,444* 0,02 27
Supervisor/manager expectations & actions promoting safety						1 27	,576** 0,002 27	,588** 0,001 27	0,229 0,251 27	,445* 0,02 27	,558** 0,002 27	,482* 0,011 27	0,351 0,072 27
Feedback and Communication About Error							1 27	,422* 0,028 27	,669** 0 27	,642** 0 27	0,368 0,059 27	,386* 0,047 27	,524** 0,005 27
Communication Openness								1 27	0,219 0,274 27	,389* 0,045 27	,589** 0,001 27	,403* 0,037 27	0,147 0,463 27
Frequency of Event Reporting									1 27	,701** 0 27	0,338 0,084 27	0,321 0,103 27	,658** 0 27
Hospital Management Support for Patient Safety										1 27	,689** 0 27	,621** 0,001 27	,637** 0 27
Teamwork Across Hospital Units											1 27	,668** 0 27	0,268 0,176 27
Hospital Handoffs & Transitions												1 27	0,169 0,399 27
Patient Safety Grade													1 27