Introducing "healthcare resilience" in clinical risk management

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Abstract

This paper reports the results of an explorative case study in an Italian hospital and presents a conceptual framework for healthcare resilience, which clarifies why and how healthcare structures need to be resilient in order to fully deal with clinical risk. In other words, it is not sufficient to take the "path to zero harm". Healthcare companies have also to pursue strategies for maximizing the organizational resilience, in terms of *resistance, reliability, redundancy* and *flexibility*. This is quite important because, no matter which CRM technique and/or best practice is adopted, sometime adverse events occur. And, in this case, being resilient can help in dampening their negative consequences. By extending the focus of traditional clinical risk management to different kinds of risk sources (not just patient safety threats) and to different kinds of risk minimization strategies (not just minimize the likelihood of occurrence but also the risk magnitude) this paper contributes to the literatures on operations management in healthcare. The conceptualization of "healthcare resilience" and the in-depth case results allow us to offer a number of suggestions and ideas for developing further research in the field of healthcare operations management.

Keywords: Clinical Risk Management, Organizational Resilience.

Introduction

Clinical risk management (CRM) is progressively playing a more and more important role in the healthcare setting (Crema and Verbano, 2013b). In fact, today, patients and their families expect the maximum levels of quality from the healthcare system and are easily inclined to lunching lawsuits against hospitals, physicians and healthcare personnel whenever errors are made in their care process. This phenomenon has, in turn, stressed out the insurance system: the insurance premiums exponentially increase and, still worse, it happens that insurance companies sometime refuse to insure applicants. CRM aims at contrasting such phenomenon and improving the quality of the care process by "*identifying circumstances which put patients at risk of harm, and then acting to prevent or control those risks*" (Walshe, Dineen, 1998).

As reflected by such definition, the CRM mainly focuses on events that can damage patient safety. Ensuring patient safety represents the main focus of CRM and, consequently, CRM does not consider other threatening events that can represent a risk source for the achievement of other hospital objectives (e.g. making the patient care process more efficient).

In the last years, a large number of techniques (mostly adapted from the industrial and operations management setting) such as FMEA/FMECA, RCA, etc., have been studied, used and re-invented, with the aim of preventing risks, so to minimize the likelihood of adverse events' occurrence (Kohn et al., 2000). Furthermore, a number of CRM best practices (for example those proposed by the Joint Commission, the independent, not-for-profit organization, that accredits and certifies health care organizations, www.jointcommission.org) have been proposed in order to minimize the adverse events' occurrence likelihood (the so called "path to zero harm"). Contrarily, very few studies and/or managerial practices exists related to how dampening the bad consequences of adverse events (the so called magnitude dimension of the risk). Nevertheless, no matter which powerful CRM preventive strategies are implemented within healthcare structures, adverse events sometime occur and hospitals and healthcare structures have to deal with these situations by increasing their resilience; in particular, Organizational Resilience (OR) is defined by the British Standards Institutions within the standard BS65000 (Guidance for Organizational Resilience) as the "*ability to anticipate, prepare for, and adapt reserved respond to events - both sudden shocks and gradual change. That means being adaptable, competitive, agile and robust*".

The purpose of this study is to explore if and how healthcare organizations do actually implement risk management practices other than those which are usually referred to as CRM practices. In other words, we wish to extend the concept of CRM (*Extended CRM)* to a more comprehensive set of systems, processes, and practices aimed at managing every kind of adverse event that may threaten the achievement of every kind of hospital objective. Furthermore, beyond the classical CRM preventive approach, the extended CRM embraces the adoption of resilience practices (*Healthcare Resilience*), with the goal to reduce the magnitude dimension of the risk.

To this purpose, in this paper we try to answer to the following research questions: (1) Do healthcare organizations implement *Healthcare Resilience* practices, i.e. risk management practices that consider the "magnitude" dimension of risk? (2) Do healthcare organizations adopt *Extended CRM* practices, i.e. practices to contrast those risks that threat the achievement of their organizational objectives other than the patient safety?

By virtue of the study's explorative nature and because the existent knowledge is quite limited and uncertain, we used the *Case Research* method (Yin, 2009) to address our research scope; the study was conducted at an Italian hospital, the data were collected by semi-structured interviews, and were triangulated with documentation and direct observations. The findings of this study are quite interesting and tell us that healthcare organizations actually adopt risk management practices that go beyond the traditional CRM practices. Of course, given the explorative nature of the research, we are aware that results cannot be generalized but we believe they can constitute a strong motivation for the research towards the outlined direction.

Conceptual Framework
Thanks to a literature review about CRM and OR, it was possible to define a conceptual framework, which is useful to understand the concepts to analyse in depth through the interviews. It includes the principal constructs emerged from the literature review, with reference both to CRM and OR, and is reported in figure 1.

Traditional CRM (practices for contrasting adverse event occurrence)

CRM is intended as process, which aims to improve the quality of the care process by "*identifying circumstances which put patients at risk of harm, and then acting to prevent or control those risks*" (Walshe, Dineen, 1998). We analysed the literature on the most used techniques and methodologies in CRM, such as FMEA/FMECA (Bonfant et al., 2010), HFMEA (DeRosier et al., 2002), RCA (Wu et al., 2008), but also the younger and more innovative techniques such as CREA (Trucco, Cavallin, 2006) and the *Systematic Methodology for CRM* developed by Gagliano et al. (2001). We also considered in our analysis the Joint Commission CRM best practices. From the analysis, we observe two particular characteristics: the first is that the goal is to preserve exclusively the patient safety, consequently other aspects or objectives that the healthcare organizations have to achieve are not covered; the second is that the techniques and best practices aims at reducing the risk by only focusing on reducing the probability of occurrence of adverse events. Metaphorically, it's possible to imagine the CRM as a "barrier" that protects the objective *patient safety* from the *threatening events* attack by reducing their occurrence likelihood (figure 1.b). In sum, since the patient safety isn't the only objective, we can observe that the other kinds of hospital objectives are not protected. Also, the traditional CRM barrier aims at reducing the risks by diminishing the likelihood of occurrence, but since it's not possible to reduce it to zero, when the events happen the hospital is not prepared to contrast them.
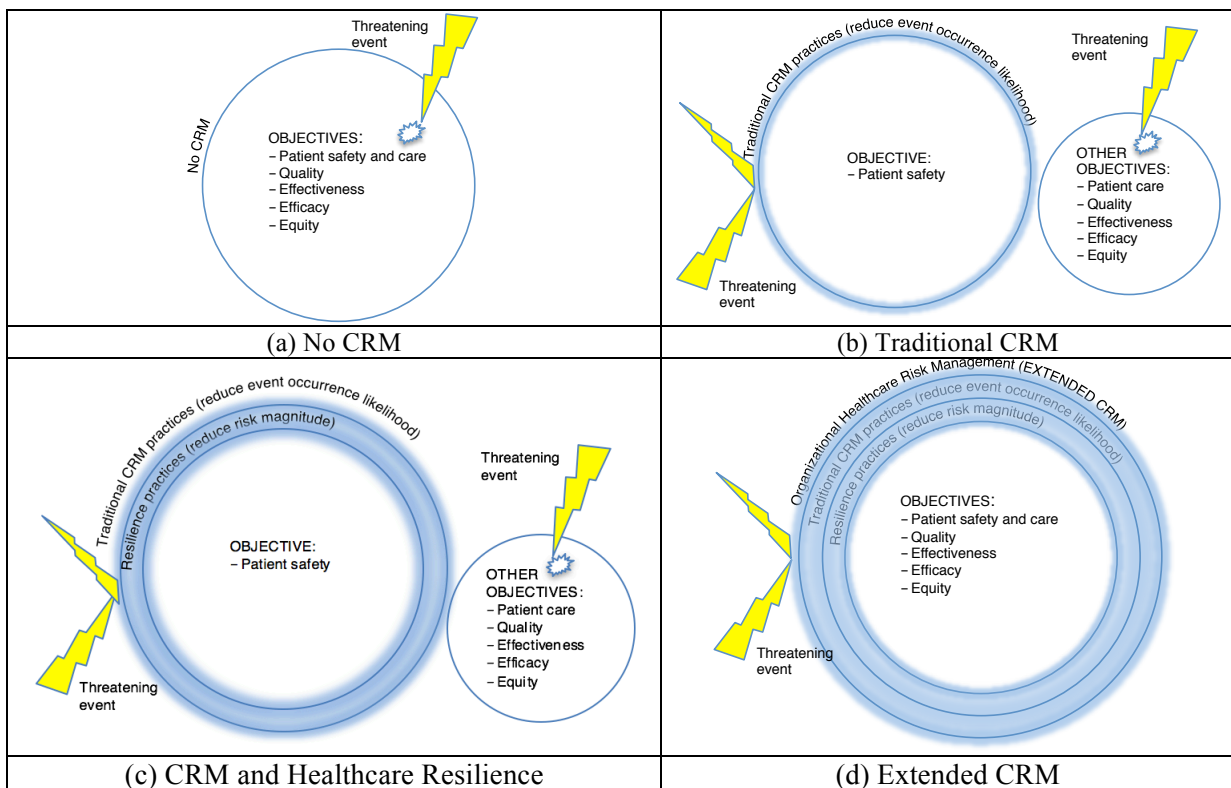

(a) No CRM	(b) Traditional CRM
(c) CRM and Healthcare Resilience	(d) Extended CRM

Figure 1 - From the traditional to the extended CRM

CRM and Healthcare Resilience (practices for reducing the risk magnitude)

As already mentioned, healthcare providers through risk management erect a barrier that protect the objectives from negative events occurrence; such barrier does not help managing the *magnitude* dimension of risk. In fact, the risk is mathematically defined as *probability X magnitude* (ISO 31000 standard for risk management). The magnitude of the risk relates to the consequences of the risk itself. So the level of risk can be

expressed as the combination of its occurrence probability and its effects. As a consequence, in order to reduce the risk it's possible to put into place practices aimed at either diminishing the occurrence probability of the adverse event or to limit the consequences of the occurred event. With the aim to reduce the magnitude dimension of risk, we consider here the resilience property: it's defined as *a measure of how quickly a system recovers from failures* (Buckle, 2000), or the *capacity of a system to experience shocks while retaining essentially the same function, structure, feedbacks, and therefore identity* (Walker et al., 2006). We can observe that resilience relates to the management of negative events (failure, shocks and so on) when they happen, thus a more comprehensive risk management approach should combine practices aimed at increasing the resilience of the hospital with the preventive methods and techniques already used in healthcare. In particular, we refer to *organizational resilience* (OR), defined by the British Standards Institutions in the standard BS65000 (Guidance for Organizational Resilience, www.bsigroup.com) as the "*ability to anticipate, prepare for, and adapt to events - both sudden shocks and gradual change. That means being adaptable, competitive, agile and robust*". Gibson and Tarrant (2010) defined four strategies for being resilient (see figure 2). Each strategy makes the organization able to manage the bad situation when it happens, so that the system performance does not significantly decrease

For this reason, in our conceptual framework, healthcare resilience is represented by a barrier, which protects the hospital objectives in those unlucky cases when the adverse event was able to pass across the first barrier, namely the traditional CRM barrier, i.e. when it effectively happened (see figure 1.c). This further barrier reduces the magnitude the risk, i.e. the bad consequences of the adverse event.
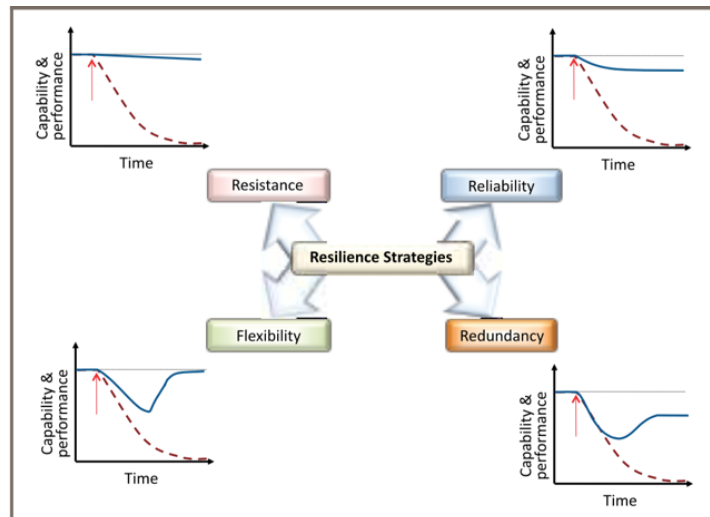

Figure 2 - Organizational Resilience Strategies (from Gibson and Tarrant, 2010)

Organization Healthcare Risk Management (Extended CRM)
There is a close link between risks, objectives and quality: UNI 11230 defines the risk as "the set of possibilities of an event and its consequences on the *objectives*", so it's possible to consider the risk as everything that may prevent the organization from the achievement of its objectives; in healthcare the main goal of hospitals and other public structure is not to make profits, but to provide *quality services*. The *World Health Organization* (WHO) gives a definition of quality in healthcare by introducing six dimensions that have to be possessed by a healthcare provider: *effectiveness, efficiency, accessibility, patient centred, equitability* and *safety* (Crema, Verbano, 2013a). These

six dimensions could represent strategic objectives, so a comprehensive risk management approach should consider all the risks threatening their achievement, not just the last on (*patient safety*).

In sum, given the above argumentations, we consider in our conceptual framework the *Organizational Healthcare Risk Management* (in brief, *Extended CRM)* as a set of practices, techniques, and methodologies aimed at protecting not only the patient safety objective, but also the other hospital objectives by both trying to diminish the occurrence probability of adverse events threatening their achievement and managing them when occurred. In figure 1(d) the third barrier metaphorically represents this concept.

Research Method

Given the conceptual framework introduced in the previous section, the main goal of this study is to investigate if and how healthcare organizations implement *Healthcare Resilience* practices (figure 1c), i.e. risk management practices that consider the "magnitude" dimension of risk, and adopt *Extended CRM* practices (figure 1d), i.e. practices to contrast those risks that threat the achievement of their organizational objectives other than the patient safety. Given the explorative nature of this goal, in this paper we conduct an in-depth case study at an important Italian hospital.

Though a single case study presents limitations in terms of statistical meaningfulness or generalization of results, there are different aspects that justify the choice. First, the healthcare is a sector with very high interaction between people, it means that it becomes fundamental to understand the phenomenon through the meaning the people give their experience more than through the extern researcher perspective, in this case the case research is preferable compared to other methodologies (Sherman, Webb, 1988). Second, an explorative case research is the best choice when in order to answer the research questions it is necessary to *explore* a new knowledge area, such as in this case where there are no studies about extended CRM or resilience in healthcare (Yin, 2009).

Our case study regards an Italian hospital and we believe there are no reasons to think it does not represent a typical Italian hospital; in this case it's possible to assume the lessons learned form this single explorative case study are informative about the experience of the average institution (Yin, 2009). In particular, the hospital is a typical Italian medium size hospital and comprises 22 wards, 198 beds, 103 physicians and 188 nurses. The hospital has a CRM operative unit, which is dedicated to monitor and control, but also to facilitate the implementation, of clinical risk management practices in all the hospital wards.

To develop the case research Yin's (2009) and Voss' et al. (2002) works were assumed as landmarks: to ensure the quality of work, multiple sources of evidence (interviews, direct observations, documents) were used to guarantee data triangulation and construct validity (Voss et al., 2002). Also, a data collection protocol was used and a database was developed to ensure the case research reliability (Yin, 2009). The case research was conducted for two months, seven semi-structured interviews were recorded and transcribed, asking questions directly linked to the concepts explained in the conceptual framework. The interviews lasted from 30 to 100 minutes, they were conducted directly in the hospital, and all grades of staff were interviewed, in particular a nurse and a head nurse, a physician and a head physician, the risk manager, the quality manager and the chief medical officer. In case of not clear answers the interviewed was contacted by email and phone calls to clarify. The direct observations in hospital wards were made in different days during the two months, focusing especially on activity

performed by operative staff. Finally, the documentation concerned all the documents somehow related to risk management, management by objectives, strategic plans and operative procedures, such as the Hospital Strategic Plan (HSP), the Health Services Plan of Action (PoA), the Sentinel Events Reports (SER), Route Cause Analysis Reports (RCA), Nurse Reports, and so on. It has to be noticed, that some interviews (risk manager, quality manager, chief medical officer) and documents (HSP, PoA, SER, RCA) were collected at the hospital level, while interviews to more operative staff (nurses and physicians) and documents related to wards (Nurse Reports) were collected at the operational unit level, specifically at the Pulmonology Ward, which consists of 5 physicians and 11 nurses.

Findings

Traditional CRM (practices for contrasting adverse event occurrence)
Today the hospital implements CRM activities focusing on adverse events representing a potential risk for the patient safety, complying with the literature's CRM definition. Besides a continuous monitoring of activities, the Clinical Risk Management Operational Unit uses both a standard template for reporting the sentinel events and various Root Cause Analysis forms, taking advantage of the Joint Commission International support.

Healthcare Resilience
Despite the adoption of resilient practices in healthcare is not formalized or contained in any hospital document, it's possible to observe how some actions performed at operative level can be considered as organizational resilience practices. In general interviewees agree that resilience is a feature all the healthcare workers should possess:

> […] *Yes of course, a complication may occur, even if it is very very uncommon. But, in case it occurs, I know how to manage it, or at least I know the way I've to proceed.* […] *I repeat, we don't have protocols or other explicit procedures, but I say the experience - and studies too, allow us to manage the adverse events.* (Physician).

By keeping interviewing operational unit people (physicians and nurses) we found that, in fact, a number of tacit resilience practices are adopted. Below we report three examples of them. The first one concerns the management of a patient fall, which was a tacit practices till few month ago and became explicit recently:

> […] *Earlier we had a procedure to assess the patient fall risk, but it wasn't written what to do after the patient fell; recently, it was revised and the CRM unit gave us this new protocol that anyway pushes us to assess the patient's condition after the fall. Furthermore if a patient falls, now we have a procedure that establish we have to immediately alert the physician, bring the patient to the Radio-diagnostic department, she/he has to be visited by a physician, and on the basis of the results the physician can decide for other clinical tests.* (Head Nurse).

The second example concerns surgery rooms management when particular and uncommon situations appear:

[…] Sometimes in operating rooms, some facility management problems happen creating critical safety and hygienical issues. Quite often, we need to close the operating room because of hygienical problems and this lasts even days. If this kind of things happens, the surgery operations which were already scheduled in that room have to be postponed. However, if the physician believes the operation cannot be postponed, she/he immediately makes a request to move the patient to other regional hospitals. (Risk Manager).

Last example concerns an excessive administration of insulin to a diabetic patient:

[…] in the unlucky case I administer too insulin and I'm afraid the patient could become hypoglycaemic, while I ask for a physician to intervene, I check-up her/him and I administer immediately glucose, even if this way of action is not written in any guideline for nurses… thanks to my experience I know it's the best thing to do while I'm waiting the physician to come. (Nurse).

Extended Clinical Risk Management (Risk Management by Objectives)
The hospital and its wards exercise their functions aiming at the achievement of objectives as defined by the *Italian Ministry of Health* and by the *Regional Department of Health*; such objectives are explicitly reported into the HSP. The objectives in HSP are decomposed into a number of actions according to what is written in the PoA. This last document defines the *inspiring principles* which rule the hospital work and provide the guidelines to follow during the objectives definition, implementation and monitoring.

However, it seems that some of the potential risks for the objectives are not covered from risk management:

[…] I think we don't have the maturity to do this (extend CRM to all the objectives) *yet, do you know what is what you say? The optimum, in the sense that I'm aware that assessing an objective I know what are the risks of not achieving such objectives, in a real manner. Unfortunately, not, it's too complicated, hypothetically yes, but in practice no. There are too factors because of it's not possible.* (Chief Medical Officer).

Also, both the HSP and PoA as managerial instruments, seems not collecting particular success by the hospital managers:

[…] Every year we define a budget where the General Manager gives us the objectives according to those defined by the Regional Department of Health. However, my impression is that there is not a strategic view in defining these objectives and most of them looks as short-term/problem solving objectives. For example a news appears on a newspaper, about the excessive waiting time for a gynaecological examination, so reducing waiting times becomes an objective… Contrarily this should be part of a higher level strategic objective definition, such as make that service more efficient, while it is not!. (Head Physician).

The interviews made with operators working in a more "operative" level, as nurses and physician, showed that operational units people consider the objectives defined from WHO right and fit to the context, and think their work is directed to their achievement. Also, despite we noted little confidence for the application of risk management to

protect the achievement of these objectives, operations unit people are relatively positive that CRM should consider even these kind of risks apart from patient safety:

> "[…] *It would make sense, there are lots of motivations, how can a ward be efficient when who has to schedule the beds isn't enough prepared or does this without considering what happens but only on the ground of I don't know what? So what happens? There are no beds, the patients are put in other wards, also far, so what efficiency and safety can be provided?"* (Head Physician).

We also observed that most of the interviewed were very sensitive to the achievement of the WHO objective *effectiveness*, which is strongly connected with the satisfaction of the patients needs (that may be different and/or independent from both the patient safety and the improvement of her/his health). One of the strongest reasons for which the clinical risk should be extended to the other objectives is grounded on the causality that links the quality dimensions to the safety, even if the WHO puts them at same level. The operators agree that *efficiency* and *effectiveness* of services represents fundamental conditions in order to assure patient care and safety.

> […] *Hypothetically I agree to extend the application of risk management to other organizational objectives, because actually the patient safety is strictly connected to them* (the objective defined from WHO). *In fact, when we talk about clinical risk procedures, we actually talk about quality management, if there is no quality there is no safety.* (Chief Medical Officer).

Discussions
Now we answer the research questions that led the case research development, providing suggestions to deal with the problems appeared.

RQ1: Do healthcare organizations implement Healthcare Resilience practices, i.e. risk management practices that consider the "magnitude" dimension of risk?

Inside the hospital there are practices directly attributable to one of the resilient strategies seen before (figure 2). We saw three examples of resilient practices applied inside the hospital: each one can be attributed to one of the four resilient strategies seen in the conceptual framework section.

The first practice deals with the patient fall management and can be associated to the resilient strategy *reliability,* given that it aims at preserving the vital functions of the subject that suffers the fall and allowing the patient to take as less damage as possible.

The second practice is related to the operating room management when an adverse event happens and it becomes impossible to follow the operations schedule. Again, such practice can be associated to the resilient strategy *reliability*. Indeed, postponing the operations of non-severe patients that, in a normal routine, would have had the priority surely does not represent a resilient practice. However finding alternative hospitals for the urgent surgery patients may represent a possible dabbing to a complete collapse of performance.

The third practice, the glucose administration for a patient that took too much insulin, can be considered a the *resistance* practice. In fact, the nurse, in the lucky case she/he detects the mistake, can immediately recover the situation without affecting the system performance (in this case the patient safety).

While we found a certain degree of implementation of resilience practice (mostly tacit), we also observed that today there are no studies in literature investigating this kind of practices in healthcare. Our study represents a first step towards filling this gap, but further research along this direction should aim at formalizing the practices, creating guidelines and protocols so that the hospital staff could follow them. In fact, given the promising results of our case research, many other resilience practices can be found by investigating other healthcare providers.

RQ2 Do healthcare organizations adopt Extended CRM practices, i.e. practices to contrast those risks that threat the achievement of their organizational objectives other than the patient safety?

Although we observed that the hospital implements CRM and few resilience practices, they don't concern hospital objectives, except the *patient safety*. However, most of the interviewed agreed there are many reasons which justify their potential inclusion in CRM. While HSP is the document where the hospital objectives are supposed to be well identified, we took a look at it and we found that most of the objectives are related to the short-term and are more or less problem solving actions. However, we analysed the actions reported into the document, so that it was simple to link them to the objectives defined from WHO. This link is justified by the presence of points in common among the *inspiring principles* of the hospital (that we remind provide the guidelines to follow during the objectives and actions definition) and the WHO objectives, namely *efficiency*, *effective* and *equality*. In 13 chapters out of 15 present in the HSP it was possible linking every action to one of the WHO objectives (table 1). The great majority of the actions relate to the objective *effective* which is the most correlated to the medical practices itself, while the other regard features which could be perceived as "minor".

Table 1 – HSP actions and WHO objectives

OBJECTIVES	N°	%
EFFECTIVE	78	71%
EFFICIENT	10	9%
ACCESSIBLE	13	12%
ACCETABLE/PATIENT CENTRED	3	3%
EQUITABLE	0	0%
SAFE	6	5%
TOTAL	110	

The actions defined in HSP reflect all the WHO objectives (apart from *equitable*), showing that extending CRM to all the actions defined in HSP could have implications in terms of achievement of the hospital quality objectives.

Conclusion
This work aims at extending the concept of CRM along two perspectives: 1) we tried to extend the concept of risk in accordance with the most recent regulations (ISO 31000 standard for risk management); 2) we tried to inherit the concept organizational resilience within the healthcare risk management.
Even if we are aware of the limitations related to the chosen methodology (case research) about the generalization of the results, we were able to answer the two research questions and conclude that the extended CRM and the healthcare resilience are already present inside healthcare systems, even if in seminal form: we found evidence that the analysed Italian hospital owns structured objectives and also partially

coherent to those defined from WHO. This make potentially possible to extend the CRM to different objective other than preserving the patient safety. Also, we observed that physicians and nurses already undertake some actions in response to the occurrence of adverse events and these actions can be considered "tacit" organizational resilience practices. This means that there healthcare systems already implement strategies aimed at reducing the magnitude of the risk, i.e. the bad consequences of negative events.

This work wants to contribute to the field of studies in CRM by introducing new concepts and ideas for the evolution of traditional CRM practices that encompasses the Extended CRM and the Healthcare Resilience.

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