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Abstract

During the last two decades, the issue of clinical risk management CRM became one of the key topics in the Health care sector due to the increasing attention to the patient safety and the increase in monetary and non monetary costs. For this purpose, in the healthcare sector have been imported risk management methods that have been successfully applied in the industrial sector, such as the Root Causes Analysis, Clinical Audit, Incident Reporting, etc.. However these methods are static and linear to study such a complex and dynamic problem as the risk management, for this reason they often do not properly support the health care managers in the adoption of the best policies able to develop a sustainable growth both in short and medium-long run. Health care organizations are complex and dynamic systems, often characterized by delay between cause and effect and many goals, interests and actors. The methodology of system dynamics is suitable to dealing with the dynamic complexity that characterizes the health care system. This work explores the role of Safety Culture index in the generation of potential medical errors by using system dynamics methodology. The hypothesis is that a safety culture assessment represents a tool for improving patient safety. We use system dynamics to explore the multidimensional facets of hospital's complex structure. By using a simulation model we want to test the role that the Safety Culture index has in the generation of adverse events, in order to identify the best policies able to achieve the optimal results with the lowest use of resources. This thesis describes a project, which is a part of a wider collaboration between the University of Palermo and the ASP6 Palermo (the Provincial body for Health Services), established in established on February 2013. The project was performed by Valentina Aiello, the author of this thesis. The fieldwork was conducted from April 2013 to June 2014 in the ward of obstetric and gynecology of a public hospital placed in a little town near to Palermo (the capital of Sicily Region), which serves approximately a population of 45.000 people.

We provide a summary of our findings and their empirical and theoretical implications and contributions. Suggestions about the power of system dynamics simulation model in capturing organizational behaviors are provided. The expected added value of this research is to provide the stimulus, for the healthcare company involved, in the adoption of policies for clinical risk management allowing on the one hand greater attention to the patient safety, and’ on other hand, the development of a sustainable growth that directs healthcare organizations to paths of excellence.

List of Acronyms

AO: Hospital

ASP: Provincial Body for Health System

ASP6: Palermo Provincial Body for Health System

BR: Base Run

CLD: Causal Loop Diagram

CRM: Clinical risk management

DRG: Diagnosis Related Groups

ES: Expensive Scenario

GMB: Group Model Building

HPS: High Performance Scenario

HSE: Health and Safety Executive

IHI: Institute for Healthcare Improvement

IOM: Institute of Medicine

JCAHO: Joint Commission

JCI: Joint Commission International

LPS: Low Performance Scenario

MCD: Major Diagnosis Category

MPC: Manufacturing Planning and Control

NHPC: Australian National Health Performance Committee

NHS: British National Health Service

P&C: Planning and Control system

RCA: Root Cause Analysis

SCI: Safety Culture Index

SD: System Dynamics

SDO: Hospital Discharge Register

SIMES: Information System for Monitoring Errors in Healthcare

SNN: Italian National Health System

SKR: Skill Ruled Knowledge model

WHO: World Health Organization

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Introduction

In recent years, the higher sensibility about patient safety, the greater stress given by the media to news related to clinical risk, the relevant increase of insurance costs and the higher number of compensation lawsuits have abruptly drawn the attention of healthcare companies' managers towards the topic of clinical risk management (CRM), namely the implementation of policies aimed at reducing the probability that a patient suffers damage during the delivery of healthcare services. As a consequence, patient safety has gained increasing interest and healthcare companies have been forced to abandon those policies aiming at profit maximization to the detriment of the quality of healthcare services. Due to this interest it became increasingly important to define patient safety. Even though the Institute of Medicine IOM[1] defines 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, adopted 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[2]: "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."

Such a change in healthcare companies' vision has been fostered by the publication of the American Institute of Medicine's report entitled "To err is human: building a safer health system" (Kohn 1999), which stressed that also healthcare professionals may commit errors as it happens in other professions. This study estimated that in United States up to 98,000 people per year die because of hospital mistakes. However, medical errors leading to patient death are much

[1] Established in 1970, the Institute of Medicine (IOM) is an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public.
[2] In: Henriksen, et al., 2008.

higher than previously thought, and may be as high as 400,000 deaths per year, according to a new study in published by James on the Journal of Patient Safety in 2013. According to the author, in United States each year preventable medical errors lead to the death 210,000-400,000 patients who seek care at a hospital. James (2013) analyzed four recent studies that used the "Global Trigger Tool" to flag specific evidence in medical errors, such as medication stop orders or abnormal laboratory results, which point to an adverse event that may have harmed a patient.
Based on the weighted average of the four studies, James (2013) concludes that at least 210,000 deaths are due to preventable harm in hospitals. But because of the tool limitations and incomplete medical records, he wrote that the number is likely twice that figure, and he hypothesizes that the medical errors are responsible for more than 400,000 deaths each year. Those data would make medical errors the third leading cause of death behind heart disease (596,577) and cancer (576,691), according to American Centers for Disease Control and Prevention statistics of 2010 (Source: Detailed Tables for the National Vital Statistics Report (NVSR) “Deaths: Final Data for 2011.” American Centers for Disease Control and Prevention).
In Europe, a *Eurobarometer survey on medical errors* was launched in 2005 by the Directorate-General of Health and Consumer Protection across the 25 member states. The problem of medical errors has not been systematically studied at the EU level before this survey. The main aim of Eurobarometer survey is to carry out the first analysis based on citizens’ perception of medical errors.
The issues analyzed in the survey are the follows:

- General perception of medical errors
- Experiences of medical errors: familiarity with the topic and concrete Experiences
- Practical implications: trust in health care professionals and hospital treatment.

With regard to the first issue (General perception of medical errors), the findings of the survey show how almost 4 of 5 EU citizens (78%) classify medical errors as an important problem in their country. At the country level, considerable variation in results can be depicted: the percentage of citizens perceiving the medical errors as an important problem for patient safety varies from 97% in Italy to 48% in Finland (media e DS). To the question “How worried should hospital patients be about serious medical errors?” 48% of the EU citizens state that hospital patients should be worried about the possibility of a serious medical error.

With regard to the second issue (Experiences of medical errors), the findings of the survey show that the 78% of the EU citizens polled have at least sometimes heard or read about medical errors (Italian 53%). Moreover 23% of Europeans citizens have been directly or indirectly affected by medical errors.

Not unexpectedly, a connection between the perceived importance and personal experiences of medical errors is observable. The citizens who have directly or indirectly experienced a medical error are significantly more likely to value the issue as very important (53% vs. 33%).

With regard to the third issue (Practical implications), the findings of the survey show that the EU citizens trust that medical professionals don’t make medical errors during the patient’s treatment. However, a high percentage of respondents have doubts about the quality of health care services; in fact, approximately the 30% of citizens don’t feel confident about medical staff. To the question “According to you, how likely do you think it would be that a patient in a (NATIONALITY) hospital would suffer a serious medical error because of the hospital doctors or medical staff?”, almost half (47%) of the EU citizens believe that it is likely to encounter a medical errors in a hospital in their country. About these data, the variation among EU Countries is notable; for instance, in Italy the 70% of citizens stating that serious medical errors are likely to happen in their hospitals. Lastly, the majority of respondents (51%) think that it is not likely that a hospital patient could contribute in avoiding a medical error, out of which 16% believe that it is all in all impossible.

All these data show that the issue of error in medicine and the quality of health care is becoming increasingly important worldwide, and some consultant organizations have been started to act in this field. Two of the most important worldwide organizations active in the field of clinical risk management are: The Joint Commission (U.S.A.) and The Health and Safety Executive HSE (U.K.). The Joint Commission JCAHO 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"[3]. Joint Commission International JCI is also one of the most important organization providing international healthcare accreditation services to hospitals around the world. In more than 100 countries, JCI partners with hospitals, clinics, and academic medical centers; health systems and agencies; government ministries; academia; and international advocates to promote rigorous standards of care and to provide solutions for achieving peak performance. In Italy, JCI has accredited 23 healthcare companies, just 3 of these are Sicilian’s hospitals (COT Cure Ortopediche Traumatologiche S.p.A Messina, Humanitas Centro Catanese di Oncologia Spa Catania and Istituto Mediterraneo per i Trapianti e le Terapie ad Alta Specializzazione Palermo).

The Health and Safety Executive is a non-departmental public body of the United Kingdom that is responsible for the encouragement, regulation and enforcement of workplace health, safety and welfare. The stated mission is to prevent death, injury and ill health in Great Britain’s workplaces.

However the CRM methods used by these organization, although more innovative than the methods used previously that were imported from other fields such as aviation or nuclear, 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, they don’t take into account the feedback

[3] http://www.jointcommission.org/

structure of the net of causality that links each other the variables of the healthcare system; they are static, they don't consider the interactions between the different risks and 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 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.

PART I

THEORETICAL FRAMEWORK

CHAPTER 1. The error in medicine: the clinical risk

1.1 Etiology of the error

In everyday life recognize errors is not so easy, first of all because an action is only recognized as error after the event and moreover some errors may only be recognized time after they occur: "Human error is a judgment made in hindsight" (Woods 1994). In order to study and examine the error we need to tie it to observable behaviors and actions.

James Reason (1990), describe the classification system of the error, known as the Skill, Rule, Knowledge (SRK) based approach developed by Rasmussen (1983). This classification is useful to identify different types of error that may occur in different situations. An human error is for Reason: "a generic term that covers all occasions in which a planned sequence of mental or physical activities can fail to achieve an intended result and where this failure cannot be blamed on the intervention of an accidental triggering source". Reason defines the SRK a performance model. Indeed, he argues that the mode in which an action is taken is a function of the familiarity of the individual with the specific task and the amount of attention (information processing) that individual must give when executing that action. The three performance modes are skill-based, rule-based and knowledge-based (figure1).

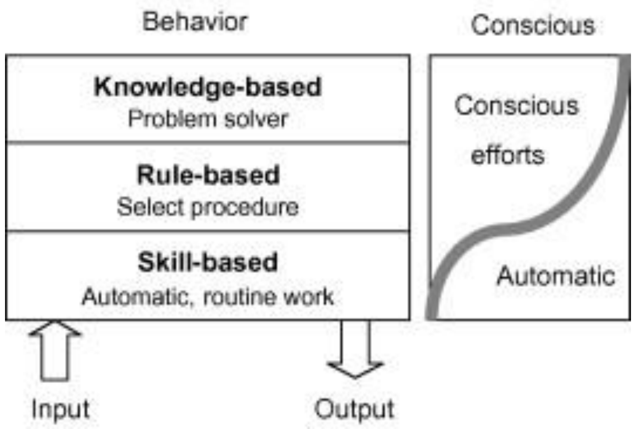

Figure 1. The performance model (Reason 1990)

Skill-based: these actions are performed automatically with low attentional control. This ability is developed after the stimulus has been repeated for several times, always in the same way. It is a type of behavior found in routine situations.

Ruled-based: these processes are associated with behavior based on selection of stored rules derived from one's recognition of the situation represented as "if X then Y".

Knowledge-based: these processes are associated with behavior in response to a totally unfamiliar situation (no skill, rule or pattern recognizable to the individual). Usually arises as a problem-solving situation that relies on personal understanding and knowledge of the system. The attentional control is high. It is therefore a rational process, which requires not only the ability to perform a task, but also information and understanding of the task itself.

The three types of behavior are learned in sequence: skill-based behaviors are not innate, but they derive from the practice of situations requiring initially the use of knowledge and ability to solve problems. Therefore any skill-based behavior was, before becoming automatic, knowledge-based and ruled-based.

At each level of performance are associated different types of error, related with the cognitive mechanisms of the reference level. In his analysis of different kind of errors, the author, identifies two main categories of them: errors of action or execution and errors of knowledge or planning (figure2). The author also takes into account the violations, which, unlike the errors, are intentional acts that deviate from the usual or expected course of actions. For the sake of brevity these last will not be analyzed.

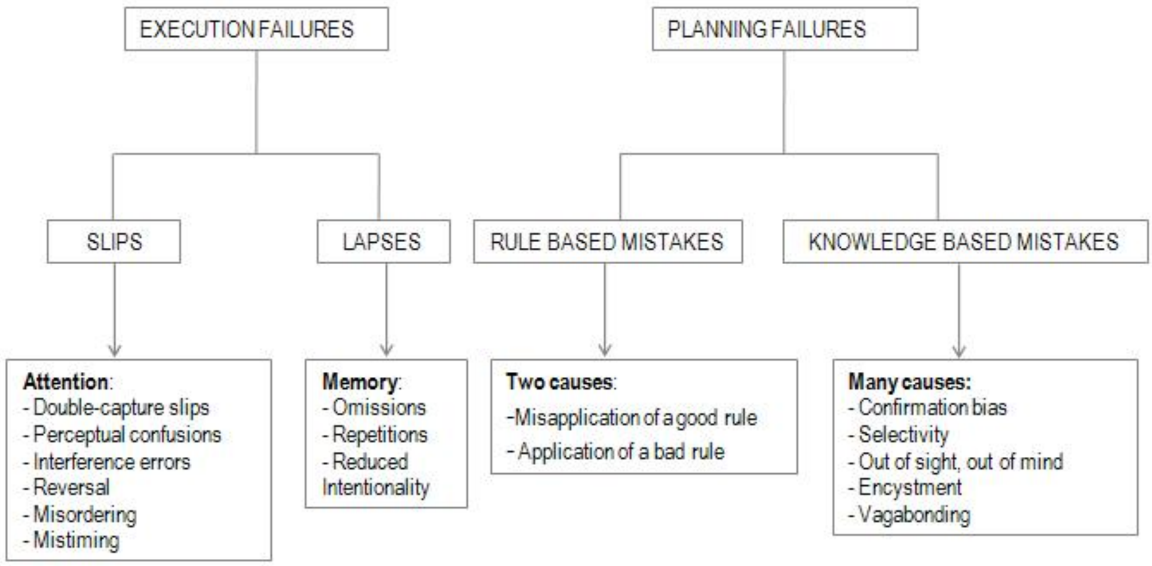

Figure2.Human error model (Reason 1990)

Errors of action (situated at the skill-based level) are slips and lapses and occur when a person knows what want to do but the action does not go according to plan. Slips as usually associated to attentional failures. They are actions performed in a different way than they were planned. Lapses are usually associated to memory failures. The action has a different result from that expected due to a memory failure. Unlike the slips, lapses are not directly observable.

Errors of knowledge or planning (situated at the ruled-based and knowledge-based levels) are mistakes. At the ruled-based level it was decided to apply a rule or procedure that does not allow the achievement of that particular goal. At the knowledge-based level they are errors of knowledge that lead to design courses of action that does not allow you to achieve the goal. They occur when the intention is clear, the action corresponds with the intention and goes as planned, but the plan was wrong. In this case failures are related with the mental processes involved in planning. They can also occur in new situations, where the solution of a problem must be found at the moment. In this case failures are related with a lack of knowledge.

1.2 Definition of clinical risk and different kind of medical errors

A clinical risk or healthcare risk is the chance of an adverse outcome resulting from clinical investigation, treatment or patient care.

As a consequence Clinical risk management (CRM) is an approach to improving the quality and safe delivery of health care by placing special emphasis on identifying circumstances that put patients at risk of harm and acting to prevent or control those risks.

In order to allow a clear understanding of the phenomenon, it is useful to define some CRM key-concepts on the base of the indication of medical errors provided by the Joint Commission:

- **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 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 a 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	Assault of patient
12	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

For each important error (sentinel event) there are some minor events (adverse event) and several hazards (near miss and no harm events). The figure 3 shows the "iceberg theory" used to represent the difficulties found in the knowledge of "swamped" events.

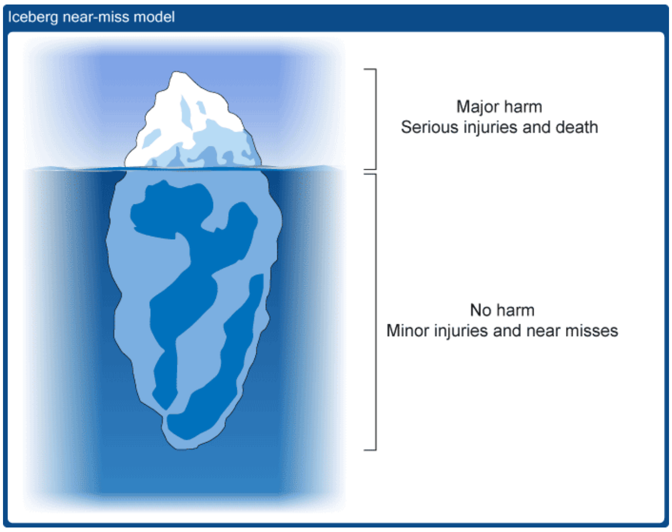

Figure3. Iceberg near miss model

There are, in fact, some smaller events that are not always "visible" to the front-line staff, or, if they are visible, their importance is underestimated, or they are kept hidden to avoid possible sanctions. However the system must identify these minor and hidden events in order to avoid important events and as a consequence improve patient safety. The iceberg theory is based on the understanding that what is hidden under the surface may be more significant that what is above, just as with an iceberg.

1.3 The evolution of error in medicine: 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. 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 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, Reason published a paper based on his previous work (1990) 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).

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 4) 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.

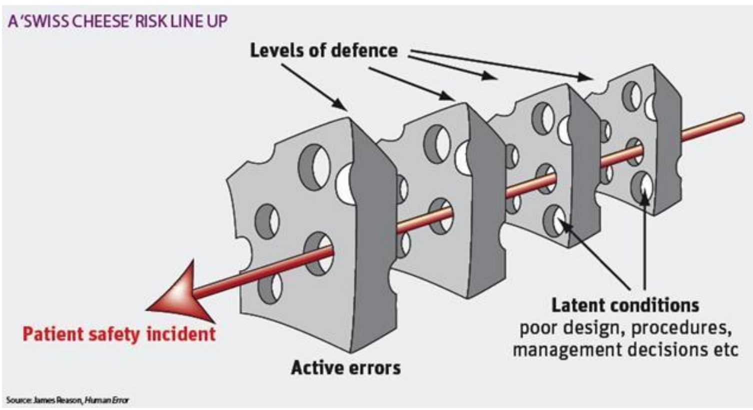

Figure 4. The “*Swiss cheese”* model (Reason 2000).

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 5) to describe the immediate errors and problems and the background latent conditions.

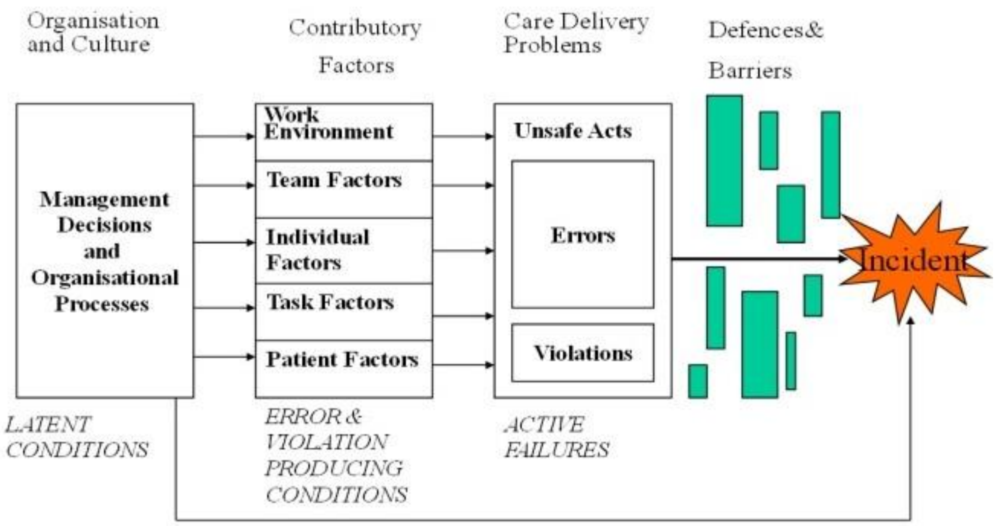

Figure 5. Organizational accident model (Reason 2000)

Vincent (1998), by using the system approach provided by Reason (1990), has studied the role of human factors in the generation of an adverse event 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 event, 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 events.
- 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 refers 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.

1.4 The evolution of CRM: from the Evidence Based Medicine to Clinical Governance.

Two different approaches, in term of operational and cultural assumptions, have been developed in the field of patient safety and quality of care delivered:

- Evidence-based Medicine, is a medical and technical approach based on the use of current best evidence in making decisions about the care of individual patients. It integrates individual clinical expertise (the proficiency and judgment that individual clinicians acquire through clinical experience and practice) with the best available external clinical evidences (clinically relevant research in the fields of accuracy and precision of diagnostic tests, the power of prognostic makers and so on). However, Evidence-based medicine is not a cookbook, it requires a bottom up approach to better integrate the two level of analysis mentioned above.

- Total Quality Management and Continuous Quality Improvement, are organizational-managerial approaches, they include continuous improvement, customer focus, structured processes, and organization-wide participation. These methodology can be defined as systemic and their merit is to analyze the elements that characterize the healthcare as a system. However they also have some limitations, first of all the lack of attention toward the clinical practice behind the organizational itself. Moreover they haven't been matched by a clear methodological framework in their application, as a consequence they are usually based on the application context and interventions are therefore not generalizable and repeatable in other contexts.

The strategy able to integrate these two approaches is the Clinical Governance, it operates both un organizational and cultural side of the healthcare context. It was used for the first time by World Health Organization WHO in 1983 to define "all activities of a healthcare company, aimed at building the relationships among the different components (organizational functions) that have clinical and organizational responsibilities". Clinical governance is described as the system through which healthcare teams are accountable for the quality, safety and experience of patients in the care they have delivered. For health care staff this means: specifying the clinical standards you are going to deliver and showing everyone the measurements you have made to demonstrate that you have done what you set out to do. The application of Clinical Governance requires a system approach able to take into account the different components of the system and their role in the generation of the healthcare companies outcome. The main components of Clinical Governance are:

- Risk management: is about minimizing risks to patient by identify what can and does go wrong during care, understanding the factors that cause and influence this and ensuring action is taken to prevent recurrence by putting system in place to reduce risks.
- Clinical audit: is a way that doctors, nurses and other healthcare professionals can measure the quality of the care they offer. It allows them to compare their performance

against a standard to see how they are doing and identify opportunities for improvement. Changes can then be made, followed by further audits to see if these changes have been successful.

- Education, training and continuing professional development. Staff must have the knowledge and skills they need to do a good job. For this reason they have to maintain and update their skills.
- Evidence-based care and effectiveness.
- Total Quality Management and Continuous Quality Improvement.
- Patient and caregiver experience and involvement.

1.4.1 CRM International context

The first CRM experience was in USA around 70s, fostered by the development, about a decade before, of a system of risk management in a business setting. This system has shown the benefits introduced by this method, and has allowed to take advantage of the experience accumulated. CRM was born in response to the “malpractice crisis” which occurred at the beginning of the seventies in the USA. This “malpractice crisis” was generated by a number of contributing factors that emerged at that time: it recorded an increase in the number and costly of care, in conjunction with a marked decrease in insurance offer, which in turn led to a drastic increase in insurance premiums. These factors put a model of care based substantially on the profit in a deep crisis. This model is based on the profit overshadows the problem of medical errors and harm to patients as a result of reliance on the capacity of absorption of such damages by the insurance system and a lack of awareness of their responsibility towards the patient. It was then that the insurance world who put a stop to the production of poor quality health services, and refused to cover the negligence of the healthcare system. The first risk management programs were designed to reduce costs through the recognition of adverse events, the reduction of complaints and lawsuits, the reduction in premiums and compensation paid. However, a study of those years reveals that most of the hospitals, while being aware of the importance of reducing accidents to the patient, enacts measures to reduce just the financial and environmental risks. Therefore they were not trying to solve the problem at its root, but they focused efforts to find a remedy to the problem of compensation lawsuits, dealing in this way with the effects, but not with the cause of the system crisis. This carelessness about the causes of the problem led, by the beginning of the eighties, to a "second crisis of malpractice," which had consequences even worse than the first. Thus it was that healthcare companies are beginning to understand that CRM is not just in terms of cost containment, but it must also deal with the organization of care and risks prevention. Starting in the eighties many projects and various non-governmental organizations were born in this direction, including the aforementioned JCAHO and JCI.

The problems analyzed in the U.S. case are common to all industrialized countries, although these have occurred subsequently. Today, almost all countries are working to implement policies for clinical risk management. One of the first European countries where the concept of CRM was introduced is Britain. The British health system, created in 1948, is indicated by the acronym NHS (National Health Service). The main stimulus in the development of CRM in Britain was the increase of lawsuits against healthcare companies, due to episodes of clinical negligence. Over the years the NHS has tried to support the implementation of clinical risk management through the adoption of a series of specific actions as the implementation of The Patient Safety Division aimed to identify and reduce risks to patients receiving NHS care and to lead on national initiatives to improve patient safety. Through the National Reporting and Learning System, the Patient Safety Division collects confidential reports of patient safety incidents from healthcare staff across England and Wales. Clinicians and safety experts help analyze these reports to identify common risks and opportunities to improve patient safety. Feedback and guidance are provided to healthcare organizations to improve patient safety.

1.4.2 CRM Italian context

Before to describe how the Italian healthcare context deal with CRM a brief description of the Italian National Health System SNN will be provided.

The SSN, following the entry into force of Legislative Decree n. 502 of 30 December 1992, has introduced to the concept of "corporatization", aimed at finding a more effective and efficient management of local health and greater satisfaction of patient's needs. The changes required by healthcare reform are to be considered in the context of a large project for economic rehabilitation and retraining of national health services. The growth of users expectations, the increased citizen's attention to the quality of services, the experience of other private companies can be considered some of the driving force of the reform process, inspired by the phenomenon of the New Public Management. The term "company" means primarily a consistent responsibility for each structure and an appropriate level of management by objectives and processes, aimed to a continuous improvement.

The Italian's healthcare reform has enable the shift from a centralized to a decentralized system of care. It has gone from a setting designed to reproduce on the territory models defined at national level to a setting that assigns to regions and individual health care companies the burden to interpret the needs and interventions territory centered. The need for greater levels of flexibility, which is important for any type of company, it becomes even more relevant in the context of health care companies, where the complexity and peculiarities typical of each area determines needs and require different organizational structures characterized by an adequate degree of flexibility. However a certain level of centralization has been maintained: at the national level the government sets the Essential Levels of Care, they comprise all of the activities, services and benefits that the SSN provides to all citizens for free or by paying a fee (ticket), regardless of income and place of residence, in order to guarantee uniformity, to all and on the whole national territory. They were defined at the national level with the Decree of the

President of the Council of Ministers of 29 November 2001, which entered into force in 2002. At decentralized level regions must: implement services and activities for the protection of health, generate and manage health care spending, establish the criteria for the funding of Provincial body for Health Services ASP, and hospitals AO. An ASP is an entity as provided by law that is responsible to manage and coordinate the services and public health activities for the whole province, it also organizes health care in its own territory and deliver it through public or private accredited institutions. Each ASP is divided into the hospital districts that represent structures provided with technical- managerial and economic-financial autonomy. The AO are significant regional or inter-regional hospitals set up in companies, because of their particular characteristics. The AO on the national territory are 102 and they have the task of ensuring the provision of health services to the citizens, in accordance with modalities and within appropriate regimes, through the effective use of available resources. The main difference between ASP and AO is in the kind of services they delivered: the activities carried out by the AO substantially consists of hospital care, while the activities carried out by ASP consists of both hospital care and community care.

In Italy, the CRM in the health sector is still considered an innovation, unlike in the U.S. or in the UK and the implementation of CRM policies looks patchy among the country. The healthcare companies have traditionally adopted an administrative approach to the problem, limiting the purchase of the insurance policy (transfer to third parties). The result has been the exclusion of healthcare companies access to information on the handling of the complaints, therefore, a weakness and excessive dependence on insurance companies. The factors that led to the introduction of CRM in Italy are related to increased insurance premiums and the progressive loss of image of healthcare companies, due to the proliferation of so-called cases of "malpractice." By now every week we learn, by the media, of damaging events occurring in health care; public opinion is becoming more sensitive topic. This has helped to create a sense of distrust in the population to healthcare organizations. If, on the one hand, the occurrence of harmful phenomena contributes to crack the hospitals' image, on the other hand these events result in an costs increase that the companies themselves have to bear.

In Italy in 1999 a document of the Charter of Security in Medical Practice and Exercise was presented by the Tribunal for Patients' Rights, subsequently refined and presented in 2000 with the title "learn from the mistake," in which were defined the criteria for error handling in hospitals and were proposed the activation in each public healthcare companies of a Risk Management Unit and the establishment for a National Documentation Centre of error logging.

As part of the activities undertaken by the Ministry of Health in terms of quality of health services, the Technical Committee on Clinical Risk Management (Ministerial Decree March 5, 2003), has been established at the Directorate General of Health Planning. The purposes of the Technical Committee on Clinical Risk are the study of the prevalence and causes of clinical risk, the formulation of general guidelines and the identification of techniques for the reduction and management of the problem. The Commission has produced a document "Risk Management in Healthcare. The problem of errors" that provides a collection of reflections and recommendations for professionals working in the healthcare environment.

Since 2004, at the Directorate General of Health Planning, it has been operational a Working Group "Assessment of methodological approaches in the field of clinical risk", to produce a report on the methodological approaches in the field of clinical risk adopted in various existing initiatives. Particular attention has been paid to the identification of practical solutions for the development of a monitoring system of adverse events, and in the way to train the health professionals. With the technical support of the Working Group, the Ministry of Health has developed a protocol for the monitoring of sentinel events to initiate, in an experimental form, a system of event monitoring and management within the health care companies on the national territory. The aim is to understand what might be the causes or contribute to the manifestation of adverse events and promote patient safety (Ministerial Circular of 13 September 2005). Along with the monitoring of sentinel events, are being developed related Recommendations specific to each event, to enable healthcare facilities to have a framework to adapt and implement in the various contexts.

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 lawsuits (this system, in use in the hospital where the research was conducted, will be better described in chapter 5).

Despite these indications of a general nature, at the local level, not all hospitals have implemented a system of clinical risk management, and where instead it is present, its function is not always integrated with business processes. By doing so it fails to provide the necessary support in the management of adverse events and it is mostly a mere compliance with the ministerial recommendations rather than a real tried to improve the quality of the health care system.

The Italian situation can therefore define patchy, with regions or health care companies in the virtuous clinical risk management and other definitely still lagging in the implementation of actual policies in this regard.

1.5 Distinctive features of the healthcare organizations

In the analysis of the healthcare companies is necessary to highlight the distinctive features of medical processes. They are in fact: unpredictable and cannot be standardized; closely related to the patient characteristics and influenced by a variety of factors, both internal and external. We can summarize the distinctive features of health care organizations in the following eight aspects: (Helmreich, 2000)

I. the close relationship between the patient and the staff, any type of intervention carried out on the patient has a high value in terms of safety, even for the health care worker. For this reason it is necessary to involve the patient, making it participant of fundamental knowledge about their own health status, and encouraging him to become the protagonist of diagnostic and therapeutic choices.

II. very high manual component in its business, despite the enormous development of assistive and diagnostic technologies, the work of the professional and his contribution is still predominant and necessary.

III. technology-intensive, the delivery of quality care always requires a greater extent in the use of highly advanced technologies. Therefore, healthcare companies are in the necessary condition of having to acquire and manage new facilities, equipment and technologies for the diagnosis and treatment, hence incurring huge costs of implementation and management.

IV. highly capital intensive, the management of a healthcare company is particularly costly.

V. professional type organization, this aspect is related to the behavior of the different professions within the organization.

VI. the extreme differentiation of product-service delivered, the activities are many and extremely varied in patient care. The most immediate consequences are: a difficult standardization of health activities; a difficulty in the analysis and evaluation of the risks related to different tasks; simultaneity between production and consumption.

VII. the organizational complexity, the high number of employees; the wide variety of services provided to users; the need to provide the services near the place of consumption; temporal continuity request.

VIII. Knowledge Based e Learning Organizations, healthcare organizations are knowledge-intensive companies. This knowledge comes from multiple sources and is closely related to the technical and professional skills of the operators. In this regard, relevant aspects are related to ongoing staff training and information to the patient.

CHAPTER 2 Organizational Culture and Clinical Risk Management

2.1 The safety culture: definitions

In complex systems that require high risk control, a "culture of risk prevention systems" has historically been built. In these systems, the error is considered a possible event and, therefore, the processes and the possible modes of failure are systematically analyzed and verified. In the healthcare sector, the blame and guilt culture, has prevented so far to tackle the problem of adverse events with the necessary transparency culture. Blame is a widespread habit in health care. Usually you shift the responsibility of an adverse event of a fault, typically the operator who has carried out "the last act of the chain of genesis of the event." Leape (1994) argues that in health care the cause of this condition lies in the relationship between health professionals and their mistakes. In everyday practice, the message is that mistakes are unacceptable.

The idea that the error is due to the fault of individual generates two negative effects:

1. The tendency to hide the errors;
2. Tendency to ignore the responsibility of the remote causes.

The promotion of a safety culture is not only a statement of purpose, but must include a systematic strategy of communication and training. It is also necessary preliminary investigation in order to know the initial conditions and then act on specific aspects of improvement.

The definition and conceptualization of safety culture mainly derived from the general concept of organizational culture. In his book In his book: Organizational Culture and Leadership (1992) Edgar H. Schein defined culture accordingly:

"A pattern of shared basic assumptions that the group learned as it solved its problems of external adaptation and internal integration, that has worked well enough to be considered valid

and, therefore, to be taught to new members as the correct way to perceive, think, and feel in relation to those problems".

Schein developed a model to explain the basic elements of cultures. His model of culture contains the following layers:

- ✓ Artifacts: they are the visible elements in a culture. Artifacts can be recognized by people not part of the culture. Artifacts can be dress codes, furniture, art, work climate, stories, work processes, organizational structures etc. The outsider might easily see these artifacts, but might not be able to fully understand why these artifacts have been established. To understand this, outsiders can look at the espoused values in the culture.
- ✓ Espoused values: they are the values normally espoused by the leading figures of a culture. Espoused values could be represented by the philosophies, strategies and goals sought realized by leaders. However, the values sought by leaders should be supported by some general and shared assumptions about how a company should be run, or how employees should be managed. If espoused values by leaders are not in line with the general assumptions of the culture, this might signal trouble.
- ✓ Assumptions: they reflects the shared values within the specific culture. These values are often ill-defined, and will oftentimes not be especially visible to the members of the culture. Assumptions and espoused values are possibly not correlated, and the espoused values may not at all be rooted in the actual values of the culture. This may cause great problems, where the differences between espoused and actual values may create frustrations, lack of morale and inefficiency. Core assumptions can be assumptions regarding the human nature, human relationships etc.

A recent literature review made by Wiegmann et all (2002) provides various definitions of the concept of safety culture:

Carroll (1998) (Nuclear power, US): *Safety culture refers to a high value (priority) placed on worker safety and public (nuclear) safety by everyone in every group and at every level of the* *plant. It also refers to expectations that people will act to preserve and enhance safety, take personal responsibility for safety, and be rewarded consistent with these values.*

Ciavarelli & Figlock (1996) (Naval aviation, US): *Safety culture is defined as the shared values, beliefs, assumptions, and norms which may govern organizational decision making, as well as individual and group attitudes about safety.*

Cooper (2000) (Theoretical): *Safety culture is a sub-facet of organizational culture, which is thought to affect member's attitudes and behavior in relation to an organization's ongoing health and safety performance.*

Cox & Cox (1991) (Industrial gases, European): *Safety culture reflects attitudes, beliefs, perceptions, and values that employees share in relation to safety.*

Eiff (1999) (Aviation, US): *A safety culture exists within an organization where each individual employee, regardless of their position, assumes an active role in error prevention and that role is supported by the organization.*

Flin, Mearns, Gordon, & Fleming (1998) (Offshore oil and gas, UK): *Safety Culture refers to entrenched attitudes and opinions which a group of people share with respect to safety. It is more stable [than safety climate] and resistant to change. Safety culture is defined as the attitudes, values, norms and beliefs which a particular group of people share with respect to risk and safety.*

The common aspects of the given definitions indicate that the culture of safety:

• refers to the values shared by all members of the group or organization (sharing - universal acceptance);

• concerns the formal aspects of safety in an organization, and often, but not exclusively, the management and supervision system;

• emphasizes the contribution of everyone, at every level;

• has an impact on the operators' behavior;

• has to do with the reward system and safety performance;

• is based on the willingness of an organization to develop and learn from mistakes and accidents;

• it is durable, stable and resistant to change.

A definition of safety culture able to consider all the elements listed above is the one of UK Health and Safety Commission in 1993: *The safety culture of an organization is the product of individuals and group values, attitudes, perceptions, competencies and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management. Organization with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of importance of safety and by confidence in the efficacy of preventative measures.*

2.2 Main indicators of safety culture

Based on literature analysis of areas where security plays a decisive role (complex socio-technical systems with high risk), leading indicators of safety culture can be summarized as follows:

1 Organizational commitment and leadership; they play a critical role in the promotion of a safety culture. The organizational commitment concerns the extent to which strategic management recognizes the safety culture as the principal value of the organization. This commitment is manifested in the ability of the management to maintain a constant and positive safety attitude.

2 Management involvement; active presence in seminars and training, the ability to stay in touch with the factor "risk" and use of communication across the entire hierarchy.

3 Effective communication; a key objective of management is to implement effective communication flows, in order to transmit the information as clear as possible at all company levels.

4 Staff Involvement and "Empowerment"; errors can occur at any level of the organization. However, often operators at the “sharp end” represent the last defense against such errors. Staff empowerment is the delegation of authority and responsibility by the higher levels of management. In this way it is obtained an increase in motivation and responsibility towards safety objectives (ownership); staff have the opportunity to intervene substantially in decisions in order to activate and achieve improvements and feels a part of the positive results achieved. An important role in this regard is played by training.

5 Reward systems; a key component of the safety culture of an organization is the way in which the secure or insecure behavior is evaluated and the consistency with which rewards and penalties are assigned in accordance with such assessments.

6 Reporting systems; an efficient and systematic reporting system is the key to identifying the weaknesses and vulnerabilities of a security system before the accident happen.

James Reason, in his work Managing the Risk of Organizational Accidents (1997) describes an high reliability organization (in term of strong safety culture) with the following characteristics:

- Informed; professionals have precise knowledge of the technical, organizational, environmental and human factors that combine to determine the errors. Those who manage and operate the system possess knowledge about human factors, technical, organizational and environmental factors that determine the security of the system as a whole.
- Reporting; both staff and management are aware of the importance of data accuracy and reward the reporting of errors and near misses.

- Just; in the organization there is a climate of trust that encourages the reporting of hazards and errors by operators.
- Flexible; responsibility to take immediate solutions for the security is given to those who work in the sharp end.
- Learning; learning from the errors.

2.3 The evolution of safety culture

Parker et all. (2006) created a framework for the evolution of organizational safety culture based on Westrum's typologies of organizational cultures. Their model consists of five safety culture levels and it is focused on different way to manage communication and information elements concerning safety.

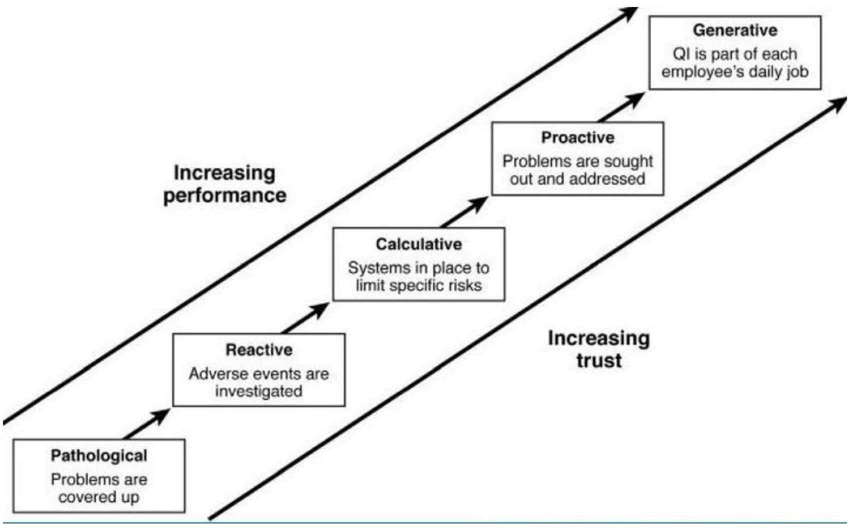

Figure 6. The evolution of safety culture, Parker et all. 2006.

Figure 6 shows the five stages of the safety culture evolution. They are:

PATHOLOGICAL. Power-oriented. Focus on the person, on individual needs and the glory. Information is a resource staff and is used to exert power. Safety is a problem caused by workers (blame culture).

REACTIVE. Rules oriented. Focus on rules, positions and functional divisions. Safety is taken seriously, but actions were taken only after the occurrence of accidents (blame culture). Lack of systematic risk management.

CALCULATIVE. Safety is driven by the management system, through massive data collections. Safety is still imposed and not sought by the staff.

PROACTIVE. Staff involvement. Proactive organization try to anticipate safety issue before they happen.

GENERATIVE. Performance-oriented. Focused on the mission. Active participation at all levels. Security as part of the business and as a priority.

It is clear that management philosophies oriented according to the first two types of organizational culture in the system produce a greater susceptibility to the onset of latent vulnerabilities (latent failures). Of course every organization has elements that reflect the philosophies of the five types. It is the different proportion or the predominance of one or other of the trends that determine the outcomes and quality of safety of the organization.

CHAPTER 3. The adverse event as a performance indicator of planning and control system in healthcare.

3.1 The reorganization of the National Health Service in Italy

The explosion of health care costs entailed by the National and Regional Governments an attention to refine techniques of planning and control in healthcare The reorganization of the National Health Service in Italy, as provided for by Legislative Decree 502/92 and subsequent modifications, has several fundamental pillars:

- the transformation of the local healthcare units USL in companies ASL with its own legal personality and administrative, organizational, financial and accounting autonomy (New Public Management)
- the widespread adoption of the budgeting, and then the activation of planning and control system P&C.

The first aspect of the legislation that has innovated the health sector is the recognition of the legal personality of the local health units and public law, endowed with organizational, patrimonial, accounting, managerial and technical autonomy. This autonomy implies the assumption by of healthcare organizations of a number of obligations and responsibilities: a) the role and responsibilities of the Director-General; b) obligation to draw up estimated and final balance sheet; c) the requirement for keeping of a cost accounting system for cost centers (responsibility centers); d) a requirement to balance the budget.

"Corporatization" means recognizing that the health care facility must be governed according to the business company principles. The recognition of the healthcare facility as a company implies that the management activities must be geared towards a fundamental principle of the economic theory: the profitability principle (for a public organization as the healthcare is, the profitability principle can be assumed as a budget balance). The budget balance must be pursued together with the effectiveness and efficiency. The efficiency expresses the capacity to use in the most rational way the resources. It is measured by the ratio between results and resources used OUTPUT / INPUT. The effectiveness expresses the capacity to achieve your desired goals. It is measured by the ratio between the results and objectives PROGRAMMED OUTPUT / OFFERED OUTPUT.

The effectiveness is divided in two dimensions: Economic effectiveness (management) expressing the adequacy of the delivered services compared to the objectives; it is focused on output (health benefit provided). Health effectiveness (impact) expressing the capacity to change the health' s needs through the service s provided; it is focused on outcome (consequences, the effects of the delivery of benefits such as halt the progression of disease or restoring the functional capacity of a person).

The second aspect of the legislation that has innovated the health sector is the creation of P&C system. The creation, within any organization, of a planning and control system, involves multiple critical elements related to the meaningful impact on key components of the environment where it is applied. The activation of planning and control system is even more problematic in a healthcare setting, in which the above mentioned difficulties are made even more critical by some elements that characterize the healthcare context (as mentioned in chapter1 paragraph 1.5).

Specifically: the objective organizational complexity, the heterogeneity of production processes, the high autonomy of the professional managers and operators, the lack of business culture and a sensitivity in the company, the tendency to an exasperated sectorization with considerable difficulty of horizontal (between different sectors of the company) and vertical (between different levels of responsibility) communication, the lack of decision support system (management of drugs, medical supplies and non-medical equipment).

The activation of a planning and control process, must be supported by an integrated training and technical assistance, which takes as a basis the following criteria:

- Involvement of all those who, for the functional position, are designed as referents for the P&C system;
- Integration between training value and concreteness operational intervention, by using the logic of learning by doing that is a condition for successful interventions;
- Utmost use of internal resources, with support, training and stimulus actions;
- Gradual and progressive approach, which should be the opportunity for an organizational simultaneous and synergic growth.

The P&C tools and procedures should allow to achieve the following objectives:

- The measurement of the total costs of the operating units to which it is applied, and the evaluation of the weight that within those overall costs single factors have (personnel, drugs, materials, equipment);
- The measurement of the unit costs for the health service (the cost of an radiology or a gynecology examination, a day hospital or a specialist check), and analysis of the variability of these costs among different departments or services (which are the differences and what are the factors that determine them);
- The calculation of a series of indicators of efficiency, effectiveness and quality which make possible the identification of diseconomies and dysfunctionality;
- Critical evaluation of a number of organizational issues that affect the effectiveness and efficiency (quantitative and qualitative resource allocation and methods of their use);
- An important enhancement of the self-evaluation and self-analysis operators' capacity;
- An overall growth of management skills.

3.2 The planning and control system P&C

Planning and control in health care has received an increased amount of attention over the last ten years, both in practice and in the literature. This attention is due to an increase in demand for health care and increasing expenditures. As a result, health care organizations are trying to reorganize processes more efficiently and effectively. Planning and control has a prosperous tradition in manufacturing MPC: "Manufacturing planning and control address decisions on the acquisition, utilization and allocation of production resources to satisfy customer requirements in the most efficient and effective way" (Graves, 2002). MPC organize planning and control functions hierarchically. It reflects the natural process of increasing disaggregation in decision making as time progresses, and more information becomes available. It also reflects the hierarchical (department) structure of most organizations. Many MPC frameworks use the hierarchical division into a strategic, tactical, and operational level. As argued by Zijm (2000), this myopic orientation to one managerial area is the main cause that these MPC frameworks are inadequate in practice. Modern MPC frameworks integrate these orientations.

Unfortunately, health care planning and control lags far behind manufacturing ones. Successful manufacturing planning and control methods cannot be directly imported in healthcare, because of the unique nature of this kind of company. Some common reasons declared in the literature of this impossibility to use P&C manufacturing methods in healthcare include:

1. Health care organizations have often lack of cooperation among internal parties (doctors, administrators, etc.). These groups have their own, sometimes conflicting, objectives.
2. Crucial information required for planning and control are often not available.
3. Managers tend not to look beyond the border of their department, and planning and control is fragmented.
4. While health care managers are generally dedicated to provide the best possible service, they lack the knowledge and training to make the best use of the available resources.

Various researchers have proposed frameworks for (hierarchical) planning and control in health care. Roth and Van Dierdonck (1995) propose a hierarchical framework based on application of the Manufacturing Resource Planning concept. This framework consider s both resource capacity planning and material planning, and focuses specifically on hospitals. It relies on diagnosis related groups DRGs which serve as the "bill of materials" in Manufacturing Resource Planning to derive the resource and material requirements of patient groups. Roth and Van Dierdonck propose to use DRGs to facilitate integrated hospital wide planning and control.

Vissers et al. (2001) propose a framework for production control in hospitals. The approach assumes the common situation that a hospital is organized in relatively independent business units. It is limited to resource capacity planning, for which it distinguishes five hierarchical levels: strategic planning, patient volumes planning and control, resources planning and control, patient group planning, and patient planning and control. These levels address "offline" (in advance) decision making. "Online" (reactive) operational control functions such as reactive planning (for example, add on scheduling upon arrival of an emergency case) and monitoring are not considered in their framework .

3.3 The principles of management control in health care

The principles of management control in health care companies are represented by:

- Economic management control. It is expressed by the costs and revenues, this principle measure the economic aspect of management.
- Monetary management control. It is expressed by the cash flows and measure the monetary aspect of management.
- Asset management control (investment). It is expressed by the capital invested and measure the pecuniary aspect of management.

- Qualitative control. The quality control today assumes a key role within the management processes in healthcare. Healthcare must take up as its main objective the creation and growth of value not intended in economic terms but in qualitative ones.
- Organizational control. The organizational control regards the interactions between the control system and the organizational system, in particular the relationship between: management style and control, motivational system and control and reward system and control.

3.4 Management Control tools

Why measuring hospital activity?

Measurement is central to the concept of quality improvement; it provides a means to define what hospitals actually do, and to compare that with the original targets in order to identify opportunities for improvement. The measurement of the product or business of an hospitals is a prerequisite both for their proper financing and for a proper performance management. Either options are especially important when it comes to public hospitals. In private hospitals, in fact, the achievement of profit guarantee that the hospital is both productive and it has set the right prices for the services provided. With the generic term of performance hospital can be indicate both the efficiency and effectiveness. The efficiency has to do with the services provided, the effectiveness with the results, in terms of health. Efficiency, in turn, has two meanings:

-Technical efficiency: the most product/service obtainable with a given use of inputs (doctors, nurses, etc..), or the lower use of the factors to obtain a given product/service.

- Economic or allocative efficiency: the most product achievable with a given cost of production (or the lowest cost for a given product/service).

To measure the effectiveness instead we must, in theory, calculate the results, expressed as effects on health for instance in life-years gained. We then calculate the hospital's operating costs, both direct and indirect. It finally puts in relation the effectiveness with costs: the greater the ratio between effectiveness and costs, in the comparison between different hospitals, shows the more effective. The effectiveness of measurement strategies depends on many variables including their purpose, the national culture, how they are applied and how the results are used.

Some tools of management control system in healthcare are:

⇒ The Analytical Accounting System. The regulatory changes on the health sector have introduced the requirement for general and analytical accounting. General accounting provides us with important information about the relationship with the external environment but it is analytical accounting that allows us to implement an effective management control at internal level. The analytical accounting system is based on the final balance per cost centers. A cost centers represent a department, division, or other subunit of an institution established within its accounting system so that the income and expenses of the subunit can be separated from the income or expenses of other centers and monitored for cost and benefit. The costs of each factors (staff, consumer goods, etc.) are allocated to cost centers in a direct way when that particular cost center is the only direct user of the resource. The cost is allocated without the execution of processing intermediates, and in a direct way, the individual cost center and the team leader can exercise a control function on the mode of formation of the values of cost and / or results associated with them.

⇒ DRG Diagnosis Related Group. The DRG system was born around the 70s, designed by Professor Robert Fetter, Yale University, as a basis for assessment of the resources in a hospital clinic. The idea was to perform a weighted categorization of cases of hospital admissions, constructing homogeneous groups of patients and in terms of the type treated, and in terms of service costs. DRGs were introduced in Italy following the establishment of the new funding system for hospital care, which took place through the Legislative Decree no. 502/92. The financing system, called perspective, has three basic characteristics listed below. The hospitals are financed according to the number and type of admissions made, no longer on the basis of the costs incurred or the number of days of hospitalization produced as implied by the old system. Fees associated with each category of admissions are pre-determined and independent of the actual costs of production incurred by the individual hospital. Each hospital may retain any positive margin budget but must deal with any negative margins resulting from an imbalance between costs and revenues. This is a system that allows us to classify all hospital's discharged patients in homogeneous groups per absorption of used resources. This aspect makes it possible to economically quantify this resources' absorption and thus remunerate any episode of hospitalization. One of the aim of the system is to monitor and control health care costs. The DRG is assigned to each patient discharged through a software that uses some variables related to the patient to give the corresponding DRG (age, sex, type of discharge, principal diagnosis, secondary diagnoses, procedures, etc.). All this information is available and used by the software following the completion, by the physician responsible for the patient's discharge, of Hospital Discharge Register SDO. The DRG consist of a three digit number (001 to 579) for a total of 538 DRGs in the current version in use in Italy since 2009 (version 24.0). The DRG are in turn grouped into MDC Major Diagnosis Category. In total the MDC are 25, each of the DRG 538 is inserted in a MDC for example the DRG 001 to 035 are part of MDC1 Nervous System. The DRG system is a system of health care description based on the assumption that similar diseases in similar wards involve roughly the same consumption of material and human resources (input). Hospital admissions that could be addressed with equal efficiency and greater economy in the use of resources are defined as "inappropriate" from the organizational point of view. The concept of the threshold is the value beyond which a case is considered outliner. For each DRG exists a threshold value, expressed in days of hospitalization; which expresses the value beyond which a case is considered outside the threshold. For each day exceeding the threshold shall be paid a supplementary fee only if the hospital days outside the threshold are considered appropriate. DRG rates are determined at the regional level on the basis of the standard cost of production.

⇒ The Reporting System. Reporting is a communication activity of relevant information about the activity carried out, concerning the achievement of a performance and the use of resources. Reports are synthesis documents that summarize the significant variables for the purposes of management control. This system aims to provide, to the different levels of responsibility within the company, the information needed to address the various actions taken by the organization to achieve its objectives. The reporting is not just an accounting tool, but it is a real operational mechanism that activates virtually the monitoring process through the analysis of the information contained herein. The management characteristics of healthcare organizations affect and complicate the design and introduction of the reporting system. The main critical factors influencing the implementation phase of the reporting system in healthcare organizations are the follows. The organizational culture. It 'important to note that in health care organizations obstructive behavior may occur towards the development of a system of management control and performance evaluation. The Technical Framework. When drafting the report timeliness with which will inform the recipients and the relevance of the data supplied to them are fundamental. Generally in healthcare organizations information are available only for costs, while the ability to correlate data between cost and performance is unsatisfactory. The structure of responsibility. Healthcare companies are characterized by the presence of multiple responsibilities due to the existence of transversal responsibilities within the organization 's. The social role played by health care companies, particularly public ones, allow the inclusion among stakeholders of business data, a broader set of stakeholders which include of course the users.

⇒ The Indicators System. Indicator measurement and monitoring serve many purposes. They make it possible to: document the quality of care; make comparisons (benchmarking) over time between places (hospitals); make judgments and set priorities (e.g. choosing a hospital or surgery, or organizing medical care); support accountability, regulation, and accreditation; support quality improvement; and support patient choice of providers. The use of indicators enables professionals and organizations to monitor and evaluate what happens to patients as a consequence of how well professionals and organizational systems function to provide for the needs of patients. Performance indicators are defined as statistics or other units of information that, directly or indirectly, reflect either the extent to which an anticipated outcome is achieved or the quality of the processes leading to that outcome. "Performance" must be defined in relation to explicit goals reflecting the values of various stakeholders (such as patients, professions, insurers, regulators). In reality, however, very few performance measurement systems focus on health outcomes valued by customers. "Measurement" implies objective assessment but does not itself include judgment of values or quality; these may be added by those who later present and interpret the data. Healthcare organizations using both outcome assessment tools and processes assessment tools as they must be able, in different ways, to measure: the cost management, meaning the ability to meet the needs of public health, using a flow of wealth considered socially and economically bearable by the community; the effectiveness of the proposed action as correspondence between quality and quantity of the activity output, and the quality and quantity of users' needs, the satisfaction of which constitutes the final result; the resource efficiency, defined as the ratio between input and intermediate output. The performance management of healthcare organizations, therefore, appears to be complex; thus it is necessary to articulate a system of evaluation and multi-dimensional, based on a set of synthetic indicators including: financial, economic, equity, efficiency, effectiveness and quality management indicators. Taking as an example the case of the Australian health care we can see as in 2001, the National Health Performance Committee (NHPC) developed a framework to report on the performance of the Australian health system, which was adopted by health ministers. The NHPC describes the framework as a structure to guide the understanding and evaluation of the health system, facilitating consideration of how well the health system or program is performing. The framework has three domains: Health Status, Determinants of Health and Health System Performance. Questions are posed for each domain and a number of dimensions have been identified within each domain. The Health System Performance domain is most directly relevant to assessment of the provision of hospital and other health-care services. The six dimensions are: Effectiveness, Safety, Responsiveness, Continuity of care, Accessibility and Efficiency & sustainability. In reference to the subject matter of this research, namely the clinical risk, we will focus on only one of the dimensions mentioned above: safety. The safety are defined as the avoidance or reduction to acceptable limits of actual or potential harm from health-care management or the environment in which health care is delivered. The Performance indicator of safety are: adverse events treated in hospitals and unplanned/unexpected readmissions within 28 days of selected surgical admissions.

As we can see in the Australian example CRM can be used as a dimension for performance management within the Planning and Control system of the healthcare companies. The number of adverse event treated in the hospital can represent a good indicator of hospital performance since clinical errors may be indicators of both the individual performance of the staff members that the overall management of the process of care delivery. Monitoring health care quality is impossible without the use of clinical indicators. They create the basis for quality improvement and prioritization in the health care system. By measuring and monitoring clinical risk indicators it is possible to further investigate the process of medical error generation in order to understand where e how intervene to ensure the improvement of hospital outcome. To ensure that reliable and valid clinical indicators are used, they must be designed, defined, and implemented with scientific rigor.

CHAPTER 4. System dynamics and clinical risk management

4.1 Traditional CRM's methods

Researches by Young et al. (2002) and Misson (2001) show that the following dimensions represent three major variables of risk management:

- **Risks to patients** – following medical ethical standards is key to minimizing risks and maintaining patient safety. This is in addition to compliance with statutory regulation, learning from complaints, and ensuring regular systems reviews and questioning by critical event audit.
- **Risks to practitioners** – ensuring that clinicians are immunized against infectious diseases, work in a safe environment, and are helped to stay current as essential parts of quality assurance.
- **Risks to the organization** – poor quality is a threat to any organization. In addition to reducing risks to patients and staff, organizations need to ensure high quality employment practices, by introducing measures to review individual and team performance, and introducing well-designed policies on public involvement.

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.

As a result, CRM systems are essentially dedicated to delivering risk reduction strategies. With this purpose, CRM goals include:

- identification of risks,
- prevention of harm, injury and loss,

- controlling systems and processes with the aim of eliminating or reducing severity of damage.

It is important to note that healthcare companies adopt strategies to identify potential causes of active or latent errors. They also implement organizational procedures aimed at eliminating the causes of the identified errors. 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.

a) The **Root Cause Analysis** (RCA) is a defined process that seeks to explore all of the possible factors associated with an incident by asking: what happened, why it happened and what can be done to prevent it from happening again. RCA is based on the systemic approach provided by Reason and it is aimed to find the *root cause*, namely the cause that can be reasonably identified as basic and that is under the direct control of the management. Starting from the systemic perspective proposed by Reason, the root causes lie usually to the level of latent failures (organizational and work environment). As a consequence, the management should not focus on the analysis of errors at the level of active failure, but always investigate "what is behind" (figure 7).

Figure7. Systemic approach, based on Reason 2000.

A number of models have been developed using root cause analysis principles, but all the models ask the following set of questions:

- ✓ What happened?
- ✓ Who was involved?
- ✓ When did it happen?
- ✓ Where did it happen?
- ✓ How severe was the actual or potential harm?
- ✓ What is the likelihood of recurrence?
- ✓ What were the consequences?

The defining characteristics of root cause analysis include:

- o review by an inter-professional team knowledgeable about the processes involved in the event;
- o analysis of systems and processes rather than individual performance;
- o deep analysis using "what" and "why" probes until all aspects of the process are reviewed and contributing factors are considered;
- o identification of potential changes that could be made in systems or processes to improve performance and reduce the likelihood of similar adverse events or close calls in the future.

b) The Clinical Audit involves systematically looking at the procedures used for diagnosis, care and treatment, examining how associated resources are used and investigating the care effects on the outcome and quality of life for the patient (Department of Health USA 1993). In particular, Clinical Audit takes into account all the aspects of patient care, from assessment to outcome (see figure 8).

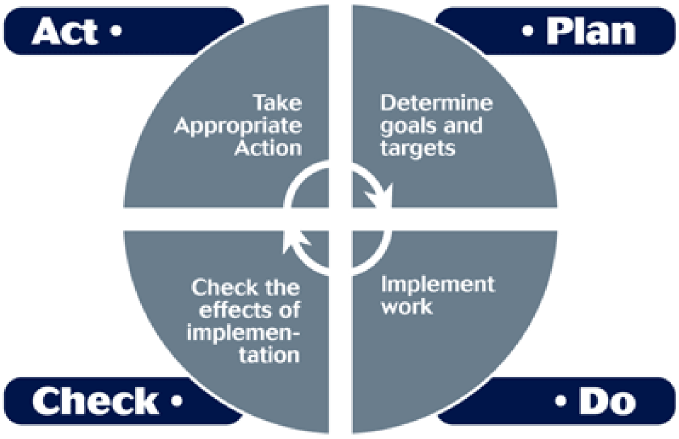

Figure8. Audit cycle.

The main stages of the clinical audit process are:

1) select a topic.

2) review literature

3) set standards

4) design audit

5) collect data

6) analyze data

7) feedback findings

8) change practice

9) set-review standards

10) re-audit.

c) The Incident Reporting method consist of a systematic event recording activity. Precisely, it implies the use of forms that are filled out in order to record details of an unusual event that occurs at the facility, such as an injury to a patient. The aim of Incident reporting is to document the exact details of the incident, in order to gather data that will be useful to draw up strategies of improvement. Generally, according to healthcare guidelines, the report must be filled out as soon as possible following the incident (but after the situation has been stabilized). This way, the details written in the report are as accurate as possible. The main reason for reporting incidents to improve patient safety is the belief that safety can be increased by learning from incidents and near misses, rather than pretending that they have not happened. Each National Healthcare Executive provides a different Incident Reporting procedure to the healthcare companies.

4.2 New tools for CRM

The methods listed above are reactive methods. They are used just after that an adverse event has occurred. For this reason they cannot support the hospital management to set proactive CRM policies.

In recent years two of the most important worldwide organization active in the field of clinical risk management developed two proactive methods able to identify critical areas for the healthcare.

The Institute for Healthcare Improvement IHI[4] formed the Idealized Design of the Medication System Group in May 2000. This group of 30 physicians, pharmacists, nurses, statisticians, and other professionals established an aim to design a medication system that is safer by a factor of 10 and more cost effective than systems currently in use. They developed the IHI Global Trigger Tool for Measuring Adverse Events that provides an easy-to-use method for accurately identifying adverse events (harm) and measuring the rate of adverse events over time. Tracking adverse events over time is a useful way to tell if changes being made are improving the safety of the care processes. The Trigger Tool methodology is a retrospective review of a random sample of inpatient hospital records using “triggers” (or clues) to identify possible adverse

[4] The Institute for Healthcare Improvement (IHI), an independent not-for-profit organization based in Cambridge, Massachusetts with the mission to **i**mprove health and health care worldwide.

events. Since its development in late 2003, use of the IHI Global Trigger Tool has spread from collaborative projects to large-scale improvement efforts, including IHI's 5 Million Lives Campaign. The IHI Global Trigger Tool has become a tool that hundreds of hospitals in multiple countries now use to monitor adverse event rates while working to improve patient safety. The IHI Global Trigger Tool requires manual review of closed inpatient records (records with completed discharge summaries and coding). A team of 2 auditors and 1 doctor examines a sample medical records in order to identify where is the trigger in the process of delivery of care. In this way it is possible to implement improvement actions on specific aspects of the system to prevent certain errors may occur in the future. The IHI Global Trigger Tool contains six "modules," or groupings of triggers. Four of the groupings are designed to reflect adverse events that commonly occur in a particular unit; the Cares and Medication groupings are designed to reflect adverse events that can occur anywhere in the hospital. The six modules are:

- Cares
- Medication
- Surgical
- Intensive Care
- Perinatal
- Emergency Department

If a trigger is identified in a record, the "positive trigger" indicates only the presence of a trigger, not necessarily an adverse event. Reviewers will find many positive triggers, but will identify many fewer adverse events. Occasionally, reviewers will find adverse events with no antecedent trigger. However, a positive trigger most often is not an adverse event in and of itself; rather, it is just a clue that one may have occurred.

The JCI works to improve patient safety and quality of health care in the international community by offering education, publications, advisory services, and international accreditation and certification. In more than 100 countries, JCI partners with hospitals, clinics, and academic medical centers; health systems and agencies; government ministries; academia; and international advocates to promote rigorous standards of care and to provide solutions for achieving peak performance. The process of accreditation by the JCI is a voluntary process through which an organization can request to be certified ensuring compliance with specific standards. The standards are organized around and grouped by the important functions common to all health care organizations. The standards are divided into two sections: patient-centered functions and organization functions.. These functions apply to the entire organization as well as to each department, unit, or service within the organization. The survey process gathers standards compliance information throughout the entire organization, and the accreditation decision is based on the overall level of compliance found throughout the entire organization .

Section one Patient-Centered Standards:

– Access to Care and Continuity of Care

– Patient and Family Rights

– Assessment of Patients

– Care of Patients

– Anesthesia and Surgical Care

– Medication Management and Use

– Patient and Family Education

Section two Health Care Organization Management Standards:

–Quality Improvement and Patient Safety.

–Prevention and Control of Infections.

–Governance, Leadership, and Direction.

–Facility Management and Safety.

–Staff Qualifications and Education.

–Management of Communication and Information .

The correct implementation of these standards help the management to set quality and safety level for the whole organization in order to prevent the possibility that an adverse event may occur.

4.3 CRM traditional methods' pitfalls

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 lawsuits 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.

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

System Dynamics SD is a methodology for understanding the behavior of complex systems over time. It deals with internal feedback loops, time delays, stocks, and flows that affect the behavior of the entire system. These elements help describe how even seemingly simple systems display baffling nonlinearity (Sterman 2001; Repenning 2001). SD uses tools like causal mapping and simulation modeling (Bendoly et al., 2010). Traditional SD models incorporate bounded rational individuals’ decisions as well as heuristics and biases, and examine their impact in complex dynamic settings, where the results of individuals' decisions change the future state of the system which, in turn, influences future decisions.

Research by Bendoly et al. 2010 demonstrates that there are two types of misperceptions of feedback: structure and dynamics. Misperceptions of feedback structure are caused by mental maps that have a poor representation of the complexity of the real system; for instance, a mental model that ignores important feedback processes in the system. Misperceptions of feedback dynamics are caused by inaccurate mental models of how the system behaves. In this case, a mental model that fails to capture the impact caused by accumulations will poorly infer their dynamics. Sterman's work (1989) suggests that the misperception of feedback arises from people's adoption of deficient dynamic mental models that guide decisions. These deficiencies include:

- an event-based perspective, focusing on specific events instead of the system structure that generates them;
- an open loop view of causality where previous decisions lead to outcomes and do not change the current state;
- failure to understand the impact of delays and of accumulations by not separating cause and effect;
- insensitivity to nonlinearities that alter the structure and behavior of the system.

These misconceptions may cause decision making errors (Bendoly et al. 2010).

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[5]: 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

[5] Based on Goldsmith and Siegel (2011).

(Jones et al., 2006); Obesity (Homer et al., 2006); and chronic illnesses more generally (Hirsch and Immediato, 1999). Literature focusing on management includes: Electronic Health Records Adoption (Erdil & Emerson, 2008); Patient flow (Wolstenholme, 1999); Safe Design Capacity (Wolstenholme et al, 2007); and Waiting Lists (Van Ackere and Smith 1999). These scientific contributions highlighted the numerous advantages of using SD models to manage the complexity characterizing the healthcare sector.

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. Homer and Hirsch realized that the best way to explain the value of system dynamics modeling is through a model. They focused their attention to a challenge question: "Why is it that, despite repeated calls for a greater emphasis on primary prevention of chronic disease, the vast majority of health activities and expenditures in the United States are made not for such prevention but rather for disease management and care?" (Homer and Hirsch 2006). To answer to this question the authors have built a relatively simple model (figure 9). The model demonstrates how "upstream prevention may become inadvertently *squeezed out* by downstream prevention and suggests that a focusing of resources on life-extending clinical tools may ultimately hurt more than it helps" (Homer and Hirsch 2006).

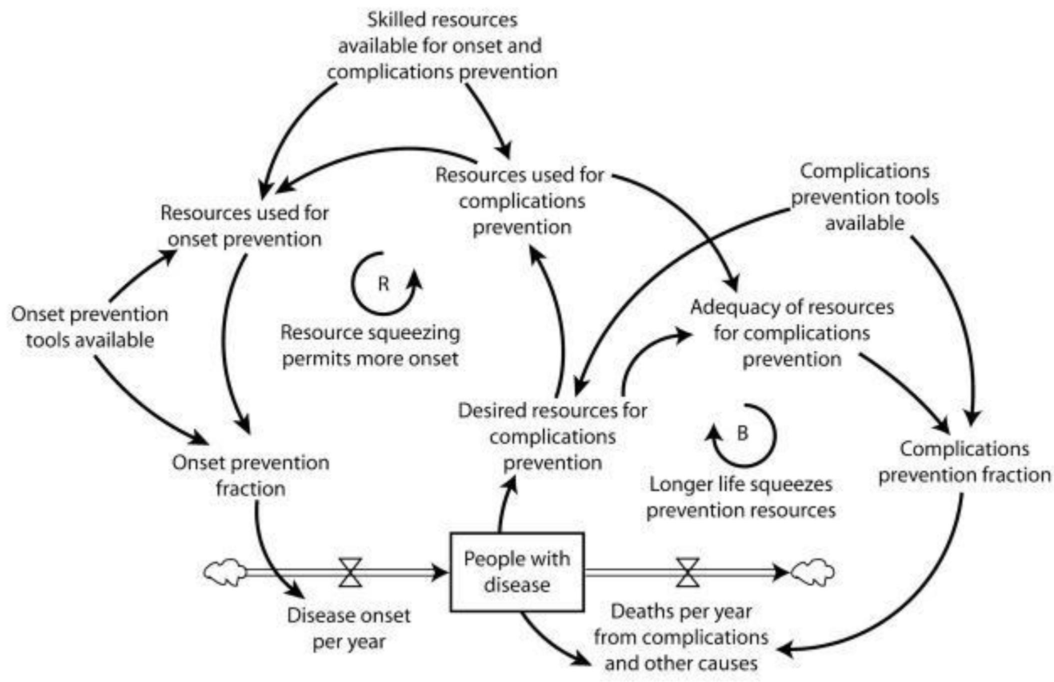

Figure9. A simple model of chronic disease prevention (Homer & Hirsch 2006).

Wolstenholme is one of the leading researcher in the world about the application of system dynamics methodology to healthcare sector, and from this point of view is one of the main node of the international scientific network about this topic. He has an international reputation in both academia and business for his work in the development and application of systems thinking and system dynamics. He has worked at board level in a number of major public and private organizations this work has involved the personal construction of over 50 system dynamics models. Models in health and social care have included ones to analyze delayed hospital discharges, capacity planning, mental health reform, social service planning and dynamic cost benefit analysis.

In reference to cost benefit analysis, the author underlines the value that system dynamics can add to conventional cost benefit analysis. He argues that “dynamic factors are often left out of cost benefit analysis simply because they cause too much complexity for decision makers, whereas system dynamics allows these factors to be included without masking the clarity of the case” (Wolstenholme 2007). From this evidence seems clear how cost benefit analysis and system dynamics are very complimentary and should be used together in strategic planning.

PART II

THE RESEARCH

CHAPTER 5 The research

5.1 Problem definition

This research is part the agreement between the University of Palermo and the ASP6 Palermo (the Provincial body for Health Services) established on February 2013. This agreement is based on information and knowledge provided by a task force of (technical) experts about Clinical Risk Management and System Dynamics. The aim of the agreement is to achieve a better understanding of the issue itself and to establish some policies able to capture the processes of error generation and to adjust them.

The interest in the specific topic of CRM arises from an increasing patients awareness about their rights and the importance attributed by health care companies to the quality of their services. In particular, in the second half of 2010 inside ASP6 Palermo, the management has started a business plan for clinical risk management. The plan envisaged two different levels of intervention, on the one hand, the implementation of a system for the recognition of sources related to the adverse event (SIMES data stream), and on the other hand, the diffusion of a patient safety culture, achieved through the learning potential derived from the error. Starting from the end of 2010 the ASP6 Risk Manager publishes an annual CRM report in order to monitor the progress of the phenomenon and to publicize the results achieved. The following data were extracted from these annual reports, more specifically CRM annual report 2010, 2011, 2012 and 2013[6]. Despite the implementation of this business plan for clinical risk management, in 2010, the ASP6 Palermo recorder an increase in lawsuits (from 36 in 2009 to 69 in 2010) due to the late adoption of this policies during the year and the prevalence of a blame culture in the

[6] These annual reports are available at the website http://qualitarischioclinico.asppalermo.org
Unfortunately we have no historical CRM data for the period 2009-2010, for this reason we assume the value of certain variables in accordance with the client as explained in the next chapter.

ASP. In order to better implement the business plan for clinical risk management in 2011, the ASP6 management defined a capillary organizational structure and implemented a network of contact points for the management of clinical risk composed of: 5 medical directors, one for each ASP6's hospitals who are also responsible for promoting and implementing the project Patient Safety & Emergency Department, sponsored by the Sicily Region Department of Health in collaboration with the Joint Commission International and 41 health workers, one for each operational unit of the 5 ASP6's hospitals. In addition, in order to develop a patient safety culture among staff a 40 hours training course was targeted to the 41 operational units representatives and a website was launched (http://qualitarischioclinico.asppalermo.org). The website has the aim to make more accessible the information concerning the CRM both to staff and citizens. Again in 2011, the management has focused the attention on spontaneous incident reporting of adverse event (near miss and no harm event) and encouraging reporting by staff through awareness campaigns. The effect of these CRM policies is visible in the follow table (table 3)

	2010	2011	2012	2013
Sentinel event	10	3	2	1
Lawsuits	69	60	100	152
Incident reporting	5	70	101	89

Table 3 Distribution of ASP6 absolute values for annual flows

As can be seen from the table, sentinel events and lawsuits have declined. At the same time, spontaneous incident reporting have significantly increased.

In the past years, the ASP6 clinical risk database included only info relating to sentinel events, lawsuits and incident reports. In 2012, three other sources of information were indentified to be developed in the coming years (verification of the implementation of the standard Joint Commission International, verification of the implementation of the Ministerial

Recommendations and patients' complaints). Again in 2012 a protocol for the management of adverse events has been defined and distributed, to all operational units of the Hospitals and Health Care Departments. The protocol requires that the event is subjected to a timely and preliminary analysis to determine whether you can include it in sentinel events. If these inclusion criteria are met and the sentinel event is defined, then we proceed to a root cause analysis carried out by a special commission. The root cause analysis is aimed to identify the improvement actions to be made in order to improve patient safety. Moreover, as envisaged by Ministerial Decree 11 December 2009, the event must be signaled by SIMES data stream (this system will be better described in chapter 5).

As shown in table 3, compared to previous years, during the course of 2012 we have seen a considerable increase in litigations; this is probably due to the increasingly popular method of processing personal problems in legal disputes. It should however be pointed out that in previous years the total amount of the settlement has not yet exceeded for more than 10% (<€ 50,000) of the entire allowance applied by the insurance, even if some lawsuits are still active and being defined. The processed data show the following distribution of litigations: personal injury 30%, unintended needle penetration 28%, fall 19%, death 11%, wrong surgery 4%, misdiagnosis 3%, assault of staff member 2%, omitted diagnosis 1%, irregularities in the informed consent 1%, necessity of a new surgery 1%. Lastly, as expected from the project Patient Safety & Emergency Department, in 2012 ASP 6 hospitals are subjected to two different assessments: self-assessment by the Joint Commission International JCI referent present in each hospital, and the on-site visit, carried out by the JCI evaluators.

During 2013 work continued on the line taken in previous years, namely, operator training and improving the system of event reporting. Moreover at the beginning of 2013 ASP 6 signed the agreement with the University of Palermo of which this research is part.

5.2 Research hypothesis

In accordance with the problem definition discussed in the previous section, a research hypothesis has been formulated. To address the defined problem, the research project was designed to investigate the relationships between the Safety Culture index in the hospital's ward and the occurrence of various types of adverse outcomes in the clinical practice. The research hypothesis is that through a cultural change in the considered hospital ward – more in detail, from a blame culture to a patient safety culture - it is possible to foster a reduction in medical errors and, hence, an increase in hospital reputation and attractiveness. The development of a System Dynamics model, that will constitute a comprehensive causal representation of the fundamental characteristics of the CRM, represents the fulfillment of this research hypothesis. We believe 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 growing belief is that an healthcare company will be able to avoid medical errors harm if it will create and sustain a strong safety culture among personnel. 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. In order to transform culture it is important to first understand and evaluate 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). The questionnaire (described in detail in section 5.4.2) measures the Safety Culture Index SCI that represents the average value of different dimensions such as Communication openness, Non punitive response to error, Overall perception of safety etc.

By using a simulation model we want to test the weight that the Safety Culture index has in the generation of medical errors in order to identify the most effective and efficacy policy.

5.3 Research description

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 45.000 people (some macro-variables of the hospital and the operational unit involved in the research are shown in the table 4). 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.

MACROVARIABLES	**HOSPITAL**	**OBSTETRICS AND GYNECOLOGY WARD**
BEDS	87 ORDINARY 18 DAY HOSPITAL	10 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	4197 IN 2009 4208 IN 2010 4124 IN 2011 4238 IN 2012 4025 IN 2013	800 IN 2009 890 IN 2010 720 IN 2011 914 IN 2012 773 IN 2013
RISK MANAGER	YES	YES
SYSTEM OF COMPLAINS MANAGEMENT	YES	YES
INCIDENT REPORT	5 (2010) 32 (2011) 29 (2012) 14 (2013)	0 (2010) 16 (2011) 1 (2012) 1 (2013)
LAWSUITS	69 (2010) 11 (2011) 37 (2012) 23 (2013)	4 (2010) 2 (2011) 4 (2012) 2 (2013)
SENTINEL EVENTS	10 (2010) 1 (2011) 1 (2012) 0 (2013)	4 (2010) 0 (2011) 1 (2012) 0 (2013)

Table 4. 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 in December 2010 the ward of obstetrics and gynecology has been closed due to the died of a newborn. It is not the first time that in the ward a newborn deaths occur. Six infants or fetuses close to the birth, died in two and half years prior to the date of closure of the ward as a result of the umpteenth death. In this year several investigations have been opened in addition to the judiciary also by the parliamentary committee on Medical Malpractice and by the Regional Department of Health. But the first "strong" act it was decided only after the death of the seventh baby, by the ASP, which closed the department 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 (change 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 2011 allowed 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).

Furthermore it was decided to focus just on the obstetric and gynecology ward and not on its outpatient clinic. The reason is primarily 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).

5.4 Research methodology

5.4.1 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, as explained above, 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 clinical risk management system which requires the involvement of Hospitals and individual wards as described in section 5.1 (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 (2011-2012-2013) three different training courses about 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 lawsuits. SIMES data stream it is composed of three different forms to be filled: form A, form B and form 3 lawsuits. 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 JCI 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 litigations 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 late 2010, for this reasons we have incomplete data for 2010 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 years (see table3).

5.4.2 Exploring the professional staff's CRM culture and calculate the Safety culture index

A questionnaire was administered to the whole personnel of the ward (10 doctors, 10 obstetricians, 12 nurses and 1 OSS medical support staff), in order to explore the perception about the patient safety culture and clinical risk among ward's staff. Moreover we calculate the Safety culture index among personnel. 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 1). The questionnaire is focused on patient safety issue and on error and event reporting.

The dimensions investigated by the questionnaire are the follows:

I. BACKGROUND VARIABLES

What is your primary work area or unit in this hospital?

How long have you worked in this hospital?

How long have you worked in your current hospital work area/unit?

Typically, how many hours per week do you work in this hospital?

What is your staff position in this hospital?

In your staff position, do you typically have direct interaction or contact with patients?

How long have you worked in your current specialty or profession?

II. OUTCOME MEASURES

Frequency of Event Reporting

When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported?

When a mistake is made, but has no potential to harm the patient, how often is this reported?

When a mistake is made that could harm the patient, but does not, how often is this reported?

Reliability of this dimension—Cronbach's alpha (3 items) = .84

Overall Perceptions of Safety

Patient safety is never sacrificed to get more work done.

Our procedures and systems are good at preventing errors from happening.

It is just by chance that more serious mistakes don't happen around here. (reverse worded)

We have patient safety problems in this unit. (reverse worded)

Reliability of this dimension—Cronbach's alpha (4 items) = .74

Patient Safety Grade

Please give your work area/unit in this hospital an overall grade on patient safety.

Single-item measure—grades A through E as response categories.

Number of Events Reported

In the past 12 months, how many event reports have you filled out and submitted?

Single-item measure—numeric response categories.

III. SAFETY CULTURE DIMENSIONS (Unit level)

Supervisor/manager expectations & actions promoting safety

My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures.

My supervisor/manager seriously considers staff suggestions for improving patient safety.

Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts. (reverse worded)

My supervisor/manager overlooks patient safety problems that happen over and over. (reverse worded)

Reliability of this dimension—Cronbach's alpha (4 items) = .75

Organizational Learning—Continuous improvement

We are actively doing things to improve patient safety.

Mistakes have led to positive changes here.

After we make changes to improve patient safety, we evaluate their effectiveness.

Reliability of this dimension—Cronbach's alpha (3 items) = .76

Teamwork Within Hospital Units

People support one another in this unit.

When a lot of work needs to be done quickly, we work together as a team to get the work done.

In this unit, people treat each other with respect.

When one area in this unit gets really busy, others help out.

Reliability of this dimension—Cronbach's alpha (4 items) = .83

Communication Openness

Staff will freely speak up if they see something that may negatively affect patient care.

Staff feel free to question the decisions or actions of those with more authority.

Staff are afraid to ask questions when something does not seem right. (reverse worded)

Reliability of this dimension—Cronbach's alpha (3 items) = .72

Feedback and Communication About Error

We are given feedback about changes put into place based on event reports.

We are informed about errors that happen in this unit.

In this unit, we discuss ways to prevent errors from happening again.

Reliability of this dimension—Cronbach's alpha (3 items) = .78

Nonpunitive Response To Error

Staff feel like their mistakes are held against them. (reverse worded)

When an event is reported, it feels like the person is being written up, not the problem. (reverse worded)

Staff worry that mistakes they make are kept in their personnel file. (reverse worded)

Reliability of this dimension—Cronbach's alpha (3 items) = .79

Staffing

We have enough staff to handle the workload.

Staff in this unit work longer hours than is best for patient care. (reverse worded)

We use more agency/temporary staff than is best for patient care. (reverse worded)

We work in "crisis mode," trying to do too much, too quickly. (reverse worded)

Reliability of this dimension—Cronbach's alpha (4 items) = .63

Hospital Management Support for Patient Safety

Hospital management provides a work climate that promotes patient safety.

The actions of hospital management show that patient safety is a top priority.

Hospital management seems interested in patient safety only after an adverse event happens. (reverse worded)

Reliability of this dimension—Cronbach's alpha (3 items) = .83

IV. SAFETY CULTURE DIMENSIONS (Hospital-wide)

Teamwork Across Hospital Units

There is good cooperation among hospital units that need to work together.

Hospital units work well together to provide the best care for patients.

Hospital units do not coordinate well with each other. (reverse worded)

It is often unpleasant to work with staff from other hospital units. (reverse worded)

Reliability of this dimension—Cronbach's alpha (4 items) = .80

Hospital Handoffs & Transitions

Things "fall between the cracks" when transferring patients from one unit to another. (reverse worded)

Important patient care information is often lost during shift changes. (reverse worded)

Problems often occur in the exchange of information across hospital units. (reverse worded)

Shift changes are problematic for patients in this hospital. (reverse worded)

Reliability of this dimension—Cronbach's alpha (4 items) = .80

The Hospital Survey on Patient Safety Culture was originally developed, pilot-tested and revised in the USA and then released by the Agency of Healthcare Research and Quality. 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.

5.4.3 Designing the causal loop diagram (CLD) and building the Stock and Flow Model

A section of group model building 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.

CHAPTER 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 (table 5 correlations). Moreover the collected data have allowed to determine the overall Safety culture index (67,34%) by calculating the scale means.

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

Table 5 Correlations

The data analysis has demonstrated significant correlations between some dimensions (as shown in the above table), and the most relevant in the light of the research are the following:

- "Organizational learning- continuous improvement " and "feedback and communication about error" (.568). This result shows that the communication of feedback has a positive effect on learning within the organization. The promotion of "learning organization", in which one learns from the mistakes that occur in the organization, provides a learning about the error and the process who caused it and prevents a possible reappearance.
- "Organizational learning- continuous improvement " and "frequency of event reporting" (.584). Referring back to the previous data, these data show how to work in an environment in which is promoted a “no blame culture”, creates the conditions for which each individual becomes a participant in the development of safety within their workplace. In this way it is assimilated the importance and necessity of adverse event reporting, actual or potential, which could have a significant impact on both the patient and the whole organization.
- "Organizational learning- continuous improvement " and "hospital management support for patient safety" (.507). This result highlights the importance of a proactive safety management. It is necessary to provide subjects with the tools and conditions fostering

the reflective function. Through this reflective function staff will be able to understand what is happening in the environment and act accordingly in the most effective way to ensure a good level of safety.

- "Organizational learning- continuous improvement" and "patient safety grade" (.597). This correlation reflects the results already discussed in the previous correlations. A work environment that encourages continuous learning, positively affects the level of patient safety.
- "Non-punitive response to error" and "hospital management support for patient safety" (.414). This correlation suggests that a management that takes account of the possible causes that led to the incident, promotes a non-punitive attitude to the error, reinforcing, therefore, a proactive reporting of adverse events by the staff.
- "Overall perception of safety" and "supervisor/manager expectations & actions promoting safety" (.508). The perception that people have of the level of safety within their Operational Unit, is influenced by the actions implemented by the manager, which promote a safety culture.
- "Overall perception of safety" and "feedback and communication about error" (.549). Individuals who continually receive information, feedback and encouragement for their work, perceive the work environment as more functional and safe.
- "Overall perception of safety" and "hospital management support for patient safety" (.551). As seen in the previous result, also in this case a management that implements actions to promote a well-functioning and coordination of the activities has a positive influence on the perception of safety.
- "Supervisor/manager expectations & actions promoting safety" and "feedback and communication about error" (.576). The first dimension refers to the actions promoted by management to promote a safety culture. Among these, one of the most effective refers to stimuli provided by the management, in order to promote a communication about error

within the organization. This communication about error must be organized in such a way as not to put the individual in a position of fear possible negative consequences from a error reporting.

- "Supervisor/manager expectations & actions promoting safety" and "communication openness" (.588). Even in this case it is possible to note how the action taken by management, foster effective communication within the team. This is a very important factor because, as the literature has shown extensively, most of the adverse events occurred precisely because of communication errors.
- "Supervisor/manager expectations & actions promoting safety" and “teamwork across hospital units” (.558). As you can see even from the previous correlations, the activities implemented within the operating unit are directed also at the development of group cohesion, communication and non-competitiveness among members. Individuals interact and depend on each other and they are projected towards a common goal. By doing so, it may reduce the incidence of error associated with clinical problems in the teamwork management.
- "Supervisor/manager expectations & actions promoting safety" and “hospital handoffs & transitions” (.482). This latter dimension includes the transitions of patients from an operating unit to another, but also from a work shift to another, when there is a high probability that it falls in error, for example due to the loss of clinical documentation. This often occurs in moments of great activity, very frequent condition in a hospital setting. The transfer of information, therefore, is a crucial moment, which should be well controlled and regulated by the Manager, thus contributing to the development of safety.
- “Feedback and communication about errors” and “frequency of even reporting” (.669). There is a good correlation between these two dimensions. This shows as reinforcements, not punitive, in response to the actions of the staff, foster a positive attitude towards the

reporting of adverse events, vital action for the promotion of organizational learning, which acts as a support for the containment of possible future errors.

- "Feedback and communication about errors" and "hospital management support for patient safety" (.642). Process management for safety purposes, includes communication of adverse events and the use of feedback about the work of each staff member. These dimensions have a significant correlation, noting the need for functional involvement and the active role undertaken by the various company actors.
- "Frequency of event reporting" and "hospital management support for patient safety" (.701). The decisions of the Executive Board, in relation to the coordination and development of team work, have a positive influence on the frequency with which the individual reports an event. In fact, despite this action is entirely voluntary, it needs to be understood and implemented by staff members, in order to better know how to use the prevention's tools.
- "Frequency of event reporting" and "patient safety grade" (.658). It is clear then as a high frequency event reporting is associated with a high level of patient safety. Only through continuous monitoring of the errors you can come to a real improvement of the patient's health conditions.
- "Hospital management support for patient safety" and "hospital handoffs and transitions" (.621). This result indicates the need for the establishment of procedures and protocols, clear and easily accessible to everyone, through which you can mitigate risks associated with incomprehension and misunderstanding that often occur during hospital handoffs and transitions.
- "Team work" and "staffing" (-.489). This is the only negative correlation emerged in data analysis. It shows how excessive turnover can damage the cohesion of the team and as a result, the health services provided to the patient. The turnover, now more than ever, it is a common problem in many companies, which also affects the cost in the financial

statements of the company. Moreover within the team, we witness the cleavage of the relations among members, creating a sense of mistrust and misunderstanding between the members of the working group.

6.2 The causal loop diagram

The data collected with the group model building session allowed identifying some of the main cause-effect relationships characterizing the organizations system. As it is showed in the causal loop diagram (figure 10), 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 *lawsuits* that are related to a loss of *image*. The loss of *image* has a return in term of loss of *patients* (loopB1).

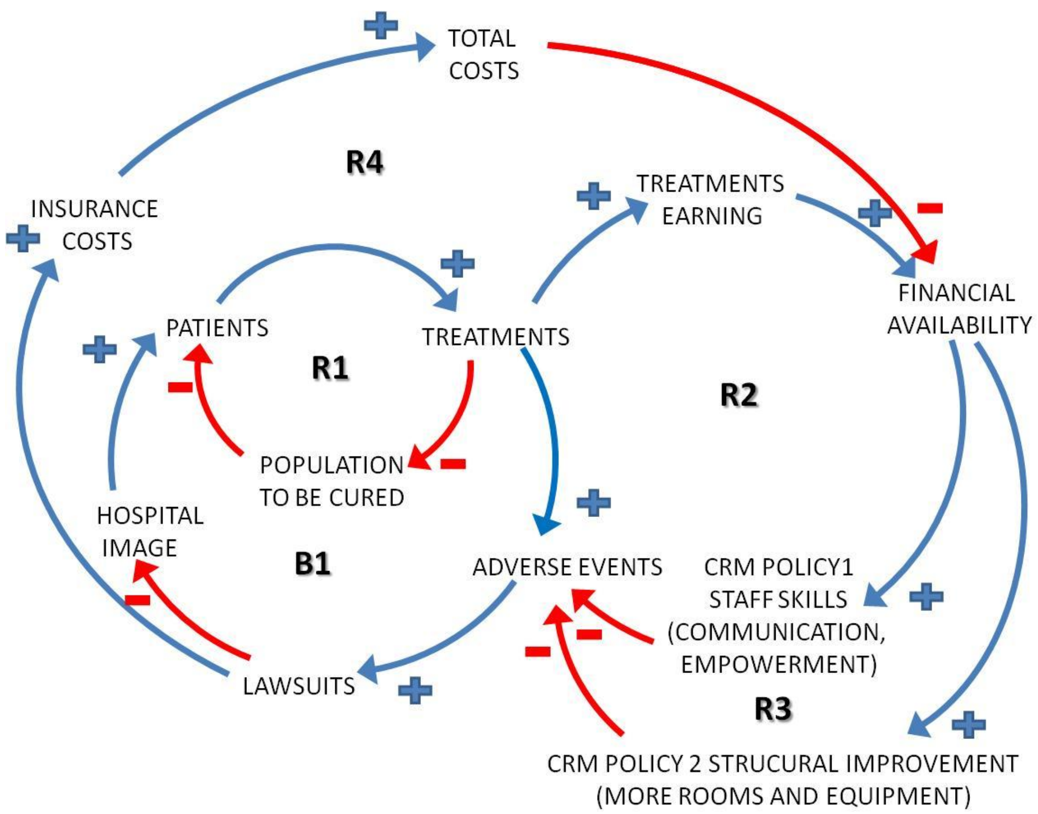

Figure 10. The Causal Loop Diagram

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 expected that the *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 *lawsuits*, 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 *lawsuits*. In this way the *costs* related to insurance and compensations lawsuits 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

6.3.1 Model overview

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. This section describes what the model does (namely, the dynamics of which variables is generated, or, a scope of the model) and for which time period. Based on this description, the purpose of the model is explained.

The model focuses on the dynamics of medical error generation in the obstetrics and gynecology ward of the choose hospital. Then the model is used to test the effect of different policies and to evaluate the most effective and efficient. The choice of policies to be tested through the model arises both from the information obtained through the semi-structured interviews administered to the main hospital's key actors of risk management, and the analysis of CRM successful case studies. The choice of this particular policy tool is described and supported by the relevant explanations in chapter 7 Scenario Analysis.

The time frame of the model simulation is 9 years, from 01/01/2009 to 01/01/2018. The first four years represent the historical behavior of the ward (even do for 2009 and 2010 we have some lack of information about CRM because procedures and tools for CRM were introduced just in late 2010), it was used to test whether the model was able to reproduce the real ward performance.

The model is pursued as intuitive model, in a sense that it provides a highly aggregate overview of the system. For this reason the model can be used as a good starting point for any further analysis.

6.3.2 Model assumptions

The scope of the model along the dimensions described above (the dynamics of which variables is generated and time) reflects a set of assumptions made throughout the modeling process. The discussion of the model's assumptions brings the description of the model from a very general overview level employed in the previous section to a more detailed description as the assumptions clearly demonstrate how the chosen scope of the model translated into particular modeling choices.

6.3.2.1 Assumption 1: Model boundaries

Every feedback system has a closed boundary within which the behavior of interest is generated. When you create a model you need to clearly define the system boundary, it contains all the variables present in the model. The following components are present in the final model:

- Must be necessary. In the present work we chose to focus the attention just on the obstetrics 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).
- Should be aggregated. In the present work we chose to treat the economic and financial sector as aggregated data in the model. The reason is primary related to the difficulty in obtaining historical data about this sector. In fact, even do the ward has to work as a cost center, as explained in section 3.4 of the present work, it hasn't its accounting system so that the income and expenses of the subunit can be separated from the income or expenses of other centers and monitored for cost and benefit. The expense of the ward are separated and treated from different department (the cost related to the personnel are treated by Human Resources department, the cost of electricity and other electric consumptions are treated at whole hospital level and so on). The economic sector is just used to evaluate, in a aggregate way, the effects of the managerial decisions in the term of financial sustainability. Also the patient chain sector is treated as aggregated data in the model. The patients are not divided by DRG due of the normal distribution of the error among the different treatment (DRG).

In addition, to better specify the model boundary it is necessary to separate the model variables in endogenous (variables involved in the feedback loops of the system) and exogenous (variables whose values are not directly affected by the system). The system dynamics model instead of relying on exogenous forecasts generates the important variables, chosen to be within its boundary, endogenously. In this way we can clearly see how the variables in the model influence each other through the feedback loops comprising the structure of the system. In the present work the variables chosen to be exogenous are the following:

-P*atient capacity*, we set the patient capacity of the ward to 10 patients.

-A*verage time to treat*, we set the value of the variable according with the average of the each year of the reference period 2009-2010-2011-2012-2013. From 2013 in advance we lock the last average value used for 2013 (3,37 day).

-A*verage income per patient*, we set the value of the variable according with the average of the each year of the reference period 2009-2010-2011-2012-2013. From 2013 in advance we lock the last average value used for 2013 (1768,70 euro/people).

-*Percentage of no harm events, %*. Based on the analysis of the historical data of the ward we set the percentage of no harm event to 16%.

-In the legal sector of the model we set as exogenous the diverse percentage of litigations arose from different kind of error. We assume that each sentinel event result in a lawsuit so we set the value of *% of lawsuits from sentinel event*s to 100%. We assume that just the 10% of adverse event occurred in the ward result in a lawsuit so we set the value of *% of lawsuits from adverse events* to 10%. Both *average cost per won lawsuit* and *average cost per loosed lawsuit* are set as exogenous and are respectively: for adverse events 2000 euro/event per won lawsuit and 25.000 euro/event per loosed lawsuit; for sentinel events 15.000 euro/event for won lawsuit and 1.200.000 euro/event for loosed lawsuit. The percentage of distribution of loosed and won lawsuits are set exogenously as follow: for adverse events 60% of won lawsuits and 40% of loosed lawsuits, for sentinel events 90% of won lawsuit and 10% of loosed lawsuit. At last, the lawsuit timing is set to 10 years for lawsuit deriving from sentinel event and 2 years for lawsuit deriving from adverse events.

- The *depletion time* of the *lowering in patient safety index* is set exogenously to 20 years. We set this value by using some theories about knowledge obsolescence (Rosen, 1975). The obsolescence is defined as a negative change in capital values that are solely a function of chronological time. Obsolescence occurs because stock of knowledge available to society change from time to time.

-*Proximity* represents the effect of proximity in choosing a hospital. Empirical evidence from health care markets clearly points to the importance of geographic proximity being a key determinant of patient choice and in understanding provider's response to potential competition. Research by Dixon et al. 2010 stated "Although when presented with a list of factors, patients gave convenience and transport a relatively low ranking, when interviewed about which hospital they chose and why, proximity to their home was often the first factor mentioned". The area were this research was carried out has only one public hospital with a obstetric and gynecology ward within about 30 km. The population of the area is accustomed to make use of the services of the hospital but young people also tend to move in the other hospitals, both public and private. For this reason we decide to set the value of this variable to 100% per year because proximity doesn't change during years but we decide to attribute a specific the weight (50%) to this variable in the generation of hospital attractiveness.

-*Percentage of ward fixed costs* is set exogenously to 90% of the total yearly income of the ward coming from DRGs. The reason of this choice is the same that guide the choice to treat the economic and financial sector as aggregated data in the model: the lack of information. For this reason we assume a margin per year of about 10% of the total yearly income deriving from DRGs.

6.3.2.2 Assumption 2: Safety culture index

The stock "Safety Culture index" (SCI) represents the level of safety culture among staff of the ward and it's composed by the different dimensions measured by the questionnaire administered to the whole ward's staff (Nieva & Sorra, 2003). However we decide to use just 10 of the 13 dimensions measured by the questionnaire to create define our stock Safety culture index. We decide to not consider three dimensions classified in the questionnaire as Outcome Measures, namely: frequency of event reported, overall perception of safety and patient safety grade. The dimension Frequency of event reported was used as a value that depends directly by the patient safety grade index and this will be better described in section 6.3.2.5.

The value of the stock “Safety culture index” was measured in the ward at the end of 2013 and it was 67,34% based on the scale means of the questionnaire’s answers (Nieva & Sorra, 2003). 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 (01/01/2009) of the simulation was set at 33,67% (50% less than the value measured on 2013). This value arises from some info about the CRM level before 2011 collected during the interview with the CRM’s hospital key actors.

6.3.2.3 Assumption 3: effect of patient safety index on medical error

This assumption follows from the previous one. We decided to create a graph function to explain the effect of the Safety culture index on medical errors. We assume that when the value of “Safety culture index” is at his maximum (100%) there are no medical errors, so the value of the “effect of safety culture index on medical error” is zero, it means zero error each treatment. When the value of “Safety culture index” is at his minimum (0%) the value of the “effect of Safety culture 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 Safety culture index on medical error”) in a range from 1% and 10% 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). For this reason with the maximum level of the Safety culture index 100% we have 1% of possibility to occur in an error and with the minimum level of Safety culture index 0% we have 10% of possibility to occur in an error.

6.3.2.4 Assumption 4: effect of clinical error on Hospital Reputation

We assume that different kind of errors have different kind of effect on hospital reputation. Of course sentinel events have more impact on the hospital reputation so we assign a weight of 65% in the definition of hospital reputation. On the contrary, adverse events have just a weight of 35% in the definition of hospital reputation due to the minor incidence of the consequences of the event. We decided to create a graph function to explain the relationship between the amount of the errors occurred in the hospital and their effect on hospital reputation. We assume that when the amount of errors occurred in the hospital is 0 the hospital reputation is at its maximum 100%. With just one error the hospital reputation drops to 54% till reaches its minimum value of 0,6% with 13 or more errors occurred in the hospital.

6.3.2.5 Assumption 5: Percentage of Error Reported based on Safety Culture Index

We assume that the percentage of event reporting of the ward depends by the level of Safety culture index among staff. The event reporting refers to spontaneous reporting of adverse events, near miss and no harm event implemented by the ASP6 in addition to the SIMES data stream (reporting of sentinel event and lawsuits set up by the Ministry of Labor, health and Social Policy in 2010. We create a graph function to illustrate how the level of Safety culture index affects the event reporting. When the level of Safety culture index is at its maximum 100% the percentage of event reporting in the ward is 100%, when the level of Safety culture index is at its minimum 0% the percentage of event reporting in the ward is 0,6%. The behavior of the graph function follow a S-shape curve.

6.3.2.6 Assumption 6: Percentage of ward fixed costs

Due to the lack of detailed and specific information about the ward's expenses we decide to treat the financial sector in the model by using aggregate data and assumption. As explained in the section 6.3.2.1 of this work we assume that *Percentage of ward fixed costs* is exogenous and we set it to 90% of the total yearly income of the ward coming from DRGs.

6.3.2.7 Assumption 7: Cost and timing of lawsuits

In the legal sector of the model, as for the financial one, we suffer a lack of information due to the nature too private and personal of the information concerning the causes and costs of the latter. For this reason we have moved through of the assumptions that have guided us in setting the values of some parameters already described in section 6.3.2.1.

6.3.2.8 Assumption 8: Percentage of incident report that need a corrective action

We assume, based on info collected in the ward, that just 2% of the events reported need a corrective action. The others 98% are minor or just casual events that not need to be deeper analyzed.

6.3.2.9 Assumption 9: Historical data for 2009

Due to a lack of information available in term of number of patients and number of DRGs for the year 2009 we decide to set this values in accordance with the client. We assume that the number of patient for 2009 was 800 and the average income per patient (coming from DRG) was 1990 euro.

6.3.2.10 Assumption 10: Percentage of gap filled through policy 1 and policy 2.

The table 6 shows the assumptions that have guided us in the choice of the weights to be given to the effect that policies 1 and policy 2 respectively have on the various dimensions of safety culture index considered in the model.

Dimensions	Policy 1	Policy 2	Motivation
Supervisor/manager expectations & actions promoting safety	20%	80%	Policy 1 affects the supervisor expectations since we can suppose that supervisor, as a consequence of the investment in new equipment provided by the hospital, will be more overburdened about the safety procedure adopted by the staff and their suggestions. On another hand, policy 2 affects supervisor expectations since we can suppose that the way to establish patient safety procedures and consider staff suggestions can be better improved by the diffusion among staff of a safety culture through information communication and staff training.
Organizational Learning—Continuous improvement	25%	75%	We suppose that policy 1 just has a lower effect in comparison to policy 2 since we assume that information, communication and training are more effective in the diffusion of an organizational learning in comparison with the acquisition of new equipment. Of course also new equipment can affect the way staff learn by the error and improve its performance (for instance by using ICT device) but policy 2 allows to create the base for learning by the errors since only through the widespread diffusion of the safety culture staff can really experience a continuous improvement.
Teamwork within units	15%	85%	This dimension refers to the teamwork within the unit where of course policy 2 information, communication and training can better help staff to achieve quality results in term of mutual support and respect, with training staff learn how to deal with teamwork and how to better interact with it. Also policy 1 can help to better organize teamwork within unit since new equipment can support the staff in the teamwork (for instance a new ICT device can help the workers to work quickly).
Communication openness	0%	100%	We assume that policy 1 has no influence on this dimension since no new equipment can affect the communication openness. The whole influence on communication openness is given by policy 2 since information communication and training influence the way staff interact and offer support one each other. the diffusion of a safety culture through information and staff training allow that employees feel comfortable in expressing their opinions, even if they are in contrast with those of superiors.
Feedback and communication about error	30%	70%	We assume that policy 1 has a very lower effect on feedback and communication about error in comparison to policy 2, since new equipment can just facilitate the way to communicate feedback to staff or to inform staff about error happened in the hospital but it cannot influence how staff discuss ways to prevent errors from happening again. this last aspect is better influenced by policy 2 since through information and communication staff back to think on the events that have occurred in the hospital in order to analyze them and prevent a reoccurrence.
Non punitive response to error	0%	100%	There is no effect of policy 1 on Non punitive response to error since new equipment cannot affect the way staff feel their mistakes are treated. In this case the whole effect on Non punitive response to error is attributable to policy 2 since the shift from a blame culture to a safety culture takes place mainly through continuous staff training and information.

Staffing	60%	40%	We assume that policy 1 affects the way staff work in "crisis mode", since new equipment can help to better implement procedures in the hospital (for instance if we buy a new ecograph we can handle the workload with the same staff). On other hand policy 2 affects the way staff perceive the best for patient, staff learn through training and information new skills that allow to handle crisis in the ward.
Hospital Management Support for Patient Safety	40%	60%	We assume that policy 1 affects the hospital management support for patient safety since with the purchase of new equipment management show to be interested to maintain an high level of service quality in order to promote patient safety. In the same way with policy 2 the hospital management provides a work climate that promotes patient safety since with staff training and continuous information and communication the personnel feel to be insert in an environment where the safety is a priority.
Teamwork across units	50%	50%	We suppose that both policies affect in the same way this dimension since both new equipment and communication, information and training affect the cooperation and coordination among hospital units. With new equipment, such as ICT, we can better coordinate the work across units since we can better organize the workflow avoiding bottlenecks and poor coordination between units. With staff training and communication we can improve staff skill and motivation in order to create a work environment where is not unpleasant to work with staff from other hospital units.
Handoffs and transitions	75%	25%	We suppose that policy 1 has a strong effect since new equipment supported by ICT devices can help staff to better deal with shift change and information exchange avoiding lost of information and things "fall between cracks".

Table 6 Percentage of gap filled through policy 1 and policy 2.

6.3.3 Model structure

Figure 11 shows a section of the stock and flow model describing the hospitalization process: sector 1 patient chain. 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 two possible outflow: one is “other hospital inpatient rate” which 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 stocks and flows (“population waiting for treatment rate”, “population waiting for treatment”, “inpatients rate”, “inpatients”, “patient treatment rate”, “patient discharged” and “recovery rate”) which 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).

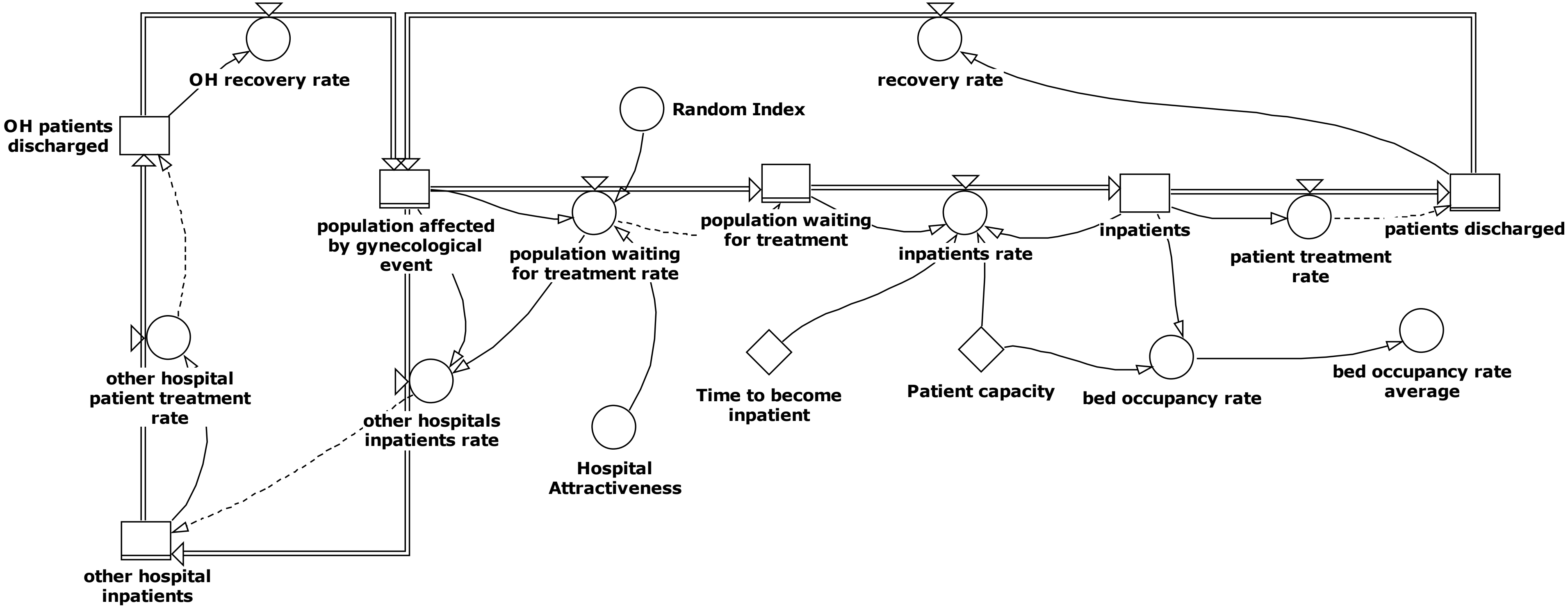

Figure11. Sector 1: Patients chain

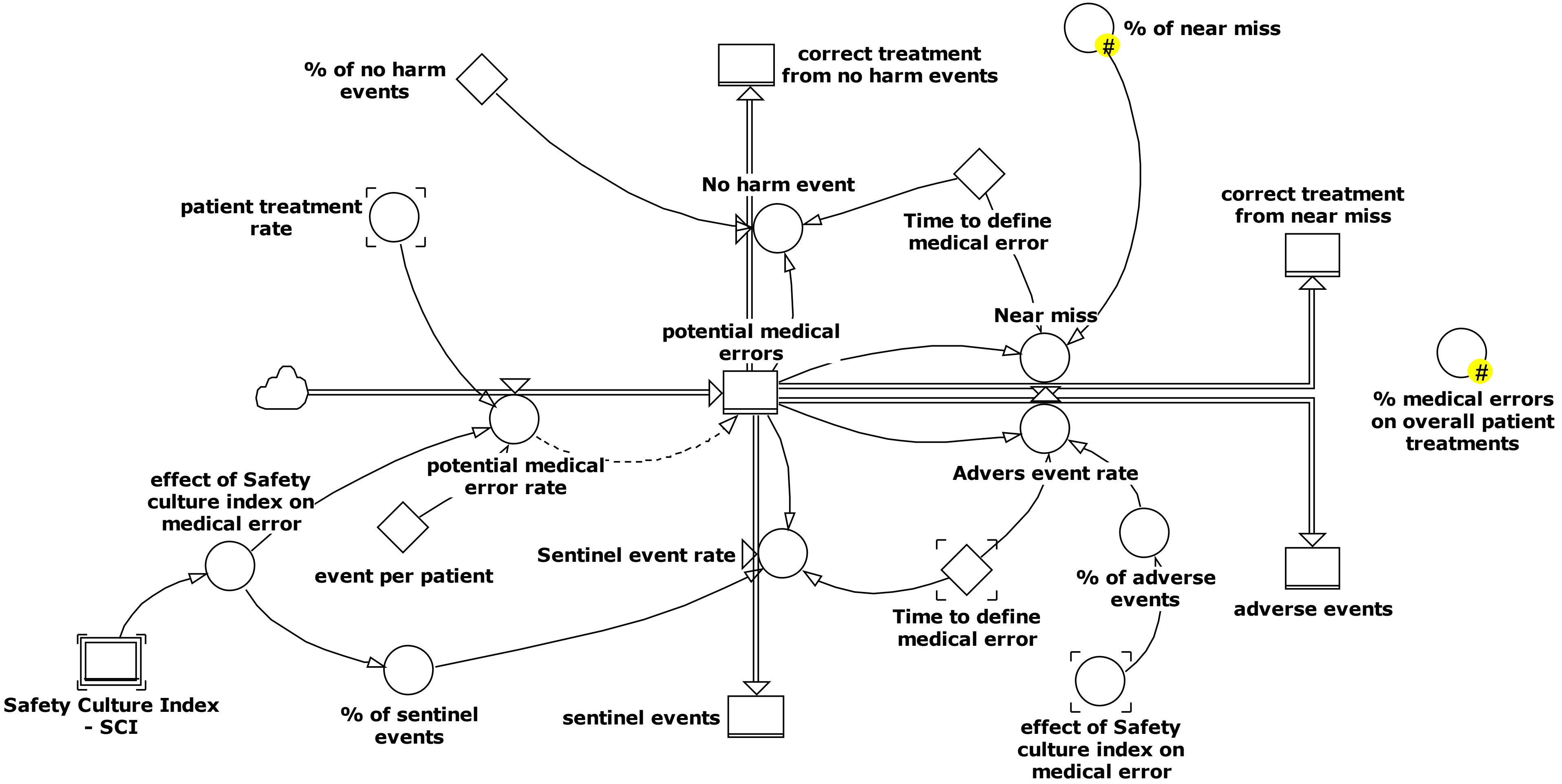

Figure 12. Sector 2: the dynamics of errors

Figure 12 shows a section of the stock and flow structure, sector 2 dynamics of errors, describing the dynamics of errors in the obstetric and gynecology ward. 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 Safety culture index in the generation of clinical errors. It depends by the stock "Safety culture 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 for 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 1% and 10% 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). From the stock "potential medical errors" there are four outflow "sentinel event rate", "adverse event rate", "near miss rate" and "no harm event rate" and their respective stocks which represent the different kind of error wherein a hospital can occur. The flow "no harm event rate" is regulated by a fixed frequency percentage (16%) based on literature data analysis and the historical data analysis of the hospital. The flow "sentinel event rate", depends by the level of the effect of Safety culture index on medical errors. We create a graph function to explain how the level effect of Safety culture index on medical errors affects the percentage of sentinel events that can occur in the ward.

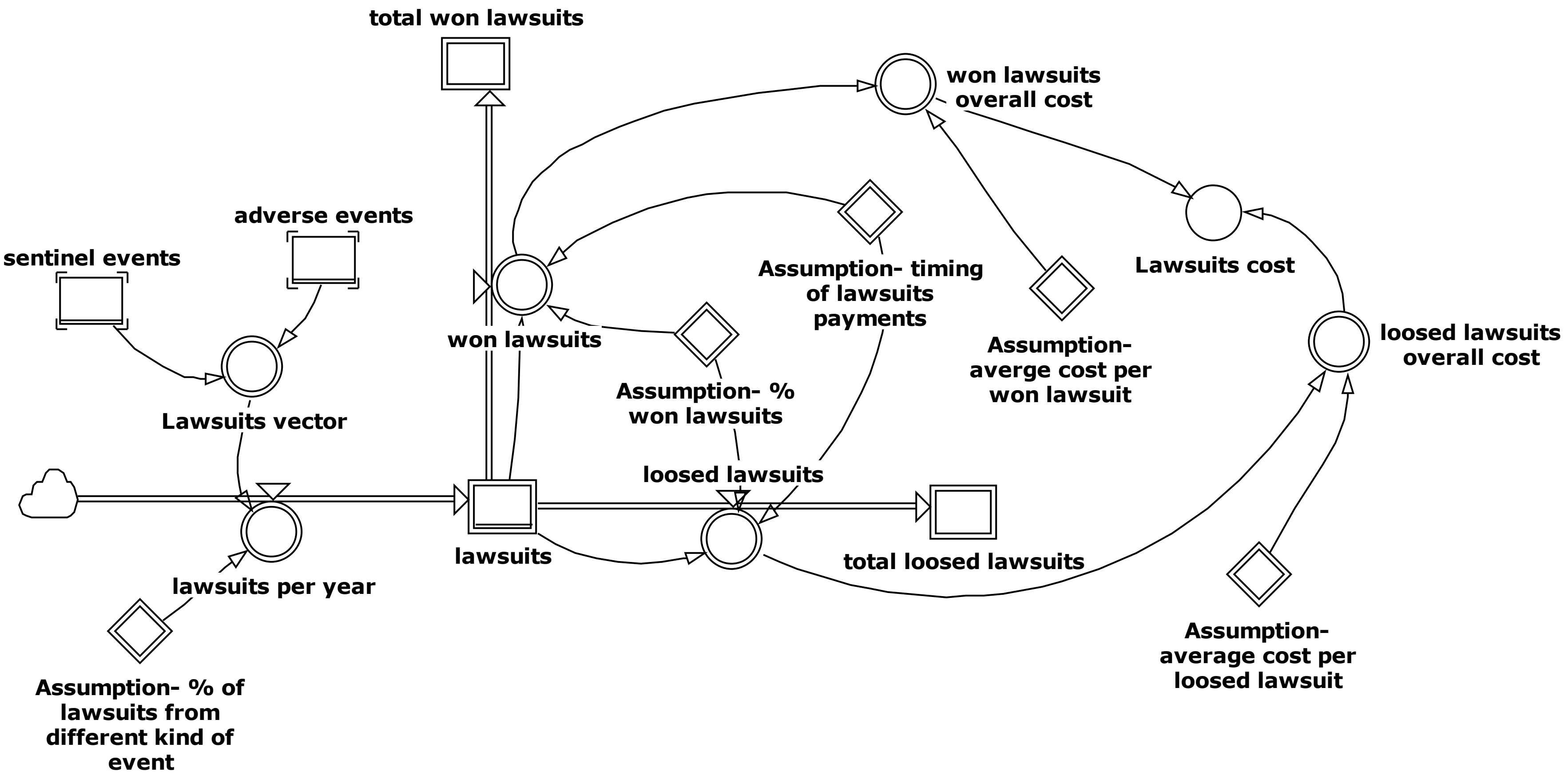

Figure 13. Sector 3: Legal sector.

We hypothesized that when the level of “effect of Safety culture index on medical errors” is at its maximum 10% the percentage of sentinel events is 5% and when the level of effect of Safety culture index on medical errors is at its minimum 1% the percentage of sentinel events is 0,01%. In the same way, the flow “adverse events rate” depends by the level of the effect of Safety culture index on medical errors. We create a graph function to explain how the level effect of Safety culture index on medical errors affects the percentage of adverse events that can occur in the ward. We hypothesized that when the level of “effect of Safety culture index on medical errors” is at its maximum 10% the percentage of adverse events is 30% and when the level of effect of Safety culture index on medical errors is at its minimum 1% the percentage of adverse events is 0,15%.

The flow “near miss” represents the net value deriving from the following equation: *100%-('% of adverse events'+'% of no harm events'+'% of sentinel events').* It means that the percentage of distribution of near miss is variable and depends by the value of distribution of the other kind of medical errors.

We also create a variable “Percentage of medical error on overall patient treatments” made by the “errors per year rate” divided by the “patient treatment rate”. The value of this variable represents an output index that tell us the percentage of error over 100 treatments (we assume we have 1 treatment per patient).

Figure 13 shows a section of the stock and flow structure sector 3: The legal sector. The central stock “lawsuits” is determined by the inflow “lawsuits per year” made by an assumption: each sentinel event determines a lawsuits so we set the percentage of lawsuits from sentinel events to 100%, just 10% of adverse events determine a lawsuit so we set the percentage of lawsuits from adverse events to 10%. From the central stock “lawsuits” we have two outflows “won lawsuits” and “loosed lawsuits” respectively driven by different assumptions already explained in section 6.3.2.1.

Figure 14 shows a section of the stock and flow model structure, sector 4: Medical errors reporting. In this sector we have two structure that represent the incident reporting system and the sentinel reporting system (SIMES) of the ward. On one hand there is the “database simes” stock alimented by the inflow “database simes rate”. Due to the introduction on 2010 of a data stream for monitoring error in healthcare SIMES by the Ministry of Labor, Health and Social Policy each sentinel event occurred in the hospital must be reported; for this reason we create a structure where the “database simes” stock is directly feed by the “sentinel event rate”. Moreover each sentinel event reported need a corrective action in order to avoid its re occurrence.

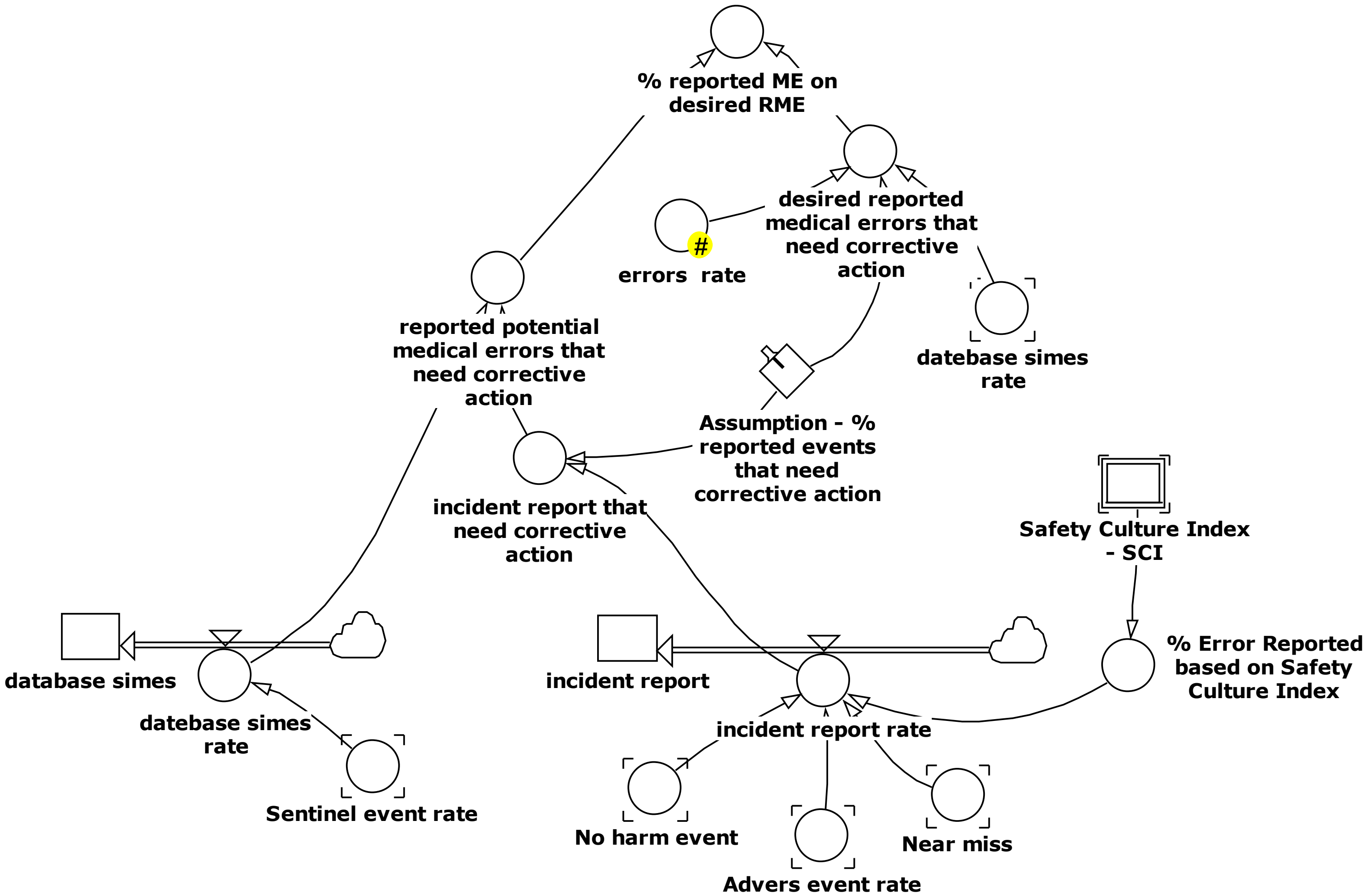

Figure 14. Sector 4: Medical errors reporting

One the other hand there is the “incident report” stock alimented by the inflow “incident report rate”. This flow depends on three variables: “no harm event”, “near miss” and “adverse event rate” which represent the other three kind of medical error that may occur in the hospital. However, since the reporting of these events is not mandatory but voluntary, we hypothesized that the percentage of reported events depends on the level of Safety Culture index present in the ward. We then created a graph function that expresses the relationship between the level of Safety Culture index and the percentage of reported events in the ward “Percentage of Error Reported based on Safety Culture Index”. When the level of Safety culture index is at its maximum 100% the percentage of event reporting in the ward is 100%, when the level of Safety culture index is at its minimum 0% the percentage of event reporting in the ward is 0,6%. The behavior of the graph function follow a S-shape curve. Moreover, no each event reported through the incident report need a corrective action. For this reason we create a variable “incident report that need a corrective action” and we assume, based on info collected in the ward, that just 2% of the events reported need a corrective action. The others 98% are minor or just casual events that not need to be deeper analyzed. Consequently the variable “reported medical errors that need corrective action” depends by the sum of the flow “database simes rate” and the variable “incident report that need corrective action”. In order to define the variable “percentage of reported medical errors on desired reported medical errors” we divide the “reported medical errors that need corrective action” by the “desired reported medical errors that need corrective action”. This last variables represent the total amount of errors reported in the ward that need a corrective actions and it is defined by the total amount of adverse events, no harm events and near miss occurred in the ward (“error rate”) multiplied by the assumption “percentage of reported events that need a corrective action” and the “database simes rate”.

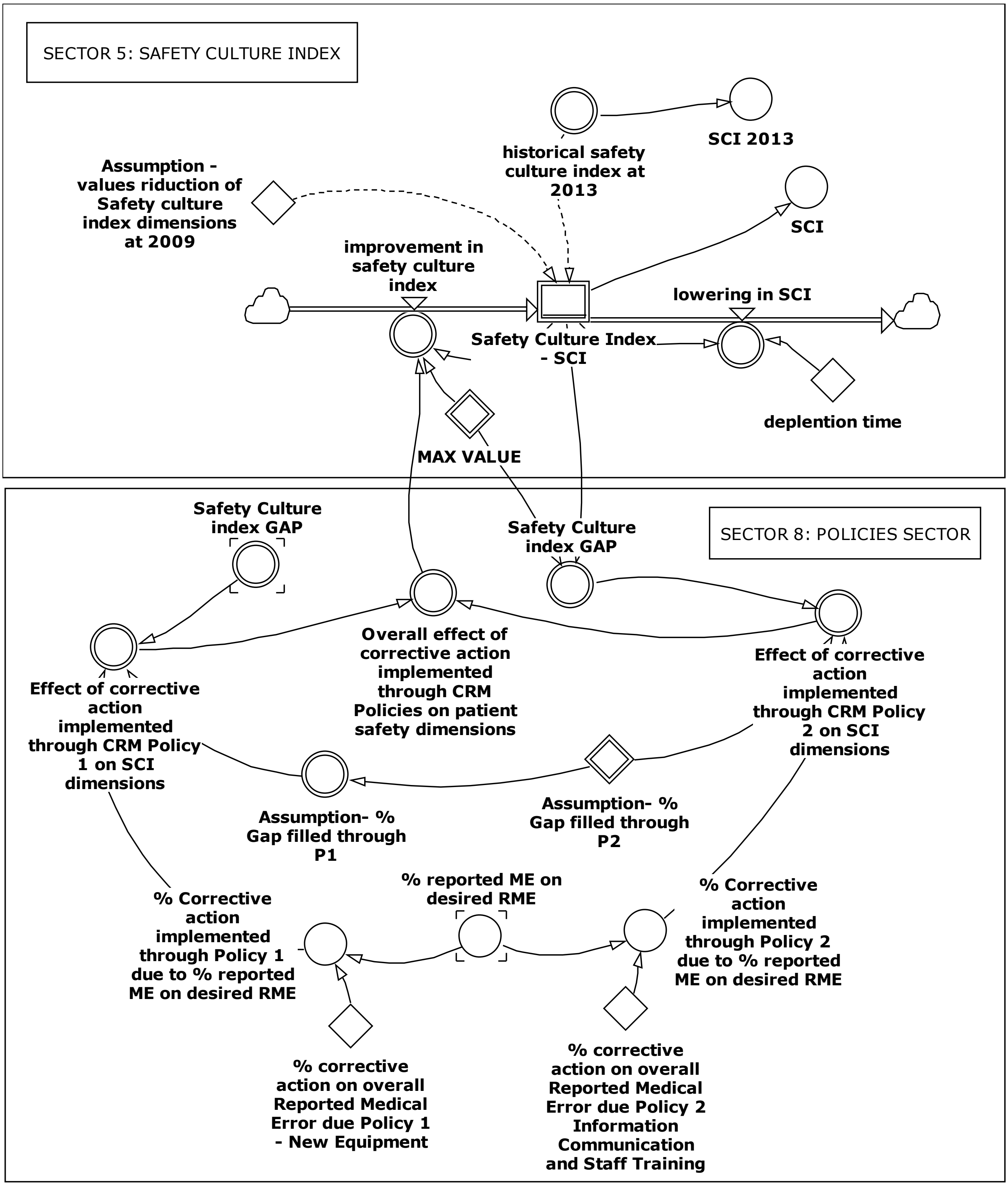

Figure 15. Sector 5 Safety culture index and sector 8 Policies sector.

Figure 15 shows two sections of the stock and flow model structure, sector 5 Safety culture index and sector 8 Policies sector. From the variable “percentage of reported medical errors on desired reported medical errors” are defined two variables “percentage of corrective action implemented through policy 1 due to percentage of reported medical errors on desired reported medical errors” and “percentage of corrective action implemented through policy 2 due to percentage of reported medical errors on desired reported medical errors” which respectively depended by the “percentage of corrective action on overall reported medical errors due to policy 1- New equipment” and the “percentage of corrective action on overall Reported Medical Errors due to Policy 2 Information Communication and Staff Training”. These last two variables represent the CRM policies implemented by the hospital and will be better discussed in chapter 7 of this work. By multiplying the variable “percentage of corrective action implemented through policy 1 due to percentage of reported medical errors on desired reported medical errors” per the “Safety Culture index gap” and the assumption “Percentage of gap filled through policy 1” we define the “effect of corrective action implemented through CRM policy 1 on SCI dimensions”. The “Safety culture index gap” is defined by the difference between the max value assumable by the Safety Culture index 100% and the value of the stock “Safety culture index”. The assumption “percentage of gap filled through policy 1” represents the weight we assigned to the effect that policies 1 has on the various dimensions of safety culture index considered in the model as already explained in section 6.3.2.10 and table 6. In the same way, by multiplying the variable “percentage of corrective action implemented through policy 2 due to percentage of reported medical errors on desired reported medical errors” per the “Safety Culture index gap” and the assumption “Percentage of gap filled through policy 2” we define the “effect of corrective action implemented through CRM policy 2 on SCI dimensions”. This two symmetrical structure based on effect of policy 1 and policy 2 on Safety culture index dimensions need to define the “overall effect of corrective action implemented through CRM policies on SCI dimensions” that will go in turn to define the inflow “improvement in safety culture index”. This one is the inflow of the stock “Safety culture index SCI”. The value of the stock “Safety culture index SCI” at the time0 01701/2009 is defined by the assumption described in section 6.3.2.2. The outflow “lowering in SCI” represent the obsolescence of knowledge. We set this value to 20 years by using some theories about knowledge obsolescence (Rosen, 1975).

Figure 16 shows a section of the stock and flow model structure, sector 6: hospital attractiveness. The assumption which drive this sector is the “Effect of clinical error on hospital reputation”. As already explained in this work, we assume that different kind of errors have different kind of effect on hospital reputation. Of course sentinel events have more impact on the hospital reputation so we assign a weight of 65% in the definition of hospital reputation. On the contrary, adverse events have just a weight of 35% in the definition of hospital reputation due to the minor incidence of the consequences of the event. We decided to create a graph function (detailed explained in section 6.3.2.4) to explain the relationship between the amount of the errors occurred in the hospital and their effect on hospital reputation. Both “Hospital reputation” and “Proximity” contribute to define the “Hospital Attractiveness” with a weight of 50% and an information delay that represents a delay in perception. These delays are used in SD to represent the time lag in processing or using information. Why do perceptions inevitably involve delays? “All beliefs, expectations, forecasts, and projections are based on information available to the decision maker at the time, which means information about the past. It takes time to gather the information needed to form judgments, and people don’t change their minds immediately on the receipt of new information”(Sterman, 2000). In addition, in order to reproduce the historical behavior of the ward, we create a variable “ward chief” since in 2012 a new ward chief, (in office just for 2012) coming from another city, has contributed to the increase in the number of patients because it has brought with him the women who were his patient.

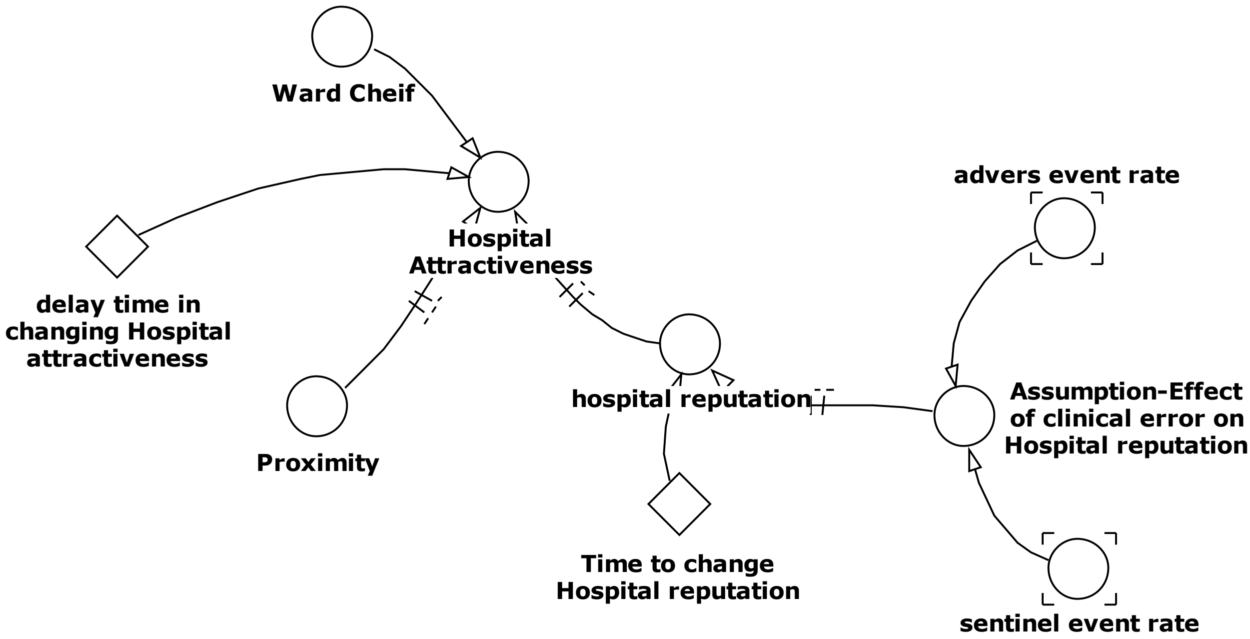

Figure 16. Sector 6: Hospital attractiveness.

Figure 17 shows a section of the stock and flow model structure, sector 7: financial sector. We already illustrate the choice to treat this sector in an aggregate way (sections 6.3.2.1 and 6.3.2.6) due to a lack of detailed information about ward' costs. The central stock "Ward financial availability" represent a net difference between the ward revenues and expenditures. The revenues are represented by the inflow "ward treatments earnings" that is the total yearly income of the ward coming from DRGs. The expenses are represented by three outflows: "ward overall fixed costs" (we set the value of this variable exogenously to 90% of the total "ward treatments earning" coming from DRGs), "lawsuits cost" (represented by the total costs related to lawsuits both loosed and won related to both sentinel and adverse events) and "CRM policies cost". This last outflow is determined by the "average cost of policy 1" and the "average cost of policy 2".

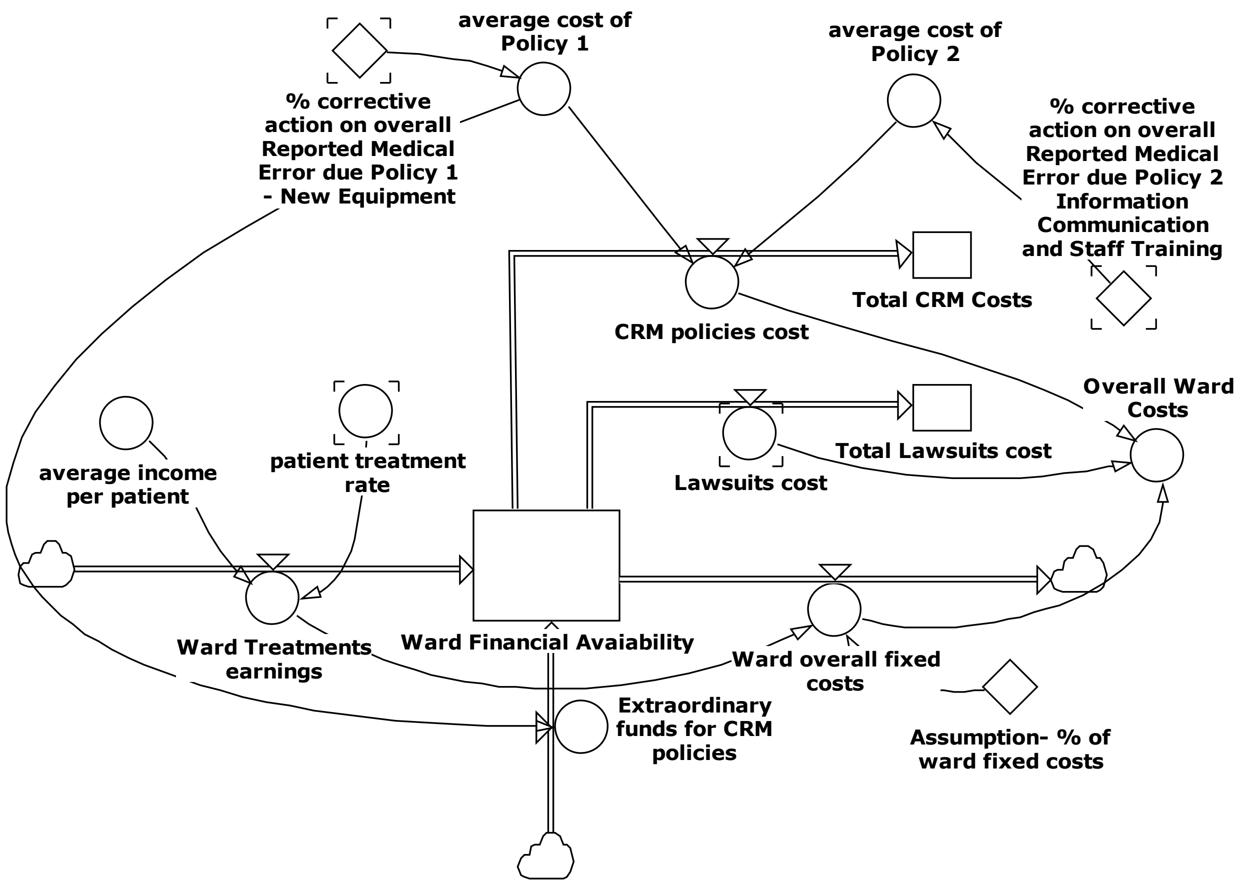

Figure 17. Sector 7: financial sector.

In order to determine the value to assign to this two variables we used some assumptions made by the researcher in accordance with the client due to the lack of information that characterized this sector of the system. For the “average cost of policy 1” we set a range of values from 0 euro (when the policy is activated at 0%) to 1000000 euro (when the policy is activated at 100%). In the same way for the “average cost of policy 2” we set a range of values from 0 euro (when the policy is activated at 0%) to 50000 euro (when the policy is activated at 100%). We also have another inflow to the main stock “ward financial availability”, the “extraordinary funds for CRM policies”. This inflow represents the amount of money necessary for the ward reorganization after its closure in 2010. We assume that the amount of money necessary for the implementation of policy 1 during the ward closure and reorganization came from Extraordinary funds provided by ASP, for this reason these costs do not affect directly the ward financial availability.

6.4 Model parameterization

There are three ways how variables parameterization was carried out throughout the modeling process (table 7). First, some parameters were derived directly from the literature and then their values were confirmed with the client. Second, some others parameters were determined based on historical data collected both in the hospital and in the ward through interviews with the CRM key actors. Third, due to the lack of information already mentioned in the previous part of the present work, some parameters were determined by assumptions made by the researcher in accordance with the client. All the parameters are supported by the relevant sources in documentation to the model (Appendix 2).

Name	Unit	Base value	Source
% of no harm events	%	16	historical data
Assumption - % reported events that need corrective action	%	2	assumption
Assumption - values reduction of Safety culture index dimensions at 2009	%	50	assumption
Assumption- % Gap filled through P1	%/yr	100<<%/yr>>-'Assumption- % Gap filled through P2'	assumption
Assumption- % Gap filled through P2	%/yr	{80; 75; 85; 100; 70; 100; 40; 60; 50; 25}	assumption
Assumption- % of lawsuits from different kind of event	%/yr	{100; 10}	assumption
Assumption- % of ward fixed costs	%	90	assumption
Assumption- % won lawsuits	%	{90;60}	assumption
Assumption- average cost per loosed lawsuit	euro/event	{1200000; 25000}	assumption
Assumption- average cost per won lawsuit	euro/event	{15000; 2000}	assumption
Assumption- timing of lawsuit payments	Yr	{10; 2}	assumption
Delay time in changing Hospital attractiveness	Yr	1	assumption
Depletion time	Yr	20	literature: Rosen 1975
Event per patient	event/people	1	assumption
Patient capacity	people/da	10	historical data
Population affected by gynecological event	People	1300	assumption
Proximity	%/yr	100	assumption
Time to become inpatient	Da	1	assumption
Time to change Hospital reputation	Yr	2	literature: Hibbard et al 2005
Time to define medical error	Da	1	assumption

Table 7. Model parameterization

6.5 Model validation

This section gives a short discussion on the definition of the validation as employed in this thesis and an overview of the validation tests relevant to this model. There is no agreed formal definition of the concept of validation in the system dynamics literature. However, there is a certain consensus that validation is a gradual process on establishing confidence in the soundness and usefulness of a model (Forrester & Senge, 1980). According to Barlas 1996, model validity means usefulness with respect to a purpose. The approach to validation in this thesis is performed in accordance with these definitions. As it follows this approach dictates an explicit formulation of the model's purpose.

As discussed deeply in this work, due to the nature of the problem and the lack of conventional reference mode and information the focus of the validation procedures is primarily on the validity of the structure of the model. This is also in line with the general approach in system dynamics methodology to model validation. Following Barlas 1996 we use three kind of test: direct structure test, structure-behavior test and behavior pattern test.

6.5.1 Direct structure tests

With this set of test we can evaluate the validity of the model structure by direct comparison with the real structure of the system (the ward), these tests do not involve simulation and are performed constantly during the model building process.

- Structure confirmation test: during each step of this project, extensively conversations and interviews have taken place with the CRM key actors of the hospital and every time a certain structure was built it was discussed and confirmed with the client to make sure that the model reflects the real structures and decision-making processes.

- Parameter confirmation test: how already explained in section 6.4 of this work, parameterization was carried out throughout the modeling process by using three sources of information: literature, historical data and assumptions.

6.5.2 Structure oriented behavior tests

By performing this group of tests we assess the validity of the structure indirectly by applying certain behavior tests on model-generated behavior patterns. These tests involve simulation and are considered to be strong behavior tests that can help the modeler uncover potential structural flaws.

- Extreme condition test: This test involves assigning extreme values to selected parameters and comparing the model-generated behavior to the observed (or anticipated) behavior of the real system under the same extreme condition. This test consists of determining the parameters to which the model is highly sensitive, and asking if the real system would exhibit similar high sensitivity to the corresponding parameters. A perfect candidate for the extreme-condition test is the “Safety Culture Index” stock. This parameter plays the important role in determining the potential for occurring in medical errors: higher SCI would mean a reduction in the medical errors occurrence, while lower SCI would result in the corresponding increase in medical errors. It is enough just to change the SCI value. At time 0 (01/01/2009), the SCI value is 33,67%. We bring this value to 0% for the first extreme condition test. What would happen in the real system? The amount of medical errors occurred in the ward, under such condition, would become in growth and the hospital attractiveness would suffer a reduction. In the same time the lawsuits costs would suffer a sharp increase contributing to raising the overall ward costs. Figure 18 shows the model’s response to the extreme condition.

Figure 18. Extreme condition test 1: Reference behavior (marked by the asterisk) is the base run of the system and the current behavior is the output of the system with the Safety Culture Index at 0%

The reference behavior (marked by the asterisk) represents the base run of the system and the current behavior represents the output of the system with the Safety Culture Index at 0%. As the figure 18 portrays the “overall events”, that represents the total amount of medical errors occurred in the ward, increases considerably compared to the reference behavior (base run) of the system. Consequently, the costs related to lawsuits, namely the “lawsuits costs”, increases and contributes to the rise in the “overall ward costs”. The “hospital attractiveness” drops to 50% and it settles to this value till the end of the simulation period. In this case the hospital attractiveness only depends by the proximity (whose the weight in the definition of the hospital attractiveness is 50%) and not by the hospital reputation. The tested formulation is robust.

Figure 19 shows a second extreme condition test. In this case we bring the value of SCI to 100%. What would happen in the real system? The amount of medical errors occurred in the ward, under such condition, would decrease and the hospital attractiveness would experience an increase. In the same time the lawsuits costs are drastically reduced because there are no errors to manage. Figure 19 illustrates the model’s response to the extreme condition, where the reference behavior (marked by asterisk) represents the base run of the system and the current behavior represents the output of the system with the Safety Culture Index at 100%. We can see as the “overall events” are less in comparison to the base run of the model. However the curve shows a steady increase that depends in one hand by the structure of the model (we hypothesized, based on literature review, that in the generation of medical errors two kind of event are not under the management control: the near miss and the no harm event. For this reason even with the maximum level in SCI we still have some errors in the ward). On the other hand by the effect of the depletion rate over the Safety Culture index stock, this causes the appearance and the follow increase of adverse event. For the same reason we can also expect the appearance and the follow increase of sentinel event but, due to the long time necessary for the obsolescence of knowledge and the effect of Safety culture index on sentinel event, many years are required before the sentinel events appear in the ward. Figure 20 shows the simulation result of sentinel event under such condition with a long time horizon (2009-2029). As we expect around 2023 the sentinel event rate starts and it suffer a steady increase years by years due to the depletion in SCI. This last evidence shows as without any CRM policy even the best ward, in term of Safety Culture diffusion, suffers the obsolesce of knowledge that is responsible of the lowering in SCI. With regard to the “lawsuits costs” we have no expenses because we have no errors to deal with and consequently we have less “overall ward costs” (in this case the cost are just related to the fixed ward costs and no to the lawsuit management). Lastly, the “hospital attractiveness” under such condition is very high in comparison to the reference behavior. It starts approximately to 100% and it stays more or less stable to this value till the end of 2013. After this data, due to the “lowering in patient safety index” driven by the “depletion time” (value set exogenously to 10 years, as already explained in section 6.3.2.1) the value of this variable starts to decline. The tested formulation is robust.

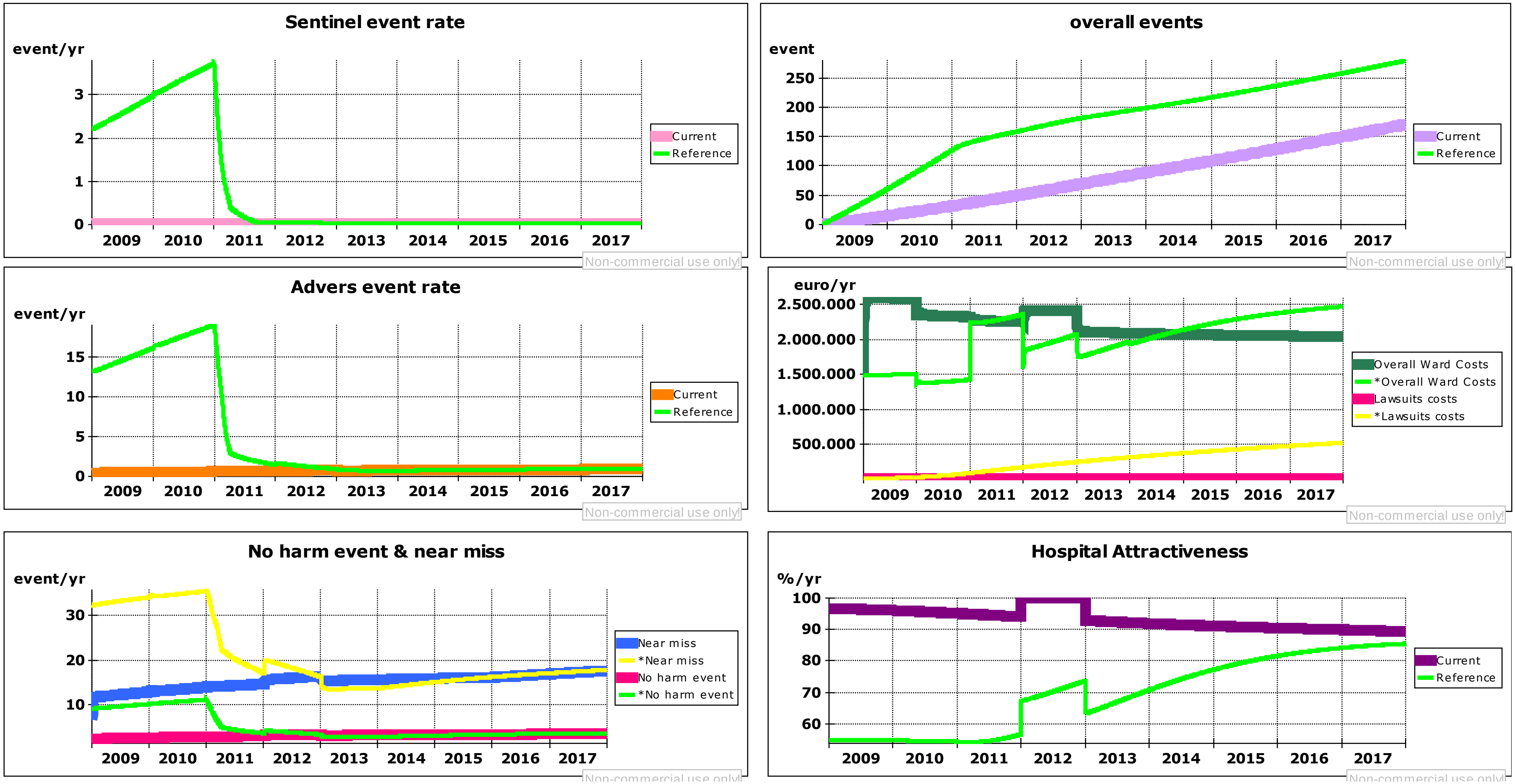

Figure 19. Extreme condition test 2: Reference (marked by the asterisk) is the base run of the system and current is the output of the system with the Safety Culture Index at 100%

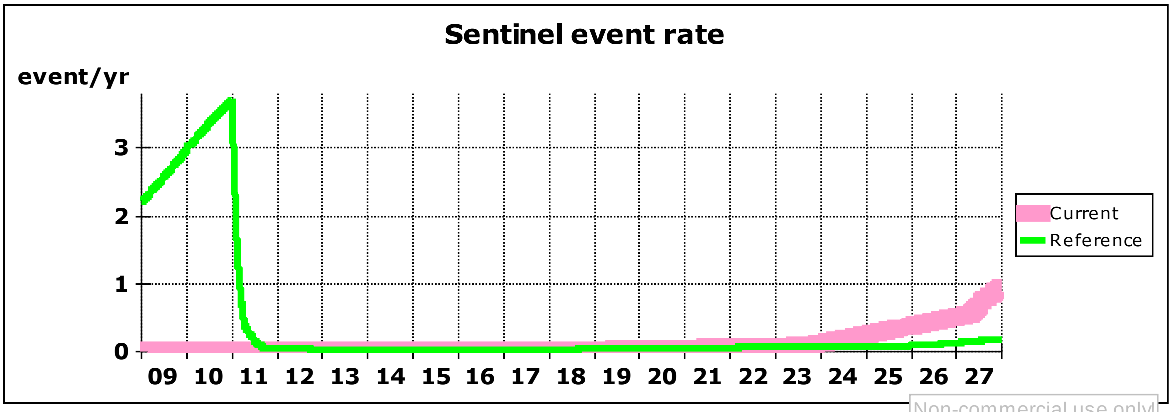

Figure 20. Long run Sentinel event rate response to extreme condition test 2: SCI equal to 100%.

- Partial model test: this test, also knew as "cutting loop" was performed during the model building process. The partial model test help to confirm the functionality of separated sector of the model in order to understand, before to put the sector together, if there are some potential structural flaws. Each sector of the model was tested through the partial model test together with the client, in order to evaluate if the behavior generated by the sector reproduce the behavior of the real system. Thus, the partial model testing confirmed the functioning of sectors separately as intended.

6.5.3 Behavior pattern tests

These tests are used to evaluate if the behavior generated by the model corresponds to the one observed in the real system. Normally this involves comparing the generated behavior with the reference mode. However, as already deeply explained, our reference mode suffer a lack of information due to the newest introduction of a CRM department in ASP6, for this reason we evaluate the behavior generated by the model in accordance with the client in order to observe if the behavior produced by the model is able to reproduce the one of the real system. More precisely, all the generated behavior patterns were presented to the client and confirmed whether they represent a reasonable behavior or not.

CHAPTER 7: POLICIES ANALYSIS

7.1 Policies choice and description

Based on the analysis of the system described in the previous section, conducted together with the client, two different policies have been tested and compared with the purpose to estimate the effect of such policies on Safety Culture Index and consequently on ward's performance. In effect, the amount of medical errors can be considered (as already declared in section 3.4) as a performance index for the hospital, it tells us how the hospital personnel and the hospital management deal with patient safety. Indicators for performance and outcome measurement allow the quality of care and services to be measured.

In the previous chapter we built the confidence in the system dynamics model developed for addressing the research objectives of this study. Once the confidence is established, we can declare that we have a valid theory explaining why "the things behave as they do". However, an explanatory model is often not enough to address the initial problem; often we invest into our understanding of a system with an idea to design improvements that may hopefully alter its behavior. Namely, an explanatory system dynamics model be would normally followed by a policy model, incorporating the policy structure(s). An interesting circumstance of the current case is that the explanatory model was already being built with a concrete idea of which policy would be incorporated into the structure. Essentially, the explanatory model was tailored to provide the simulation environment for testing concrete policies. Thus, a choice for the policy structure was predetermined because the chosen policies are those that the ASP management has implemented over the past years to cope with the events that have occurred in the ward between 2009 and 2010 described in the section 5.3, namely: "Policy 1- New equipment" and "Policy 2- Information, communication and staff training".

“Policy 1- New equipment” refers to structural interventions that have been implemented in the ward during the closure and reorganization of the ward (such as the placement of the delivery room and operating room on the same floor) and also to some ward’s needs that have emerged during the interviews conducted with the CRM key actors, illustrated in the section 5.4.1 and during the several meeting with the client (such as the purchase of new ecograph, the implementation of the computerized medical record, the purchase of new furniture for the patient rooms and so on). We assume that the costs for the implementation of policy 1 range from a minimum of 10.000 € when the policy is launched at 5% (it means that the ward sets up just few corrective measures, for instance maintenance of equipment or purchase of new surgical tools) to a maximum of 1.000.000 € when the policy is launched at 100% (it means that the ward sets up all the corrective measures necessary, for instance the building of a new delivery room).

“Policy 2- Information, communication and staff training” refers to interventions that have been realized in the ward after the implementation by ASP6 of the a business plan for clinical risk management in 2010 (such as the launch of the website, the implementation of the SIMES data stream, the staff training course) illustrated in section 5.1. We assume that the costs for the implementation of policy 2 range from a minimum of 4.500 € when the policy is launched at 10% (it means that the ward sets up just few corrective measures, for instance maintenance of the website or the organization of an event focused on patient safety and open to all the patient and their relatives) to a maximum of 50.000 € when the policy is launched at 100% (it means that the ward sets up all the corrective measures necessary for instance a intensive training course for the whole staff).

We assume that each policy has a different effect on the various dimensions of Safety Culture index considered in the model. These different effects and their reasons are explained in table 6.

In order to test and compare the effect that the different policies have on Safety Culture index four different scenario have been launched in the model.

7.2 Cockpit description

After having built the System Dynamics model, a specific decision cockpit has been developed, again utilizing Powersim Studio 7. The System Dynamics decision cockpit allows an easy management of system levers and help to evaluate the result of the *what-if* analysis. What-if analysis is a data intensive simulation whose goal is to inspect the behavior of a complex system under some given hypotheses called scenarios. In particular, what-if analysis measures how changes in a set of independent variables impact a set of dependent variables with reference to a given simulation model and it is useful to take the most appropriate decision for a particular context. It is important to notice that there is an essential difference between what-if analysis and simple forecasting, this latter are extensively used in the banking and insurance fields. In fact, while forecasting is normally carried out by extrapolating trends out of the historical series, what-if analysis requires simulating complex phenomena whose effects cannot be simply determined as a projection of past data.

Figure 21 shows the simulation cockpit. The chosen variables inserted in the cockpit represent the variables and their relative values that we want to monitor in order to evaluate the effect of the CRM policies. These variables are the follows:

-Percentage of error reported based on Safety Culture index

-Overall ward costs

-CRM policies and lawsuits costs

-Sentinel event rate

-Adverse event rate

-No harm event and Near miss

-Ward financial availability.

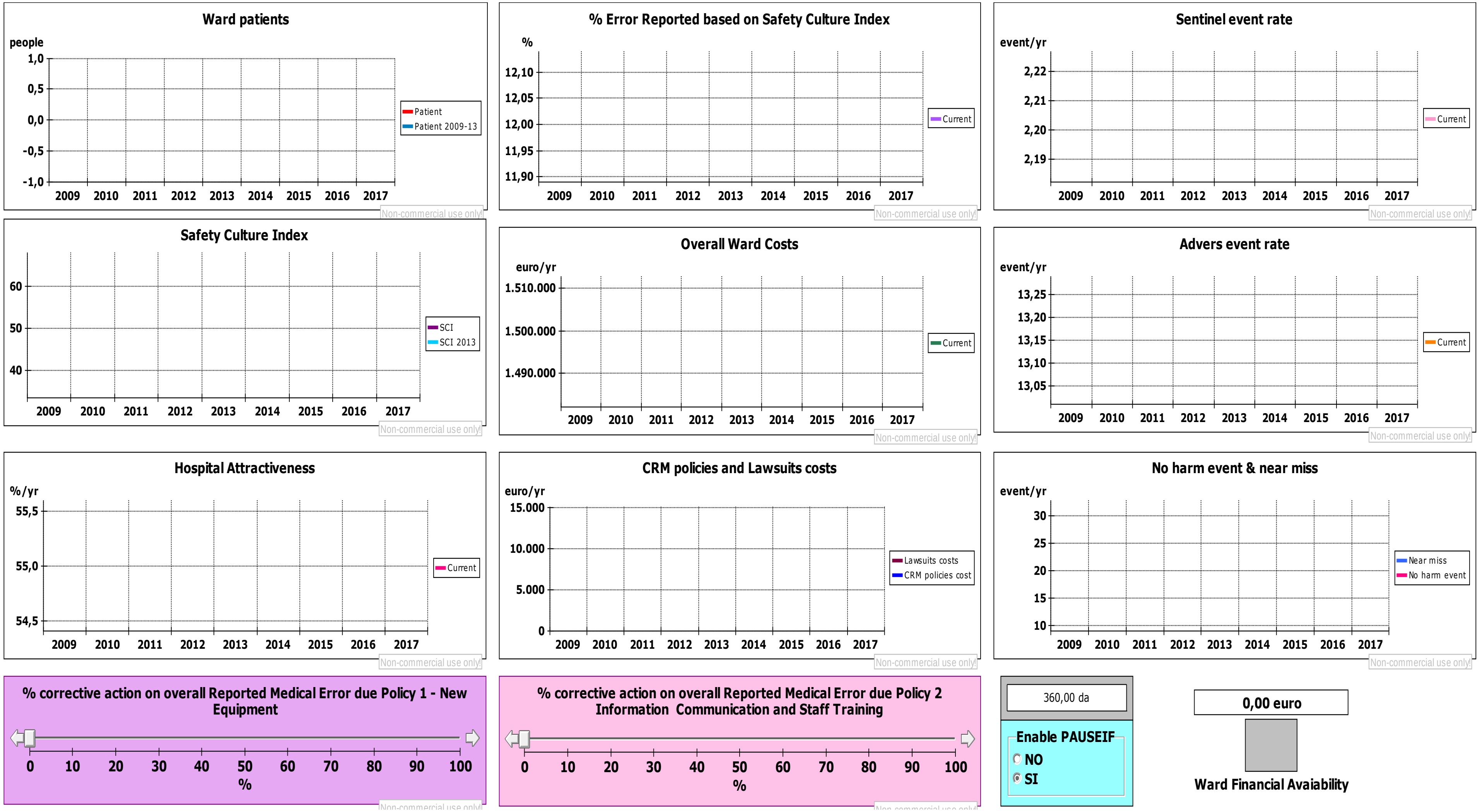

Figure 21. Simulation cockpit.

7.3 Scenario analysis

For the scenario analysis a nine year time horizon is considered. The first five years of the simulation run (2009 - 2013) have the scope to replicate the past ward's performance. The last four years (2014 – 2017) show the expected effects of adopted CMR policies on ward performance. We decided to simulate three different scenarios and to compare them with the reference base run scenario. The different scenarios considered in this paper are showed in table 8.

	Base Run		**Low performance scenario**		**High performance scenario**		**Expensive scenario**	
Years	*Policy 1*	*Policy 2*	*Policy 1*	*Policy 2*	*Policy 1*	*Policy 2*	*Policy 1*	*Policy 2*
2009	0	0	0	0	0	0	0	0
2010	0	0	0	0	0	0	0	0
2011	90	90	90	90	90	90	90	90
2012	0	80	0	80	0	80	0	80
2013	0	80	0	80	0	80	0	80
2014	0	20	0	0	30	70	90	90
2015	0	15	0	0	20	70	80	80
2016	0	15	0	0	10	70	80	80
2017	0	10	0	0	10	70	80	80

Table 8. Scenario description

More in detail, we depict the following scenarios:

- The base run scenario (BR) represents the real behavior of the ward in the past years. After 2013 we assume, based on ASP6 Palermo business plan for clinical risk management launched in the second half of 2010, that the ward will implement few CRM policies by focusing just on policy 2 as shown in table 8.
- The low performance scenario (LPS). This is also called the no policies scenario. In this case it is assumed that the hospital decides to cut to zero the investment in CRM policies after the implementation of the CRM policies implemented during the years 2009-2013. As a consequence no corrective action will be implemented over clinical event after 2013.

- The high performance scenario (HPS) is used to describe the system behavior under optimal conditions. We assume that, after 2013 the management decide to still invest both on policy 1 and policy 2 as shown in table 8.
- The expensive scenario (ES) represents a scenario where the ward makes strong investments both in policy 1 and policy 2 as depicted in table 8.

The following figures show the simulation results of the considered scenarios.

7.3.1 Base run vs. Low performance scenario (LPS)

Figures from 22 to 30 show the simulation results from the LPS scenario compared with the base (reference) run. The reference run (marked by the asterisk) represents the base run, the current run represents the simulation results from the worst scenario.

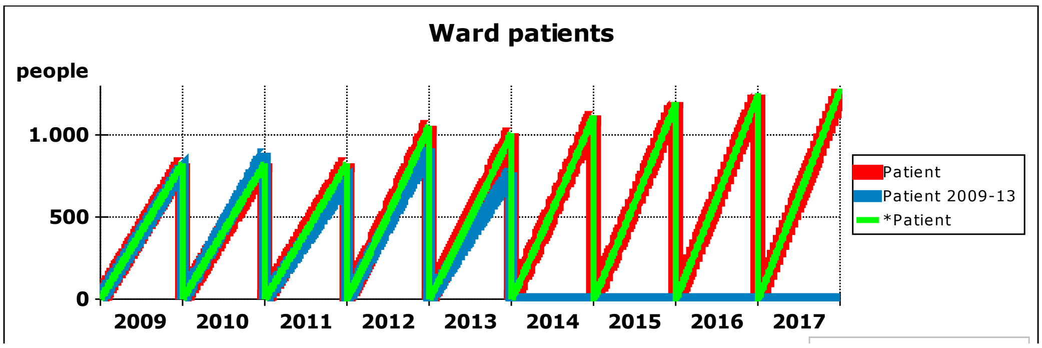

Figure 22. Ward patient. Base run (reference) and LPS (current).

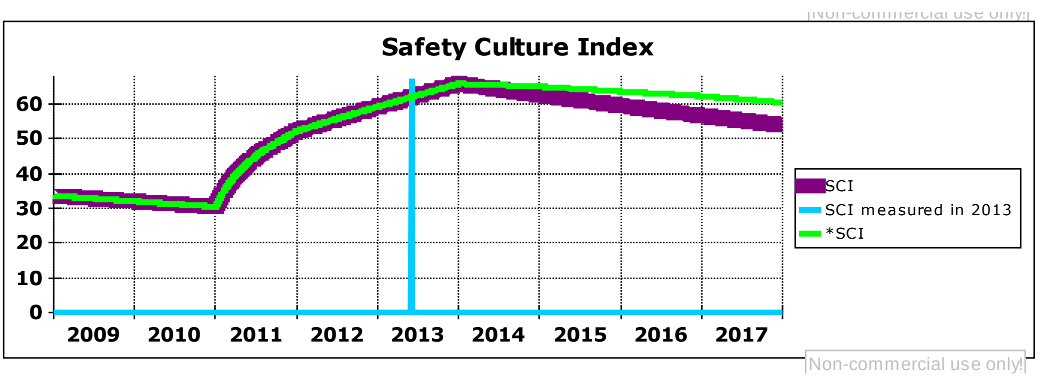

Figure 23. SCI. Base run (reference) and LPS (current).

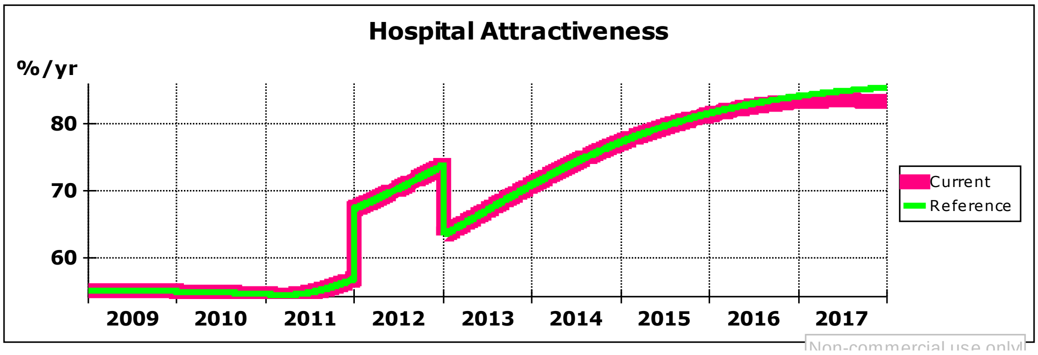

Figure 24. Hospital Attractiveness. Base run (reference) and LPS (current).

The figure 23 shows a stronger reduction in SCI from LPS then from BR after the stop of CRM policies implementation. The hospital attractiveness (fig. 24) stops growing in 2015 due the stop of CRM policies, and we can expect a decreasing pattern in the long run. As we can observe, the hospital attractiveness starts to decrease with a delay with respect to the CRM policies stop, this because we build the hospital attractiveness by using the *delayinf* function that represents an information delay resulting from the time required to perceive and act upon information. As a consequence, we can expect a reduction in the number of ward patients due to the reduction in hospital attractiveness, however we can observe this reduction just at the end of the simulation period (fig 22) and we need to consider a longer time horizon to see the stronger decrease in patients.

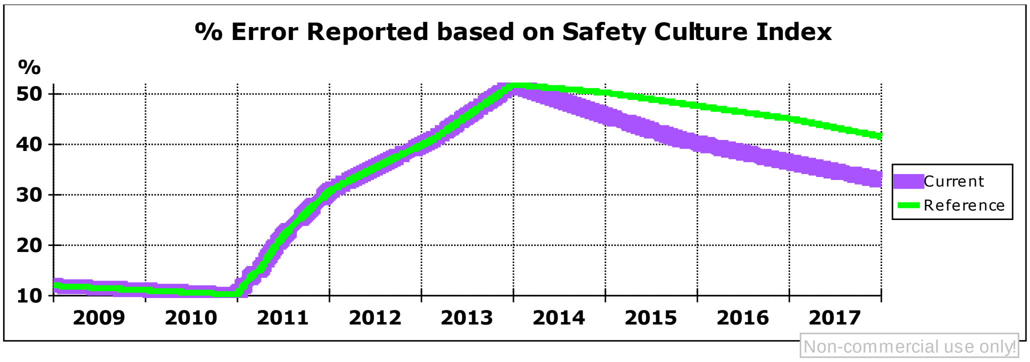

Figure 25. Percentage of error reported based on SCI. Base run (reference) and LPS (current).

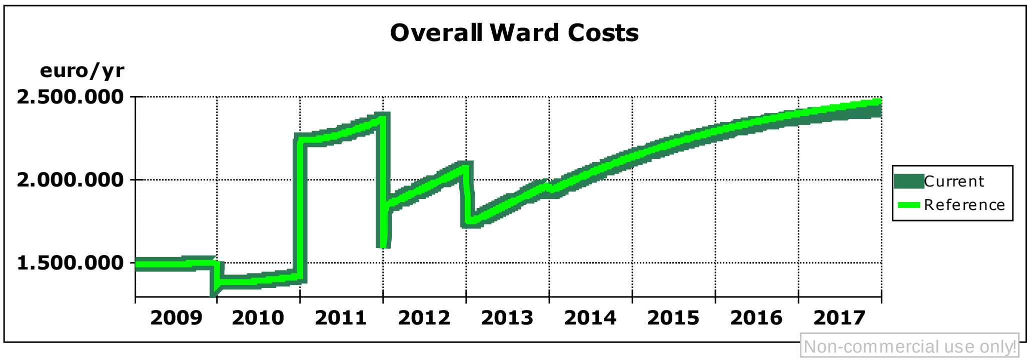

Figure 26. Overall ward costs. Base run (reference) and LPS (current).

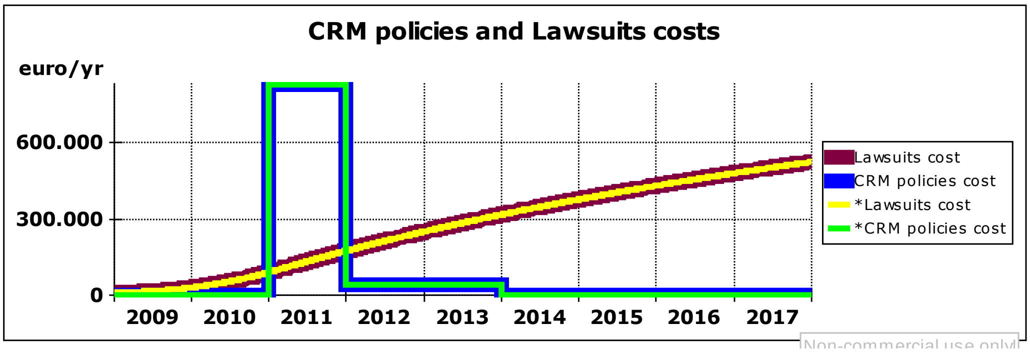

Figure 27. CRM policies and lawsuits costs. Base run (reference) and LPS (current).

The percentage of errors reported based on Safety Culture index follows the same curve of the Safety Culture index (fig 25), we have a reduction of this variable just after the cut in CRM policies implementation because this variable depends directly by the value of SCI as explained in section 6.3.5.2. There are no big differences between Overall ward costs, CRM policies cost and Lawsuits costs in LPS and BR (fig. 26 and 27) because in the base run, after the big CRM policy investment, the ward reduced the CRM policies investments to the minimum (as explained in table 8) and no other CRM policies are implemented in the follows years. In the LPS we do not observe CRM policies costs because no policies were implemented after 2013. However the amount of CRM policies cost are very similar for the WS and for the BR because in the BR the policies implemented after 2013 are very limited, they just cost 4500 euro per year. Moreover, because of the investment made by the management from 2010 to 2013, even with no

CRM policies implementation there aren't new sentinel events in the ward in the short run and consequently there aren't new lawsuits to deal with in the current run (see figure 28).

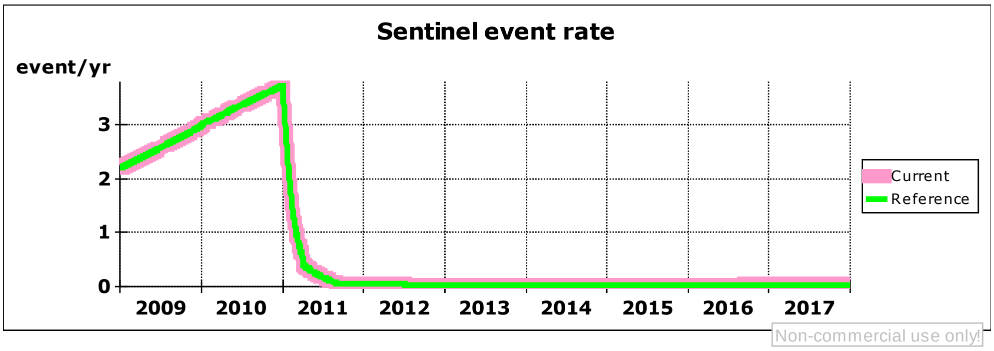

Figure 28. Sentinel event rate. Base run (reference) and LPS (current).

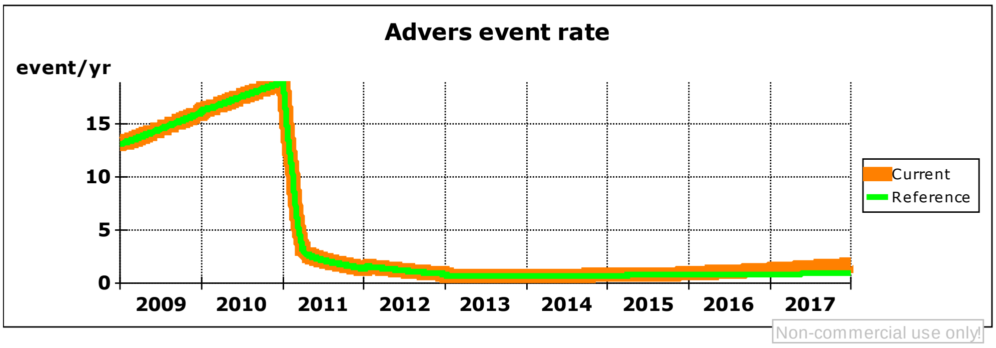

Figure 29. Adverse event rate. Base run (reference) and LPS (current).

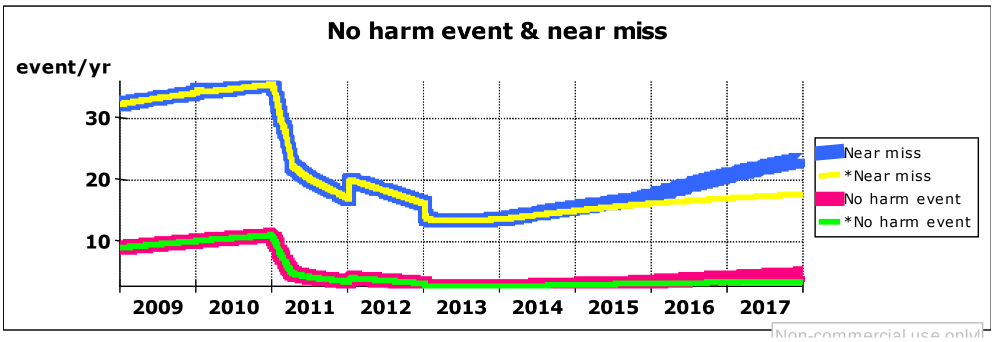

Figure 30. No harm event and near miss rate. Base run (reference) and LPS (current).

In reference to the amount of errors occurred in the ward within the LPS scenario, we expect a significant increase of them. Nevertheless we can notice a lower increase in medical errors (especially in adverse and sentinel events) in the current run as shown in figures 28, 29 and 30. However, as happened in the extreme condition test explained in section 6.5.2, we need a longer time horizon simulation to better evaluate the effects of a worst scenario. Many years are required before the sentinel events appear again in the ward because of the long time necessary for the obsolescence of knowledge and the effect of Safety culture index on sentinel event.

7.3.1.1 BR vs. LPS in 2009-2028 time horizon

In figure 31 we can evaluate some variables of the cockpit with a longer time horizon (2009-2028) to better evaluate the effect of the management choices in the long run. From 2018 to the end of the long run simulation we use the same value of the 2018 in CRM policies adoption. The simulation results show how sometimes in the short run we are no able to evaluate the real effect of our choices. By analyzing just the short time horizon we had not realized that by avoiding to implement CRM policies we would have had a recurrence of sentinel events, bringing the organization to the starting point. Just with the long time horizon we can realize the real effect of our decisions.

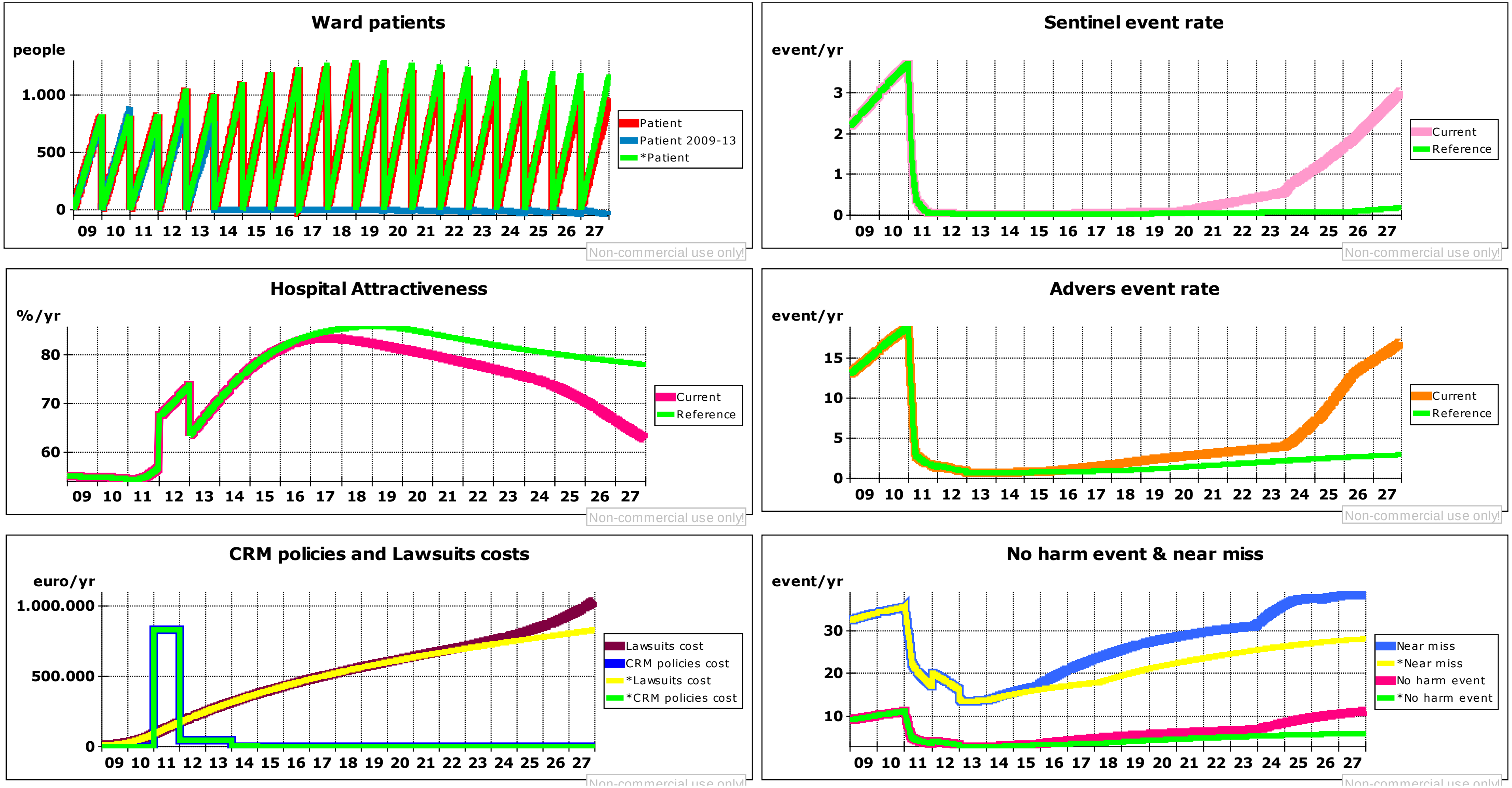

Figure 31. Long time horizon. Base run (reference) and LPS (current).

7.3.2 Base Run vs. High Performance scenario HPS

Figures from 32 to 40 show the simulation results from the HPS. The reference run (marked by the asterisk) represents the base run, the current run represents the simulation results from the HPS.

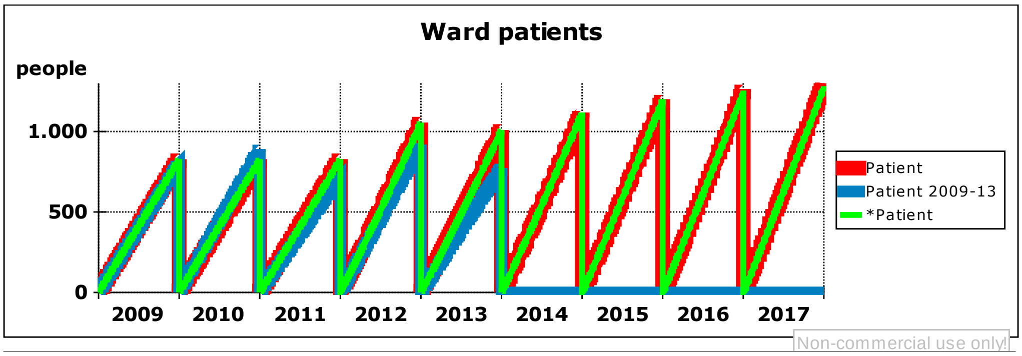

Figure 32. Ward patients. Base run (reference) and HPS (current).

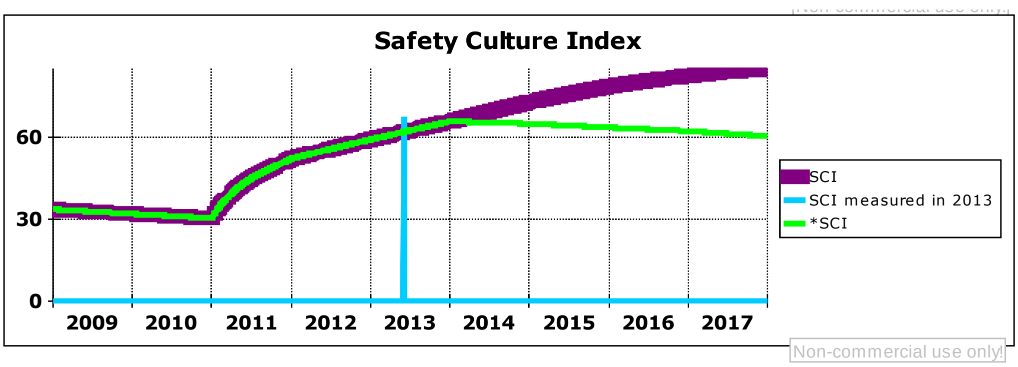

Figure 33. SCI. Base run (reference) and HPS (current).

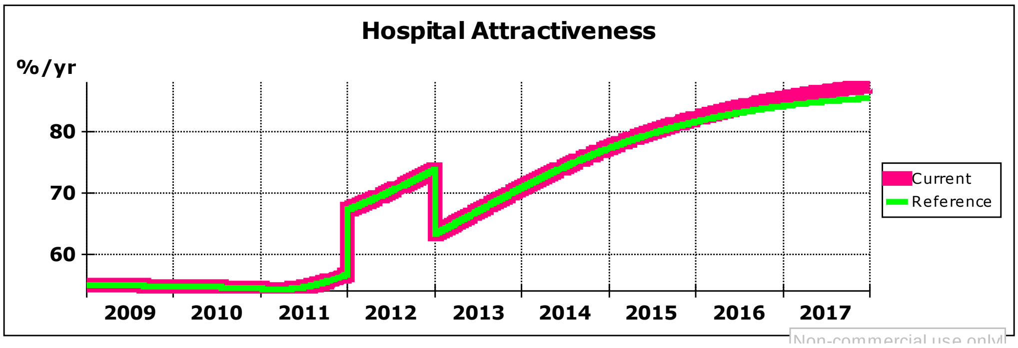

Figure 34. Hospital attractiveness. Base run (reference) and HPS (current).

As the figures 33 shows, with the HPS, we have a significant increase in SCI over the last 4 years of simulation. In this case the effect of the obsolescence of knowledge over SCI (depletion) is balanced by a steady implementation of CRM policies in the ward.

In this scenario, due to low amount of sentinel and adverse events occurred in the ward, the hospital attractiveness increase until reaches the value of 87,49% at the end of the simulation (fig 34). As a consequence the ward patient starts to increase (fig 32) and we can notice it especially at the end of the simulation period. However if we consider a longer time horizon we can see as the patients start to increase more and more over time as a consequence of the increase in hospital attractiveness (see figure 41).

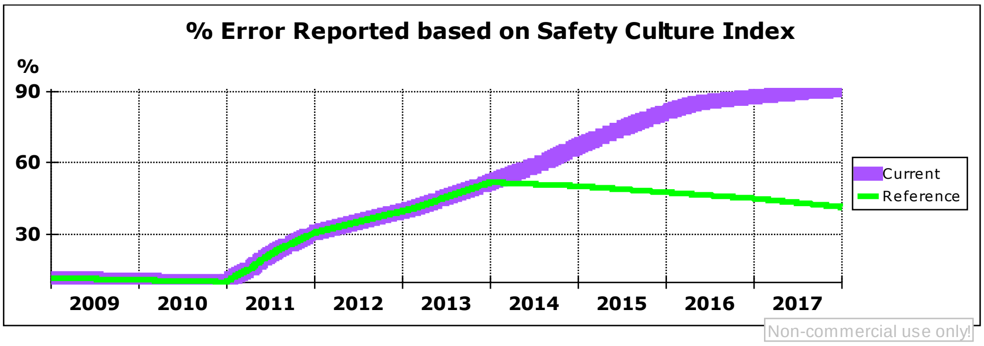

Figure 35. Percentage of error reported based on SCI. Base run (reference) and HPS (current).

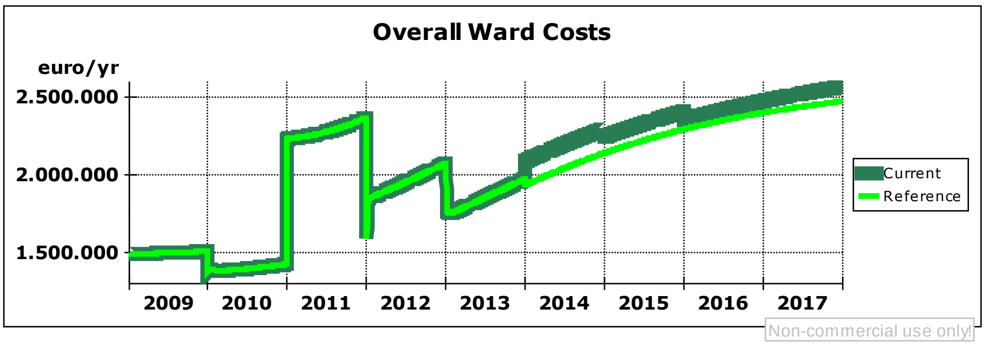

Figure 36. Overall ward costs. Base run (reference) and HPS (current).

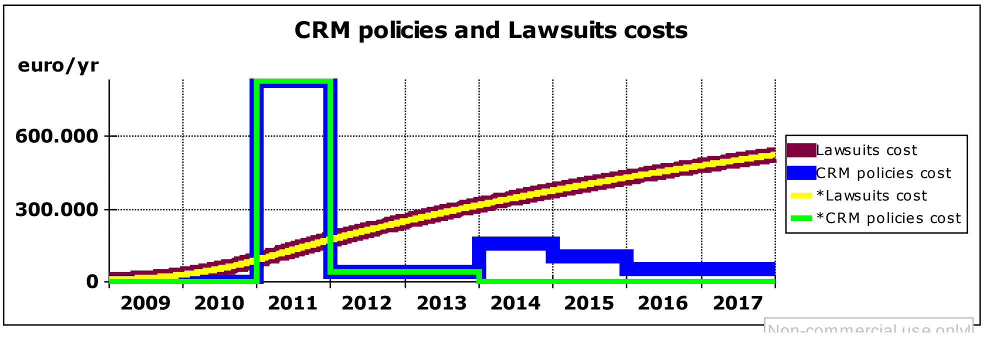

Figure 37. CRM policies and lawsuits costs. Base run (reference) and HPS (current).

As well as for the previous scenario LPS, also in the HPS the percentage of errors reported follows, for the same reasons already explained in section 7.3.1, the behavior of SCI (fig 35). For this reason we see an increase in the percentage of reported events that will have positive consequences on the possibility to take corrective actions and thus improve the quality of health services provided.

In the HPS the overall ward costs are just a bit higher in comparison with the reference run, however they can be attributed to the costs of policy implementation rather than in legal costs as depicted in figures 36 and 37. Actually we have no new lawsuits to deal with in the HPS, so the lawsuits costs are related to the lawsuits already intended to the ward in the past due to the sentinel and adverse events occurred in the previous years.

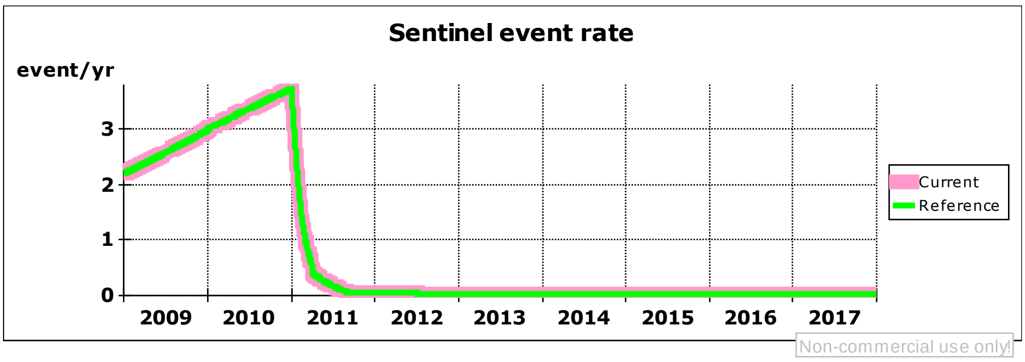

Figure 38. Sentinel event rate. Base run (reference) and HPS (current).

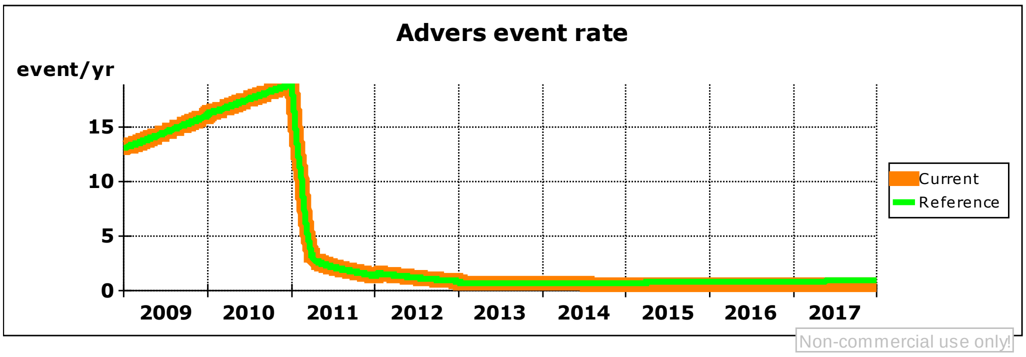

Figure 39. Adverse event rate. Base run (reference) and HPS (current).

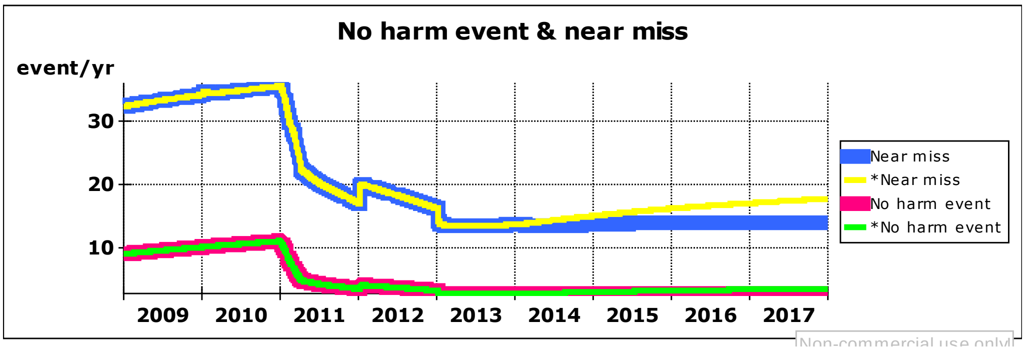

Figure 40. No harm event and near miss rate. Base run (reference) and HPS (current).

In reference to the amount of errors occurred in the ward with the HPS, we expect a significant decrease of them. Nevertheless we can notice that their amount is very similar to the one of the reference run (see figures 38, 39, 40). However, as already explained for the worst scenario, we need a longer time horizon simulation to better evaluate the effect of our decisions.

7.3.2.1 BR vs. HPS in 2009-2028 time horizon

In figure 41 we can evaluate some variables of the cockpit with a longer time horizon (2009-2028) to better evaluate the effect of the management choices in the long run. From 2018 to the end of the long run simulation we use the same value of the 2018 in CRM policies adoption. By analyzing just the short time horizon we had not realized that with this policies combination we have found the equilibrium of the system in reference of the amount of medical errors occurred in the ward with a minimum investment on CRM policies (just 53.000 euro per year).

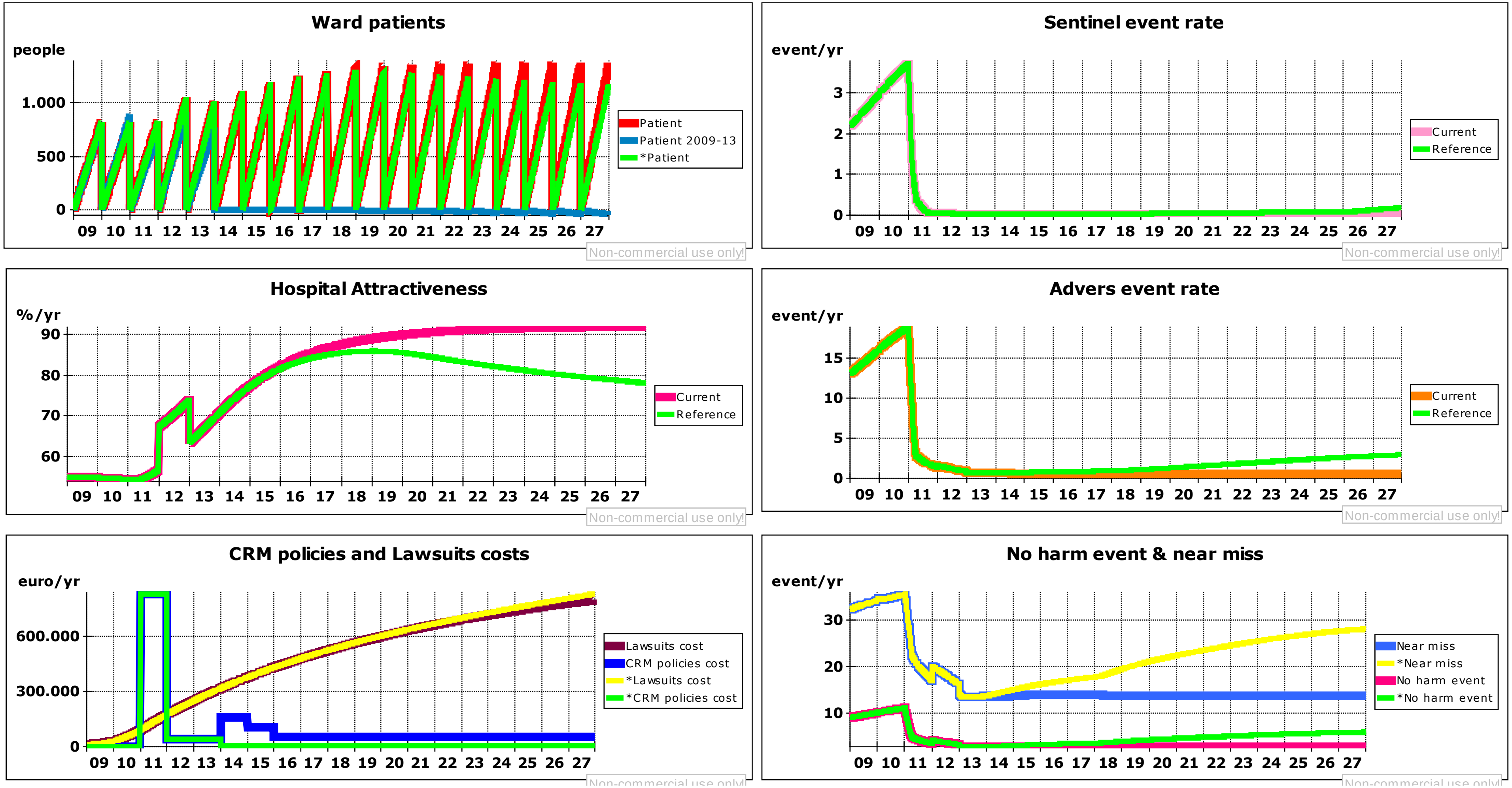

Figure 41. Long time horizon. Base run (reference) and HPS (current).

7.3.3 Base run vs. Expensive scenario ES

Figures from 42 to 50 show the simulation results from the ES. The reference run (marked by the asterisk) represents the base run, the current run represents the simulation results from the ES.

As the follows figures show, with the expensive scenario, we have more or less the same simulation result achieved with the best scenario, however, in this case to achieve the same results have been used much more financial resources bringing the skyrocketing costs. This waste of financial resources is more visible in the long run simulation

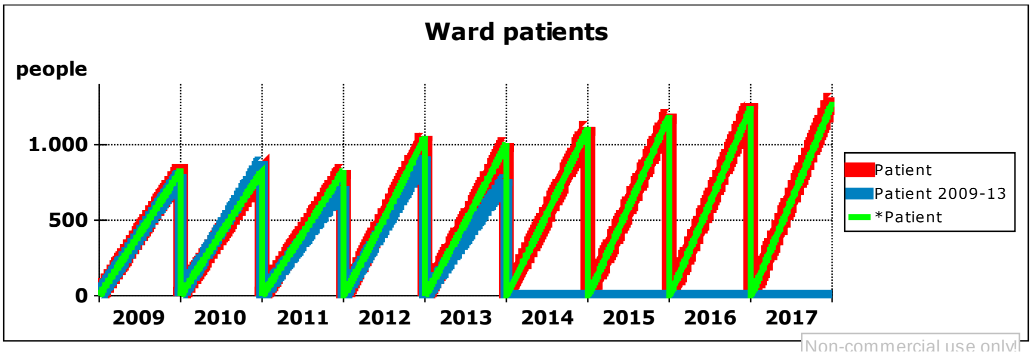

Figure 42. Ward patient. Base run (reference) and ES (current).

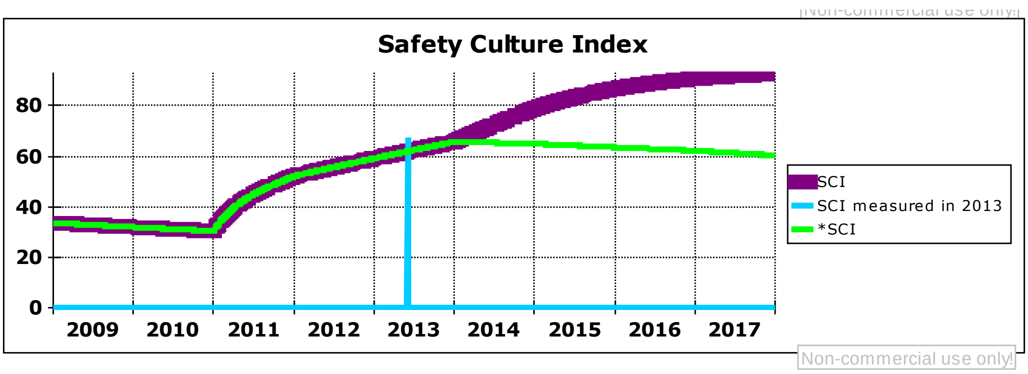

Figure 43. SCI. Base run (reference) and ES (current).

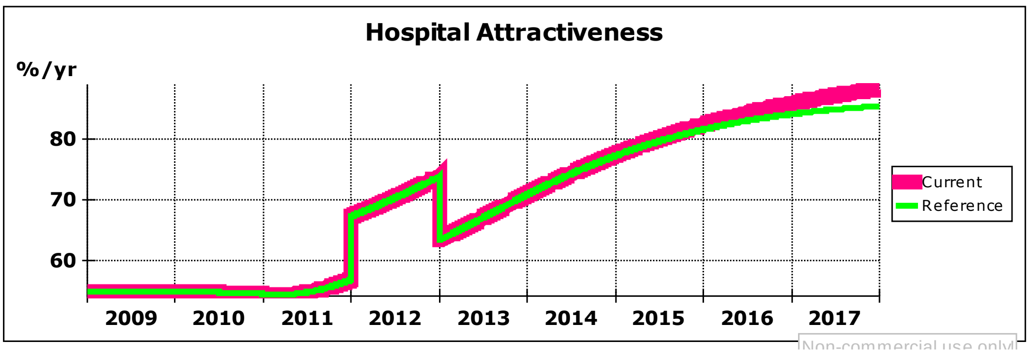

Figure 44. Hospital attractiveness. Base run (reference) and ES (current).

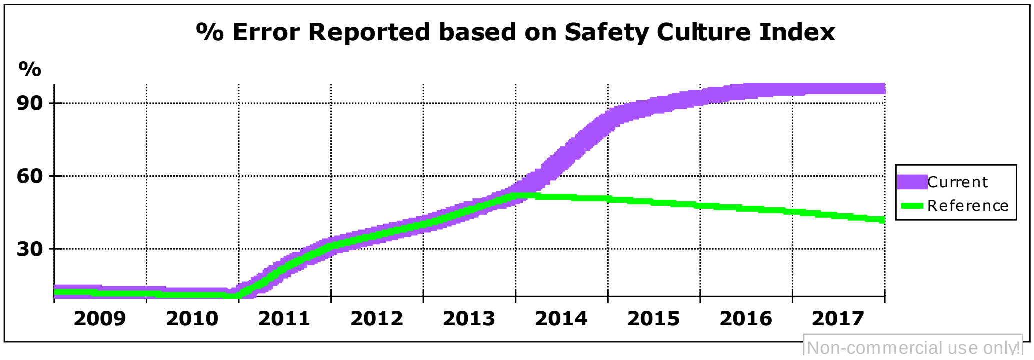

Figure 45. Percentage of error reported based on SCI. Base run (reference) and ES (current).

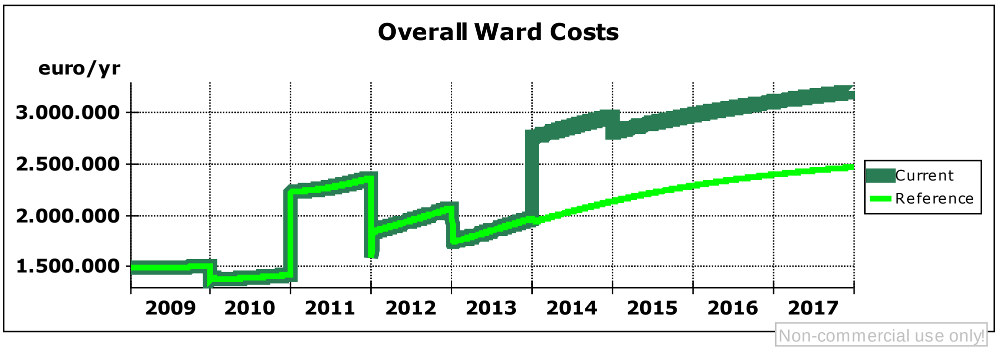

Figure 46. Overall ward costs. Base run (reference) and ES (current).

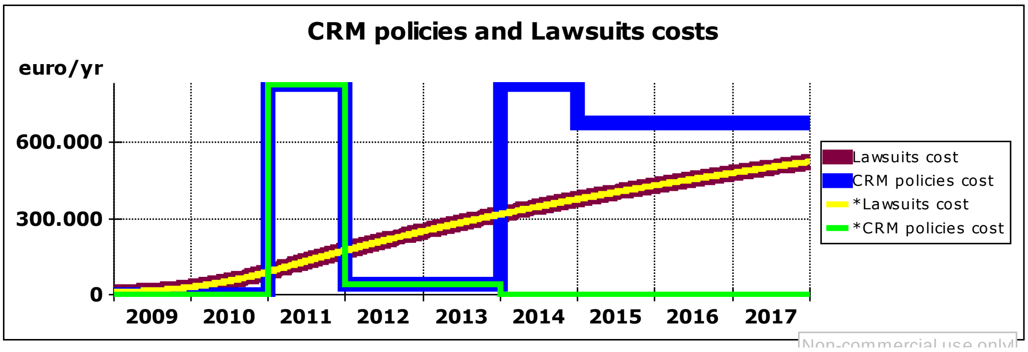

Figure 47. CRM policies and lawsuits costs. Base run (reference) and ES (current).

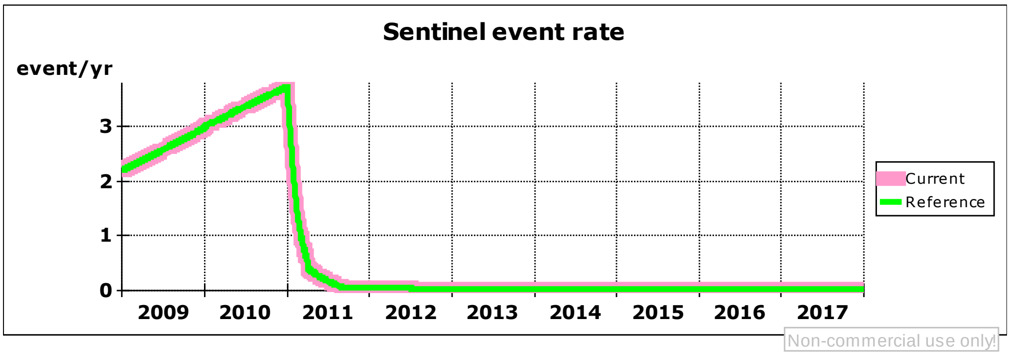

Figure 48. Sentinel event rate. Base run (reference) and ES (current).

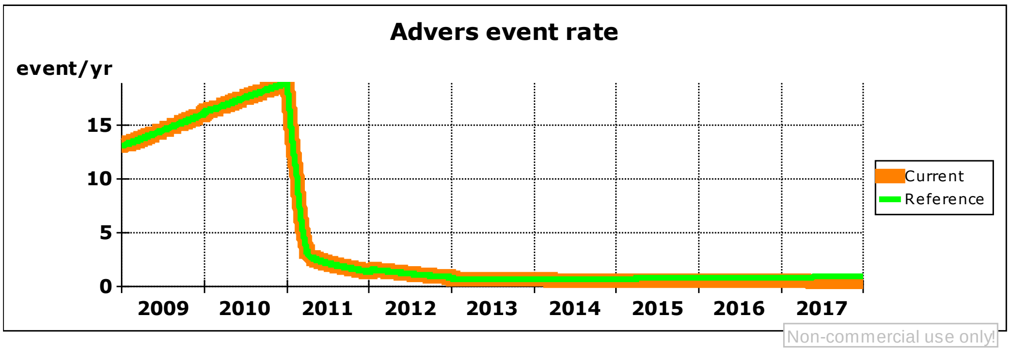

Figure 49. Adverse event rate. Base run (reference) and ES (current).

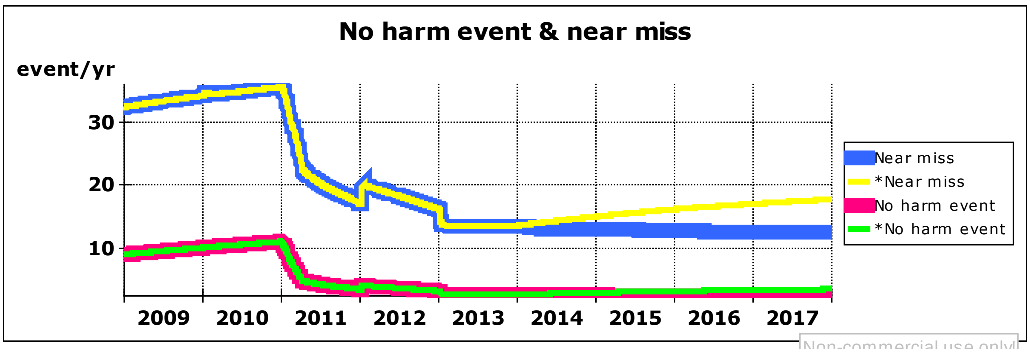

Figure 50. No harm event and near miss rate. Base run (reference) and ES (current).

7.3.3.1 BR vs. ES in 2009-2028 time horizon

Figure 51 shows some variables of the cockpit with a longer time horizon (2009-2028). From 2018 to the end of the long run simulation we use the same value of the 2018 in CRM policies adoption. Here the waste of financial resources is evident because we had already reached the goal of zero adverse and sentinel events per year only with investments in CRM policies of 53,000 Euros per year, and since the number of adverse events and sentinel cannot go below zero, all the policies implemented this scenario are absolutely unnecessary.

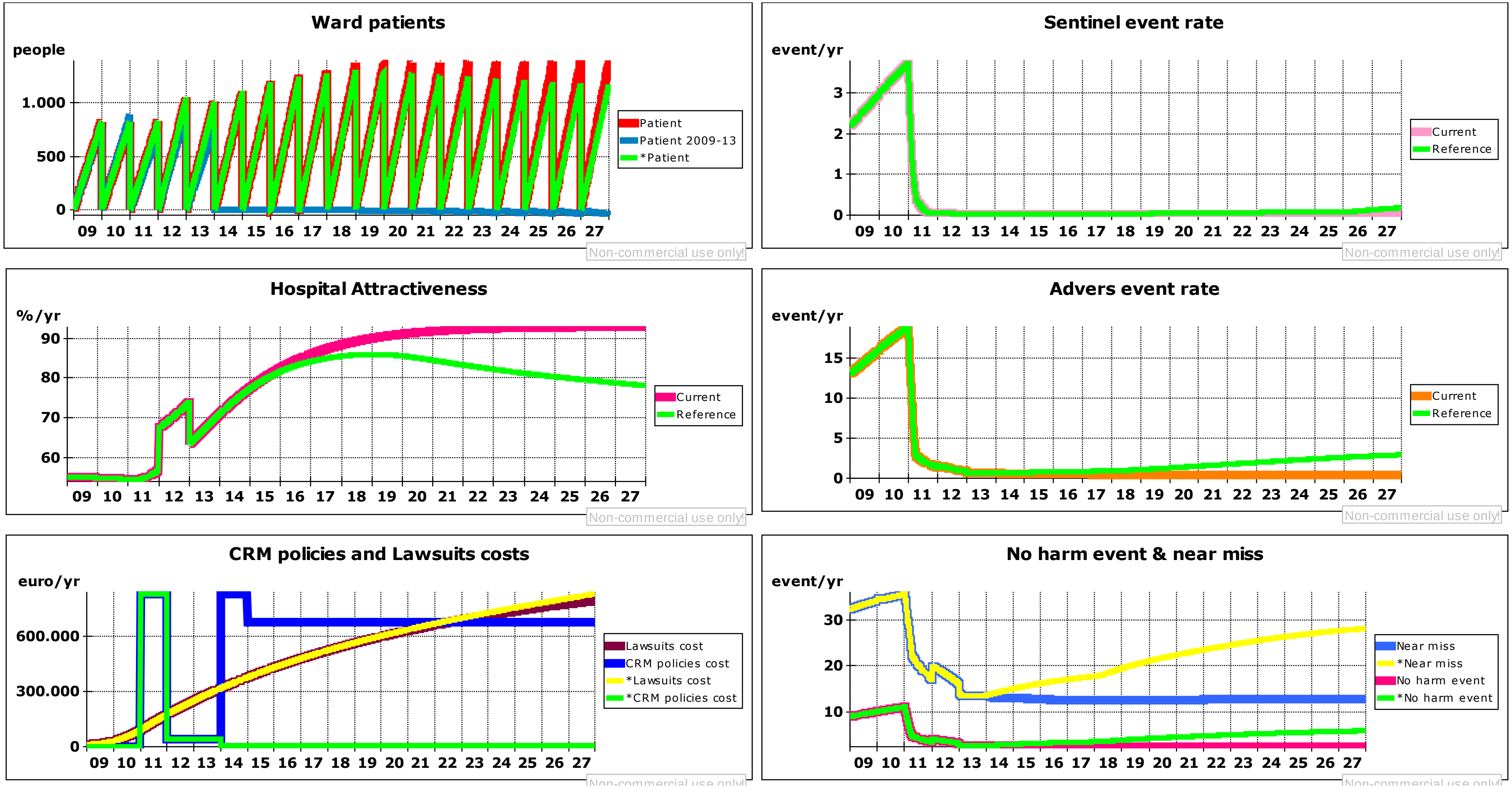

Figure 51. Long time horizon. Base run (reference) and ES (current).

CHAPTER 8. CONCLUSIONS, LIMITATIONS AND FURTHER RESEARCHES

We suppose that our study could have a broad appeal for researchers. Globally, the overall health care costs are expected to increase dramatically also due the aging phenomenon (for example, in US it will reach $4.8 trillion in 2021, up from $2.6 trillion in 2010 and $75 billion in 1970, and this means that health care expenditure will account for nearly 20 percent of gross domestic product of the U.S. economy, by 2021). The healthcare profit maximization perspective in the detriment of patient's safety is showing all its weakness and the impossibility to sustain the company growth.

Our research findings suggest that it would be convenient for healthcare companies to invest in CRM policies, in order to reduce both monetary and non monetary costs of medial errors (lawsuits, loss of attractiveness, loss of patient, ward overall costs etc.). However, as shown in the scenario analysis, it is important to understand "how much" and "where" to invest in order to avoid a waste of company resources.

Besides, our findings suggest that the proposed Best Scenario allow an effective clinical risk management without a waste of resources (as happened for the ES).

The research finding also show the relationships between the Safety Culture among staff and the occurrence of various types of adverse outcomes in the clinical practice. Based on the different scenario's simulation results, we can observe that there is an inversely proportional relationship between SCI and medical errors. This pattern confirms our initial hypothesis: through a cultural change in the ward - from a blame culture to a patient safety culture - it is possible to foster a reduction in medical errors and, hence, an increase in hospital reputation and attractiveness.

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 exogenous variables of the system 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, which takes into account their average values. Moreover our preliminary study is not able to address the initial problem in a fully way.

Nevertheless, despite these limitations, this research shows how system dynamics methodology could be really useful for planning and evaluate CRM interventions.

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APPENDIX 1: HOSPITAL SURVEY ON PATIENT SAFETY CULTURE (NIEVA, SORRA 2003)

HOSPITAL SURVEY ON PATIENT SAFETY CULTURE

INSTRUCTIONS

This survey asks for your opinions about patient safety issues, medical error, and event reporting in your hospital and will take about 10 to 15 minutes to complete.

- *An "event" is defined as any type of error, mistake, incident, accident, or deviation, regardless of whether or not it results in patient harm.*
- *"Patient safety" is defined as the avoidance and prevention of patient injuries or adverse events resulting from the processes of health care delivery.*

SECTION A: Your Work Area/Unit

In this survey, think of your "unit" as the work area, department, or clinical area of the hospital where you spend *most* of your work time or provide *most* of your clinical services.

What is your primary work area or unit in this hospital? Mark ONE answer by filling in the circle.

○ a. Many different hospital units/No specific unit

○ b. Medicine (non-surgical)
○ c. Surgery
○ d. Obstetrics
○ e. Pediatrics
○ f. Emergency department
○ g. Intensive care unit (any type)
○ h. Psychiatry/mental health
○ i. Rehabilitation
○ j. Pharmacy
○ k. Laboratory
○ l. Radiology
○ m. Anesthesiology
○ n. Other, please specify:

Please indicate your agreement or disagreement with the following statements about your work area/unit. Mark your answer by filling in the circle.

Think about your hospital work area/unit…	Strongly Disagree ▼	Disagree ▼	Neither ▼	Agree ▼	Strongly Agree ▼
1. People support one another in this unit	①	②	③	④	⑤
2. We have enough staff to handle the workload	①	②	③	④	⑤
3. When a lot of work needs to be done quickly, we work together as a team to get the work done	①	②	③	④	⑤
4. In this unit, people treat each other with respect	①	②	③	④	⑤
5. Staff in this unit work longer hours than is best for patient care	①	②	③	④	⑤
6. We are actively doing things to improve patient safety	①	②	③	④	⑤
7. We use more agency/temporary staff than is best for patient care	①	②	③	④	⑤
8. Staff feel like their mistakes are held against them	①	②	③	④	⑤
9. Mistakes have led to positive changes here	①	②	③	④	⑤
10. It is just by chance that more serious mistakes don't happen around here	①	②	③	④	⑤
11. When one area in this unit gets really busy, others help out	①	②	③	④	⑤
12. When an event is reported, it feels like the person is being written up, not the problem	①	②	③	④	⑤

1

SECTION A: Your Work Area/Unit (continued)

Think about your hospital work area/unit…	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
13. After we make changes to improve patient safety, we evaluate their effectiveness	①	②	③	④	⑤
14. We work in "crisis mode" trying to do too much, too quickly	①	②	③	④	⑤
15. Patient safety is never sacrificed to get more work done	①	②	③	④	⑤
16. Staff worry that mistakes they make are kept in their personnel file	①	②	③	④	⑤
17. We have patient safety problems in this unit	①	②	③	④	⑤
18. Our procedures and systems are good at preventing errors from happening	①	②	③	④	⑤

SECTION B: Your Supervisor/Manager

Please indicate your agreement or disagreement with the following statements about your immediate supervisor/manager or person to whom you directly report. Mark your answer by filling in the circle.

	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
1. My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures	①	②	③	④	⑤
2. My supervisor/manager seriously considers staff suggestions for improving patient safety	①	②	③	④	⑤
3. Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts	①	②	③	④	⑤
4. My supervisor/manager overlooks patient safety problems that happen over and over	①	②	③	④	⑤

SECTION C: Communications

How often do the following things happen in your work area/unit? Mark your answer by filling in the circle.

Think about your hospital work area/unit…	Never	Rarely	Some-times	Most of the time	Always
1. We are given feedback about changes put into place based on event reports	①	②	③	④	⑤
2. Staff will freely speak up if they see something that may negatively affect patient care	①	②	③	④	⑤
3. We are informed about errors that happen in this unit	①	②	③	④	⑤
4. Staff feel free to question the decisions or actions of those with more authority	①	②	③	④	⑤
5. In this unit, we discuss ways to prevent errors from happening again	①	②	③	④	⑤
6. Staff are afraid to ask questions when something does not seem right	①	②	③	④	⑤

SECTION D: Frequency of Events Reported

In your hospital work area/unit, when the following mistakes happen, *how often are they reported?* Mark your answer by filling in the circle.

	Never	Rarely	Some-times	Most of the time	Always
1. When a mistake is made, but is *caught and corrected before affecting the patient*, how often is this reported?	①	②	③	④	⑤
2. When a mistake is made, but has *no potential to harm the patient*, how often is this reported?	①	②	③	④	⑤
3. When a mistake is made that *could harm the patient*, but does not, how often is this reported?	①	②	③	④	⑤

SECTION E: Patient Safety Grade

Please give your work area/unit in this hospital an overall grade on patient safety. Mark ONE answer.

○	○	○	○	○
A	**B**	**C**	**D**	**E**
Excellent	Very Good	Acceptable	Poor	Failing

SECTION F: Your Hospital

Please indicate your agreement or disagreement with the following statements about your hospital. Mark your answer by filling in the circle.

Think about your hospital...	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
1. Hospital management provides a work climate that promotes patient safety	①	②	③	④	⑤
2. Hospital units do not coordinate well with each other	①	②	③	④	⑤
3. Things "fall between the cracks" when transferring patients from one unit to another	①	②	③	④	⑤
4. There is good cooperation among hospital units that need to work together	①	②	③	④	⑤
5. Important patient care information is often lost during shift changes	①	②	③	④	⑤
6. It is often unpleasant to work with staff from other hospital units .	①	②	③	④	⑤
7. Problems often occur in the exchange of information across hospital units	①	②	③	④	⑤
8. The actions of hospital management show that patient safety is a top priority..........	①	②	③	④	⑤
9. Hospital management seems interested in patient safety only after an adverse event happens	①	②	③	④	⑤
10. Hospital units work well together to provide the best care for patients..........	①	②	③	④	⑤
11. Shift changes are problematic for patients in this hospital..........	①	②	③	④	⑤

SECTION G: Number of Events Reported

<u>In the past 12 months</u>, how many event reports have you filled out and submitted? Mark ONE answer.

- ○ a. No event reports
- ○ b. 1 to 2 event reports
- ○ c. 3 to 5 event reports
- ○ d. 6 to 10 event reports
- ○ e. 11 to 20 event reports
- ○ f. 21 event reports or more

SECTION H: Background Information

This information will help in the analysis of the survey results. Mark ONE answer by filling in the circle.

1. How long have you worked in this hospital?
   - O a. Less than 1 year
   - O b. 1 to 5 years
   - O c. 6 to 10 years
   - O d. 11 to 15 years
   - O e. 16 to 20 years
   - O f. 21 years or more

2. How long have you worked in your current hospital work area/unit?
   - O a. Less than 1 year
   - O b. 1 to 5 years
   - O c. 6 to 10 years
   - O d. 11 to 15 years
   - O e. 16 to 20 years
   - O f. 21 years or more

3. Typically, how many hours per week do you work in this hospital?
   - O a. Less than 20 hours per week
   - O b. 20 to 39 hours per week
   - O c. 40 to 59 hours per week
   - O d. 60 to 79 hours per week
   - O e. 80 to 99 hours per week
   - O f. 100 hours per week or more

4. What is your staff position in this hospital? Mark ONE answer that best describes your staff position.
   - O a. Registered Nurse
   - O b. Physician Assistant/Nurse Practitioner
   - O c. LVN/LPN
   - O d. Patient Care Assistant/Hospital Aide/Care Partner
   - O e. Attending/Staff Physician
   - O f. Resident Physician/Physician in Training
   - O g. Pharmacist
   - O h. Dietician
   - O i. Unit Assistant/Clerk/Secretary
   - O j. Respiratory Therapist
   - O k. Physical, Occupational, or Speech Therapist
   - O l. Technician (e.g., EKG, Lab, Radiology)
   - O m. Administration/Management
   - O n. Other, please specify:

5. In your staff position, do you typically have direct interaction or contact with patients?
   - O a. YES, I typically have direct interaction or contact with patients.
   - O b. NO, I typically do NOT have direct interaction or contact with patients.

6. How long have you worked in your current specialty or profession?
   - O a. Less than 1 year
   - O b. 1 to 5 years
   - O c. 6 to 10 years
   - O d. 11 to 15 years
   - O e. 16 to 20 years
   - O f. 21 years or more

SECTION I: Your Comments

Please feel free to write any comments about patient safety, error, or event reporting in your hospital.

THANK YOU FOR COMPLETING THIS SURVEY.

APPENDIX 2: MODEL EQUATIONS

The following pages provide the complete model documentation generated by the Powersim studio 7 software, used for the model construction. The documentation includes all the equations, units, initial and parameter values and graphical functions specifications. We hope this documentation would be sufficient for better understanding of the model and potential reproduction by an interested reader.

- % Corrective action implemented through Policy 1 due to % reported ME on desired RME % '% reported ME on desired RME'*'% corrective action on overall Reported Medical Error due Policy 1 - New Equipment'
- % Corrective action implemented through Policy 2 due to % reported ME on desired RME % '% reported ME on desired RME'* '% corrective action on overall Reported Medical Error due Policy 2 Information Communication and Staff Training'

- % corrective action on overall Reported Medical Error due Policy 1 - New Equipment % 0
- % corrective action on overall Reported Medical Error due Policy 2 Information Communication and Staff Training % 0
- % Error Reported based on Safety Culture Index % GRAPH(ARRAVERAGE('Safety Culture Index - SCI');0;10;{0,6;2;4,5;10;15,5;28;41;60;85;96;100//Min:0;Max:100//}<<%>>)

- % medical errors on overall patient treatments % 'errors per year rate'*1<<people/event>>DIVZ0 'patient treatment rate'
- % of adverse events % GRAPH('effect of Safety culture index on medical error';0,00<<%>>;1<<%>>;{0,15;3,1;4,8;7,6;10,1;14,5;21,1;23,4;26,3;28,6;30//Min:0.01 ;Max:30//}<<%>>)
- % of near miss % 100<<%>>-('% of adverse events'+'% of no harm events'+'% of sentinel events')
- % of no harm events % 16
- % of sentinel events % GRAPH('effect of Safety culture index on medical error';0,00<<%>>;1<<%>>;{0,01;0,10;0,17;0,25;1,7;2,3;3;4;5;5,8;6//Min:0.01;Max:6//} <<%>>)

- % overall events % '% of adverse events'+ '% of near miss'+ '% of no harm events'+ '% of sentinel events'
- % reported ME on desired RME % 'reported medical errors that need corrective action'/'desired reported medical errors that need corrective action'

- Advers event rate event/yr ('potential medical errors'/'Time to define medical error')*'% of adverse events'
- adverse event per year deplention rate event/da PULSE('adverse events per year';STARTTIME+1<<yr>>;1<<yr>>)
- adverse events event 0 1
- adverse events per year event 0 1
- Assumption - % reported events that need corrective action % 2

- Assumption - values riduction of Safety culture index dimensions at 2009 % 50
- Assumption- % Gap filled through P1 CSI %/yr 100<<%/yr>>-'Assumption- % Gap filled through P2'
- Assumption- % Gap filled through P2 CSI %/yr {80; 75; 85; 100; 70; 100; 40; 60; 50; 25}
- Assumption- % of lawsuits from different kind of event Claims %/yr {100; 10}

- Assumption- % of ward fixed costs % 90
- Assumption- % won lawsuits Claims % {90;60}
- Assumption- average cost per loosed lawsuit Claims euro/event {1200000; 25000}
- Assumption- averge cost per won lawsuit Claims euro/event {15000; 2000}

- Assumption- timing of lawsuits payments Claims yr {10; 2}
- Assumption-Effect of clinical error on Hospital reputation %/yr GRAPH(('Sentinel event rate'*0,65)+('Advers event rate'*0,35);0<<event/yr>>;0,5 <<event/yr>>;{100;62,6;54;46;38;31,6;28,4;26;21;18;15,5;13,5;10;9;8;7;6,5;5;4;3;2;1;1;1;1;0,6;0,6//Min:0;Max:100//}<<%/yr>>)

- average cost of Policy 1 euro/yr GRAPH('% corrective action on overall Reported Medical Error due Policy 1 - New Equipment';0<<%>>;10<<%>>;{0;20000;74000;126000;280000;360000;450000;550000;630000;780000;1000000//Min:0;Max:1000000//}<<euro/yr>>)
- average cost of Policy 2 euro/yr GRAPH('% corrective action on overall Reported Medical Error due Policy 2 Information Communication and Staff Training';0<<%>>;10<<%>>;{0;4500;5500;6000;7700;10600;19000;33000;44200;49700;50000//Min:0;Max:50000//}<<euro/yr>>)
- average income per patient euro/people GRAPHCURVE(YEAR(TIME);2009;1;{1990;1808;1768,70;1781;1679,48;1679,48;1679,48;1679,48;1679,48;1679,48;1679,48;1679,48;1679,48;1679,48//Min:1500;Max:2000//}<<euro/people>>)

- Average time to treat da DELAYINF(GRAPHCURVE(YEAR(TIME);2009;1;{4,15;3,66;3,37;3,34;3,16;3,16;3,16;3,16;3,16;3,16;3,16;3,16//Min:-1;Max:11//}<<da>>);1<<mo>>)
- bed occupancy rate da inpatients/'Patient capacity'
- bed occupancy rate average da RUNAVERAGE('bed occupancy rate')

- Constant_2 da 10000
- correct treatment from near miss event 0 1
- correct treatment from no harm events event 0 1
- CRM policies cost euro/yr('average cost of Policy 1'+'average cost of Policy 2')

- database simes event 0 0
- datebase simes rate event/yr 'Sentinel event rate'
- delay time in changing Hospital attractiveness yr 1
- deplention time yr 20
- desired reported medical errors that need corrective action event/yr ('errors rate'*'Assumption - % reported events that need corrective action')+ 'datebase simes rate'

- Effect of corrective action implemented through CRM Policy 1 on SCI dimensions CSI yr^-1 'Safety Culture index GAP'*'Assumption- % Gap filled through

P1'*'% Corrective action implemented through Policy 1 due to % reported ME on desired RME'

- Effect of corrective action implemented through CRM Policy 2 on SCI dimensions CSI yr^-1 'Safety Culture index GAP'* 'Assumption- % Gap filled through P2'* '% Corrective action implemented through Policy 2 due to % reported ME on desired RME'
- effect of Safety culture index on medical error % GRAPH(ARRAVERAGE('Safety Culture Index - SCI');0;10;{10;9,7;9,25;8,7;3,73;2,8;1,75;1,5;1,4;1,23;1//Min:1;Max:10//}<<%>>)

- Enable PAUSEIF 0
- errors per yr event 0 1
- errors rate event/yr 'Advers event rate'+ 'Near miss'+ 'No harm event'

- errors per year deplention rate event/da PULSE('errors per yr';STARTTIME+1<<yr>>;1<<yr>>)
- errors per year rate event/yr 'Advers event rate'+ 'Near miss'+ 'No harm event'+ 'Sentinel event rate'
- event per patient event/people 1
- Extraordinary funds for CRM policies euro/yr IF(TIME>DATE(2012;01;01);0<<euro/yr>>;'average cost of Policy 1')

- historical Outcome Measures'Outcome Measures' {68,03; 62,59; 71,11}

- historical safety culture index at 2013 CSI {75,93; 72,69; 73,65; 69,75; 63,78; 54,07; 54,26; 67,26; 71,31; 70,74}
- historical-patient per year rate people/yr GRAPHCURVE(YEAR(TIME);2009;1;{800;890;720;914;773;0;0;0;0;0//Min:0; Max:1000//}<<people/yr>>)
- Hospital Attractiveness %/yr MIN(100<<%/yr>>; DELAYINF(((Proximity*0,50)+('hospital reputation'*0,50));'delay time in changing Hospital attractiveness';1)+'Ward Cheif')
- hospital reputation %/yr DELAYINF('Assumption-Effect of clinical error on Hospital reputation';'Time to change Hospital reputation')

- hother hospital patient discharge rate people/da PULSE('other hospitals patient per year';STARTTIME+1<<yr>>;1<<yr>>)
- improvement in safety culture index CSI yr^-1 IF('Safety Culture Index - SCI'>='MAX VALUE';0<<1/yr>>;'Overall effect of corrective action implemented through CRM Policies on SCI dimensions')
- incident report event 0 0
- incident report rate event/yr ('Advers event rate'+'Near miss'+'No harm event')*'% Error Reported based on Safety Culture Index'
- incident report that need corrective action event/yr 'incident report rate'*'Assumption - % reported events that need corrective action'
- Inpatient INITIAL people 'inpatients rate'*'Average time to treat'

- inpatients people 9,54 0
- inpatients rate people/da IF(('population waiting for treatment'/'Time to become inpatient')>= 'Patient capacity';'Patient capacity'; 'population waiting for treatment'/'Time to become inpatient')
- Lawsuits Claims event {1; 0,3} 1
- Lawsuits cost euro/yr ARRSUM('loosed lawsuits overall cost'+'won lawsuits overall cost')
- Lawsuits per year Claims event/yr 'Lawsuits vector'*'Assumption- % of lawsuits from different kind of event'
- Lawsuits vector Claims event VECTOR('sentinel events';'adverse events')

- loosed lawsuits Claims event/yr (Lawsuits/'Assumption- timing of lawsuits payments')*(100<<%>>-'Assumption- % won lawsuits')
- loosed lawsuits overall cost Claims euro/yr 'Assumption- average cost per loosed lawsuit'*'loosed lawsuits'
- lowering in SCI CSI yr^-1 'Safety Culture Index - SCI'/'deplention time'

- MAX VALUE CSI 100
- Near miss event/yr ('potential medical errors'/'Time to define medical error')*'% of near miss'
- near miss per year event 0 1

- near miss per year deplention rate event/da PULSE('near miss per year';STARTTIME+1<<yr>>;1<<yr>>)
- No harm event event/yr ('potential medical errors'/'Time to define medical error')*'% of no harm events'
- no harm event per year deplention rate event/da PULSE('no harm events per year';STARTTIME+1<<yr>>;1<<yr>>)
- no harm events per year event 0 1
- OH patients discharged people 'other hospital patient treatment rate'*1<<da>> 0
- OH recovery rate people/da 'OH patients discharged'/1<<da>>

- other hospital inpatients people 'other hospitals inpatients rate'*'Average time to treat' 1
- other hospital patient treatment rate people/da 'other hospital inpatients'/'Average time to treat'
- other hospitals inpatients rate people/da ('population affected by gynecological event'/1<<yr>>)-'population waiting for treatment rate'
- other hospitals patient per year people 0 1
- Overall effect of corrective action implemented through CRM Policies on SCI dimensions CSI yr^-1 'Effect of corrective action implemented through CRM Policy 1 on SCI dimensions'+ 'Effect of corrective action implemented through CRM Policy 2 on SCI dimensions'
- overall events event 'adverse events'+ 'correct treatment from near miss'+ 'correct treatment from no harm events'+ 'sentinel events'+ 'potential medical errors'

- Overall Population people inpatients+ 'other hospital inpatients'+ 'patients discharged'+ 'population affected by gynecological event'+ 'population waiting for treatment'+ 'OH patients discharged'
- overall population affected by gynecological event people/da 'other hospitals inpatients rate'+'population waiting for treatment rate'
- Overall Ward Costs euro/yr'Ward overall fixed costs'+ 'Lawsuits cost'+ 'CRM policies cost'
- Patient people 0 1

- Patient 2009-13 people 0 0
- Patient capacity people/da 10
- patient discharged historical people/da PULSE('Patient 2009-13';STARTTIME+1<<yr>>;1<<yr>>)
- patient discharged rate people/da PULSE(Patient;STARTTIME+1<<yr>>;1<<yr>>)
- patient treatment rate people/da inpatients/'Average time to treat'

- patients discharged people 'patient treatment rate'*1<<da>> 1
- Pausa PAUSEIF(TIMECYCLE(STARTTIME+(Constant_2*(1-'Enable PAUSEIF'))+'Pauseif Condition';'Pauseif Condition'))
- Pauseif Condition da 1
- population affected by gynecological event people 1500 1
- population waiting for treatment people 'population waiting for treatment rate'*1<<da>> 1
- population waiting for treatment rate people/da MIN('population affected by gynecological event'/1<<yr>>; 'population affected by gynecological event'*'Random Index'*'Hospital Attractiveness')
- potential medical error rate event/yr 'effect of Safety culture index on medical error'*'patient treatment rate'*'event per patient'
- potential medical errors event 'potential medical error rate'*1<<da>> 1
- Proximity %/yr 100
- Random Index 1 //NORMAL(1;0,1)
- recovery rate people/da 'patients discharged'/1<<da>>
- reported medical errors that need corrective action event/yr ('datebase simes rate'+'incident report that need corrective action')
- Safety Culture Index - SCI CSI 'historical safety culture index at 2013'-('historical safety culture index at 2013'*'Assumption - values riduction of Safety culture index dimensions at 2009') 1
- Safety Culture index GAP CSI 'MAX VALUE'-'Safety Culture Index - SCI'

- SCI ARRAVERAGE('Safety Culture Index - SCI')

- SCI measured in 2013 IF(TIME=DATE(2013;06;01);ARRAVERAGE('historical safety culture index at 2013');0<<%>>)
- sentinel event per year deplention rate event/da PULSE('sentinel events per year';STARTTIME+1<<yr>>;1<<yr>>)
- Sentinel event rate event/yr ('potential medical errors'/'Time to define medical error')*'% of sentinel events'
- sentinel events event 0 1
- sentinel events per year event 0 1
- Time to become inpatient da 1
- Time to change Hospital reputation yr 2
- Time to define medical error da 1
- Total CRM Costs euro 0 0
- Total lawsuits cost euro 0 0
- total loosed lawsuits Claims event 0 0
- total won lawsuits Claims event 0 0
- Ward Chief %/yr GRAPHCURVE(YEAR(TIME);2009;1;{0;0;0;10,5;0;0;0;0;0;0//Min:0;Max:100//}<<%/yr>>) doctor from another hospital who work in the ward during one year and attract people that usually go to other hospital
- Ward Financial Avaiability euro 0 0
- Ward overall fixed costs euro/yr 'Ward Treatments earnings'*'Assumption- % of ward fixed costs'
- Ward Treatments earnings euro/yr 'patient treatment rate'*'average income per patient'
- won lawsuits Claims event/yr (Lawsuits/'Assumption- timing of lawsuits payments')*'Assumption- % won lawsuits'
- won lawsuits overall cost Claims euro/yr 'won lawsuits'*'Assumption- averge cost per won lawsuit'