



How to combine lean and safety management in health care processes: A case from Spain



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ABSTRACT

Resource reduction and need to assure high quality levels in healthcare have induced hospitals to develop projects that report multiple performances. In order to pursue patient safety and efficiency improvements simultaneously, “lean & safety” projects (L&S projects) could be implemented, combining Health Lean Management (HLM) and Clinical Risk Management (CRM). This research aims to understand how L&S projects can be implemented. The analyzed case is an exemplary one, as it has been triggered by who is in charge of patient safety and required firstly to reduce incidents and secondly to obtain efficiency improvements. Using an interview protocol grasped from literature, data have been collected conducting semi-structured interviews, analyzing relevant archival documentation and executing observations on the field. A new framework of analysis has been created answering the research purpose.

This research represents one of the first studies that investigate characteristics of an HLM project adopted to solve CRM issues. The results suggest HLM and CRM should be considered in a new synergic methodology. First indications about how developing it are provided boosting future research.

The outcomes of this research is valuable for hospital units and health organizations that need to achieve efficiency enhancement, improving patient safety at the same time. For managing clinical processes properly, hospital managers could consider the results of this research to solve their CRM problems. The emerged evidences contribute to the development of guidelines for the implementation of “L&S” projects, pursuing multiple objectives and contributing to the growth of more safe and sustainable health care systems.

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1. Introduction

Healthcare systems have to afford multiple challenges especially during a crisis period where many governments have to spending review in order to comply with international agreements. Particularly for healthcare systems that are guaranteed and funded by public institutions, efficiency should be increased cutting wastes and costs. On the other hand, accreditation standards require high performance in terms of safety improvements. In a context where resources are scant and customers and ethical principles ask for high quality, new managerial solutions should be developed, in order to abandon the trade-off approach among diverging performance objectives and to take advantage of the benefits of different methodologies.

An increasing interest has been devoting to Health Lean Management (HLM) in academic and managerial literature. It has

been cogitated as a managerial approach that could contribute to efficiency improvements, identifying and eliminating any wastes, attributing more value to the patient and reducing costs. Few researches have analyzed the impact of this methodology on quality improvements; in particular, until now the possibility to combine Health Lean Management and Clinical Risk Management (CRM) has received scarce attention.

Through the analysis of a single case study that is peculiar for its synergic approach adopted, this research aims to grasp guidelines and key lessons from the implementation of a successful project that has led to efficiency and patient safety improvements. In the project, elements of CRM and HLM are adopted together, contributing to the development of an original process management methodology. Considering not only the hardware but also the software components of the projects, the organizational and contextual aspects will be highlighted. After presenting the national and regional context of the hospital in which the project has been developed, in the third section the emerging managerial approaches adopted in healthcare will be described (Section 2). After defining the research objectives and justifying the followed

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research methodology (Section 4), the results of the case analysis will be reported (Section 5). Discussion of results and lessons learned will be presented in the sixth section, and finally the conclusion will be drawn (Section 7).

2. The national and regional context

The Spanish National Healthcare System (NHS) is based on the article 43 of the Spanish Constitution that recognizes the citizens' rights and the universality of the system, which must be guaranteed through territorial division of powers and equitable distribution of health care resources, as well as equal access to health care. In 1986, the application of these principles started with the General Health Care Act, through which the healthcare system was conceived as decentralized, universal and tax-based financed (Segura, 1999; Reverte-Cejudo and Sánchez-Bayle, 1999). The insurance-oriented model of Bismack was substituted with the model of Beveridge financed by taxes, even if the system today includes also out of pocket payments that mean co-payment by citizens and private insurance in addition to public coverage (Veneziano and Specchia, 2010; García-Armesto et al., 2010; Rajmil et al., 2000). The contemporaneous decentralization process finished in 2002 attributing high responsibility and autonomy to the 17 Autonomous Communities, whose cohesion, strengthened also by Cohesion and Quality Law in 2003, is assured by the Interterritorial Council of the NHS (CISNS), composed by regional ministers and the national minister (García-Armesto et al., 2010; Duran et al., 2006; Lopez-Casasnovas et al., 2005). The central government is responsible for several strategic areas (García-Armesto et al., 2010). Each autonomous community can define a different organization for its territory that can be distinguished into Health Areas and Basic Health Zones; the latter ones are the smallest unit of organizational healthcare (García-Armesto et al., 2010; Borkan et al., 2010). While regional health legislation, health insurance, health services planning, management and provision fall within the competence of Autonomous Communities, the local authorities are responsible for sanitation, collaboration in health services provision and public health and community services (García-Armesto et al., 2010). In health areas, primary and specialized care are provided with few management differences among the Autonomous Communities.

The Spanish NHS has been studied by different authors and someone (e.g. De Magistris and Bobbio, 2004; Lopez-Casasnovas et al., 2005; Rico and Costa-Font, 2005) has emphasized the diversity among regions especially for the seven Autonomous Communities that have acquired independency before the others. In particular, Catalonia, being the first Autonomous region, has developed gradually a peculiar Catalan health care system (Departament de Salut, 2014) with a direct management of the public structures by the Catalan Institute of Healthcare and service coverage assigned to other public or private suppliers through an accreditation mechanism (De Magistris and Bobbio, 2004; Rajmil et al., 2000).

Lopez-Casasnovas et al. (2005) underline that this decentralized system has not generated inequalities; rather, it has increased quality improvements at least for what concerns patient satisfaction. Borkan et al. (2010) report that in 2007 the NHS developed a Quality Plan: considering inputs from local authorities, twelve strategies were developed and executed at the national, regional, and local levels to reach quality and efficiency improvements and to reduce unnecessary costs and patient waiting times.

According to Veneziano and Specchia (2010), the Spanish NHS stands out for its efficiency and the peculiarity of its primary care organization. Based on the last OECD data (OECD, 2013), Spain performs well: in particular, the life expectation is among the highest

in Europe and the hospital beds and the mortality rate are the lowest ones. Considering the waiting times calculated by OECD (2013), Spain reports lower values than the OECD average for almost the indicators.

Despite the good indicator for public debt in 2010, Spain presented poor performance for employment and economic growth and public deficit (Catan, 2008; García-Armesto et al., 2010; Gené-Badia et al., 2012). The latter problems have been faced decreasing the social spending (García-Armesto et al., 2010), criticized by Gené-Badia et al. (2012). Those authors signal a reduction in surgical and clinical activities and in major investments, an increase of delay in payments to providers and salary reductions, which were still the lowest in Europe (OECD, 2013). This occurs together with a pressure to provide high-quality universal care in a context of population growth and even more aging people besides the global financial crisis (Martin-Moreno et al., 2009; Carrasco-Garrido et al., 2009).

Gené-Badia et al. (2012) are concerned about the risk of increase people on waiting lists, bad conditions for chronic patients and low health status for population. Borkan et al. (2010) state that the agenda of Ministry officials encompasses the promotion of optimal levels of quality, equity, and innovation, improvement of human resources management and financial sustainability of the system. Multiple performances could be achieved by hospitals only adopting different managerial approaches, overcoming the trade-off theory developed by Skinners (1985), Hayes and Wheelwright (1984).

3. Emerging managerial approaches in healthcare

According to Department of Health (1998, p. 6), clinical governance is "the process by which each part of the National Healthcare System quality assures its clinical decisions". A system of continuous improvement into the operation of the whole system has to be introduced (Department of Health, 1998). In fact, through clinical governance, "organizations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish" (Scully and Donaldson, 1998, p. 62). Clinical governance is based on integration of different approaches that requires attention to infrastructure, coherence, poor performance, culture, risk avoidance and quality methods. This means a cohesive programme of actions where all the staff are involved and managerial commitment, leadership and creativity are required (Scully and Donaldson, 1998).

For some authors, clinical governance is an organizational innovation that needs a cultural change, which is not easily achievable (Walshe, 2000; Smith, 2001). Reale (2007) identifies the tools and practices for implementing clinical governance (Table 1) that could contribute to the development of an environment more conducive to patient safety.

3.1. Clinical risk management

Clinical Risk Management (CRM) is inserted among the tools and practices adopted for clinical governance. It can be defined as a managerial approach to improve the quality in healthcare placing special emphasis on the identification of circumstances that put patient at risk of harm and acting to prevent or control those risks. The aim is to both improve quality of care, in particular patient safety, and reduce the costs of such risk (Walshe and Dineen, 1998). CRM can be defined also as the system of guidelines, protocols, steps, organizational and clinical procedures adopted by a hospital to reduce the probability that events and actions, which might potentially produce negative or unexpected effects on

Table 1
Tools and practices for an operative clinical governance according to Reale (2007).

<i>Tools and practices</i>				
Involvement of the patient and its family (through patient centered paths and assessment of patient satisfaction)	Strategic capacity (vision and mission definition)	Economic resource management of clinical processes	Staff management	Performance management
Information and communication management (through ICT support)	Multidisciplinary team working	Open organizational culture	Leadership involving top management	Clinical risk management

patients' health, occur (Floreani, 2005). According to Borghesi (1985), CRM is a complex activity to reduce risks (in terms of frequency and severity) and the economic impact of their shortcomings. Based on ISO 31000 the phases of CRM process are: establishment of the context, risk assessment (risk identification, risk analysis and risk evaluation), risk treatment and two phases continually acting, such as communication with internal and external stakeholders, and monitoring and review (Purdy, 2010).

The most used tools are (Verbano and Venturini, 2011; Verbano and Turra, 2010): incident reporting, analysis of clinical records and clinical documentation, analysis of administrative data, client reports, brainstorming, Root Cause Analysis, checklist, Failure Mode and Effects Analysis – Failure Mode, Effects, and Criticality Analysis (FMEA–FMECA), Hazard Risk Assessment (HRA), Hazard and Operability Analysis (HAZOP), decision-making trees.

These instruments should be adopted to manage clinical risks that are the probability that a patient suffers any damage or inconvenience caused, even if unintentionally, by medical care provided during the period of hospitalization, bringing about prolongation of hospital stay, deterioration of health or death (Kohn et al., 1999).

Clinical risks can be classified based on (Cinotti, 2004): the safety of structures, machines, electrical systems, hazardous substances, fire/explosion; the presence of chemicals, physical and biological agents and the risks linked with the work organization, psychological and ergonomic factors and difficult work conditions.

According to Reason (1990), a human error can be interpreted and analyzed adopting a “person approach” or a “system approach”. The first one was the most diffused and eradicated during last century and it considers the human behavior as a source of error, whose variability has to be reduced. This approach stresses the human component of the safety, such as the human factor and the cognitive processes at the base of errors (Damen and Novaco, 2004). Thus, in order to prevent risks, knowledge improvement and individual training are necessary since “bad things happen to bad people” (Reason, 1990). Instead, following a “system approach”, people make mistakes also in the best organization. Error is the result of a failure of a system composed by human and technological elements that are connected, integrated and aimed to common objectives. For this reason, it is necessary to redesign processes, understanding “how and why the defenses failed” instead of finding “who blundered”. Categories of errors reported by Ministry of Healthcare (2004) are: the error in the use of medicines, surgical errors, errors in the use of equipment, tests or diagnostic procedures not executed or executed in a not appropriate way, errors in the timing.

According to WHO (2005), errors could be unintentional or intentional (violations). A medical error is a mistake made in the process of care that causes or has the potential to result in harm to patients (AHRQ, 2003). These errors increase clinical risks, which are the probability that an incident occur (WHO, 2005). An incident can be a reportable circumstance, near miss (errors blocked before reaching the patient), no harm incident or harmful incident (adverse event) (WHO, 2005). “An injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both” is an adverse event (Brennan et al., 2004, p.145).

Reason (1990) identifies three typologies of error: slips, lapses and mistakes. Slips and lapses are execution errors, while mistakes are errors that occur in the strategic planning phase (Reason, 1990; Ferner and Aronson, 2006). Reason (2000) introduces the “theory of latent error”, which underpins the system approach; according to this theory, the potential errors (called near miss events) become errors only when they bypass each defense system created by the organization (Swiss cheese model). Adopting the person approach, only the unsafe act (the active error) is identified; factors causing latent errors are far from the direct contact with the final customers and thus they are not considered. Reason (2000) claims “we cannot change the human condition, but we can change the conditions under which humans work”. A lack in a single defense organizational system is not sufficient to transform a near miss event into an error; an alignment of defects in all the defense systems is necessary, through a trajectory of accident opportunity, according to the over mentioned “Swiss cheese model”. Therefore, the erection of robust organizational barriers could avoid this trajectory reaches the patient.

3.2. Health lean management and clinical risk management

Jacobs (2006) underlines it is not corrected to state that a zero-defect condition is not achievable in healthcare as complications are unavoidable; actually, no other businesses would survive if so many defective products were permitted. Although Six Sigma allows a low percentage of errors, it is not acceptable dealing with human lives (Bohmer and Ferlins, 2006). In order to face this issue, a strategy of real-time error reporting and decentralized problem solving is encouraged, but it is very hard to implement (Sirio et al., 2003).

From a research carried out in United States by American Society for Quality (2009), it emerges that 53% of the American hospitals have adopted lean methodology. However, only 4% of hospitals report a “full deployment” of this methodology, which has been adopted to improve hospital throughput (73%), to satisfy business or cost need (68%) and to increase the service quality (56%). Health Lean Management (HLM) can be defined as a managerial approach, to identify and eliminate wastes improving flow of activities to maximize value for customers. It considers standardization and specification of work processes, organization of work in such a way that unexpected events are easy to spot, and deployment of activities that find and fix mistakes (Ohno, 1988; Womack and Jones, 2003).

In a complex organization, such as a healthcare organization, adverse events are not eliminable, thus all the possible interventions should be adopted to control clinical risks (Ministry of Healthcare, 2004).

Nolan (2000) suggests three strategies to design assistance and care systems that guarantee safety to the patient. The first one is to prevent errors caused by the seven factors of Vincent et al. (1998) (patient factors, task factors, individual factors, team factors, working conditions, organizational factors and institution context). The second strategy regards making errors visible, in order to eliminate the causes of errors. The third strategy concerns the mitigation of the effect of an error. An optimal error management integrates all these strategies. Implementing at least the first two strategies

of Nolan (2000), HLM with its principles, techniques, tools and practices could be a support for a proactive CRM. A new methodology that combines principles, tools and practices from CRM and HLM could be a solution to facing multiple challenges. As Cagliano et al. (2011) claim, the complexity of healthcare requires the adoption of tools coming from different managerial approaches; the development of FMEA and wastes tables suggests the possibility to integrate, at least at tools level, HLM and CRM. Connections between the two approaches have been demonstrated (Cagliano et al., 2011), even if a synergic methodology has been never developed (Crema and Verbano, 2013). As mentioned by Ben-Tovim (2007), error is an absolute waste for a lean thinker. He states that retrospective error analysis is not so valuable when patient safety errors occur in one out of five hospital admissions, and adding another incident reporting seems not the solution. Care processes examination and redesign allow to pursue the right objectives preventing errors, and to identify weaknesses and opportunities of improvement, fostering to act at system level rather than at individual blame (Ben-Tovim, 2007; Ben-Tovim et al., 2008). HLM projects with impacts on patient safety improvements (“Lean & Safety” projects – L&S project) deserve to be deeply investigated, in order to provide a first contribution to the development of a synergic methodology lacking in literature and to the definition of guidelines indicating how it is possible to implement projects with multiple objectives.

4. Research design

As aforementioned, a synergic methodology that combines HLM and CRM has never been developed, even if it seems required in healthcare. Starting from this exigency, the purpose of this paper is to understand how L&S projects can be implemented pursuing objectives of patient safety improvements.

Detailing this aim, the significant features that characterize L&S projects have to be analyzed: organizational aspects, phases and activities, tools, techniques, practices and key factors for a successful implementation.

Starting from the guidelines grasped in Crema and Verbano (2013) through a systematic literature review, according to the suggestion of Miles and Huberman (1994), a research framework has been created after the formulation of research objective (Fig. 1), describing the features that have to be analyzed in this research.

The analyzed subject is new, consequently considering the maturity cycle of the research, qualitative research with in-depth case studies for exploration and theory building are suggested since the knowledge are uncertain (Voss et al., 2002; Eisenhardt, 1989; Yin, 2009; Malhotra and Grover, 1998). Benbasat et al. (1987) indicate to follow case study methodology if data are collected by multiple means, the analysis regards one or only a few entities, the complexity of the unit is high and deserves to be studied intensively. The selection of this methodology is justified also by the research questions «what, how» adopted in an exploratory study (Benbasat et al., 1987; Meredith, 1998; Yin, 2009; Hedrick et al., 1993). In particular, deep single case study allows a rich description of a phenomenon in specific circumstances (Eisenhardt and Graebner, 2007; Voss et al., 2002).

Therefore, a single case study research design has been adopted in order to analyze a critical and unique case (Yin, 2009). The

selected project is one of the first L&S projects where HLM is adopted firstly to reduce incidents and secondly to obtain efficiency improvements. This project has been implemented in a particular hospital (called “Omega” to ensure its anonymity) in the Spanish context, and it is one of the few that are implementing HLM projects in this country. It was built after the year 2000, it employs about 2500–3000 people to serve a catchment area of about 600,000 persons, with more than 400 sleeps (beds). Its mission is to offer an excellent technical quality and to guarantee assistance continuity in an organization that emphasizes patient needs. This is a very peculiar context, as Omega promotes teaching, research and innovation and considers lean healthcare among the improvement approaches of the hospital. The development of the “Omega Production System” is a medium-long-term aim, thus the lean management of processes is an integral part of the hospital strategy. Omega reports high experience in HLM project implementation and plenty of HLM procedures have been formalized and documented.

The organization chart of the hospital is also peculiar: inside the department of planning and patient safety (in staff to the general direction), HLM & quality unit and CRM unit are included.

In order to guarantee reliability of the analysis, a research protocol has been developed (Saunders et al., 2009; Yin, 2009; Voss et al., 2002). In particular, based on the academic and managerial literature review (Crema and Verbano, 2013, 2015) and considering the research objective, an interview protocol has been created for data collection, including the following sections: general information, context, objectives, organization, planning, implementation, monitoring, feedback, future developments and suggestions. Data have been collected during 2013 by three researchers, one of whom was involved as observer in the project team. In this way, three sources of evidences have been considered for data triangulation assuring research validity (Patton, 2002; Yin, 2009; Eisenhardt and Graebner, 2007; Healey and Rawlinson, 1994): open and semi-structured interviews, researcher observation, analysis of documentation and archival records. Considering the different possible roles of an observer, in this case, observer-as-participant has been chosen; with a moderate participation, it was possible to have access to the field and observe without influencing it (Gold, 1958; Spradley, 1980; Kawulich, 2005; Flick, 2014). The interviews were formally conducted with the lean manager of the hospital and the manager responsible for patient safety, involved in the implemented project, in order to gain a multidisciplinary point of view. Open and qualitative questions were submitted to the interviewees. Data analysis was conducted according to indications of scholars about case study methodology (Neutens and Rubinson, 2002; Miles and Huberman, 1994; Strauss and Corbin, 1990; Glaser and Strauss, 1967). Data were reduced through coding, creating categories and variables further described. A matrix has been finally created to explain the obtained results and answer the research objective (see the structure of Table 2).

5. Results of the analysis

The selected project regards the process of drug administration and the chain of activities that precedes it. Drug is required to the internal pharmacy by the inpatient unit; then, the internal storage

ORGANIZATIONAL ASPECTS			
Triggers and objectives	Phases and tools implemented	Outcomes	Tools for assuring continuity
ENABLES AND OBSTACLES			

Fig. 1. Research framework.

Table 2
The key characteristics of the project.

PROCESS OF DRUG ADMINISTRATION				
Motivation and objectives	Trigger	Incident analysis due to complex causes		
	Objectives	<ul style="list-style-type: none"> • safety improvement (reduction of adverse events) • efficiency improvement (reduction of drug supplying costs and of expired and wasted material, optimization of the drug stock) • increase of the trust in the provider (pharmacy) and of the collaboration between pharmacy and inpatient unit • learn the methodology 		
Organizational aspects	Key roles	Leader: person responsible for inpatient unit Referent: HLM manager Tutor: person responsible for inpatient unit	External support	Not necessary
	Top management support	Definition of a strategic plan where HLM is a methodology for innovation and improvement and a long term objective is the 'Omega production system', Top management involved in the project	Employees involvement	Informed, involved, consulted
	Training	Short, at the beginning, plenty of people already trained	Team	Multidisciplinary Full-time
	Role of CRM	Propeller of the project, CRM objectives, Involvement from the beginning	Meetings	Before, during and at the end of the project
Phases (Tools)				
1. Identification of the problem (incident reporting)				
2. Definition of the objectives				
3. Planning of activities (Timetable, Plan Do Check Act (PDCA), checklist)				
4. Communication and training				
5. Data collection and analysis of the problem (Brainstorming, 5 Whys, Ishikawa chart)				
6. Generation and collection of ideas for the improvement (Brainstorming with post-its)				
7. Prioritization and planning of the activities to implement (Impact-effort matrix, PDCA)				
8. Implementation (Definition of procedures, Determination of roles and responsibilities, Visual management, One-piece flow, New safety rules, Double checks, Perfection of the Kanban, Pareto analysis, Safety coefficient)				
9. Monitoring and evaluation (Monitoring and closure meetings, n° of reported notifications, incidents-causes matrix, questionnaire for feedbacks, final presentation, PDCA, archiving and sharing of the material)				
Outcomes	Results	Reduction of adverse events, > normality of the flow		
	Changes of the organizational system	Clear definition of tasks, roles and responsibilities, small modifications of some tasks		
	Changes of the organizational climate	Proactive adoption of the tools, increase of participation and motivation		
	Employees satisfaction	Operators expectations are largely met, adequate training, high participation and motivation		
Sustainability & lean continuity	Ideas development for future, personnel involvement, future training sessions, questionnaires for feedbacks, project archiving and sharing, reference project for future, demonstration of effectiveness of HLM approach			
Enablers	Manager of inpatient unit already trained, inpatient manager leadership, multidisciplinary team, continuous application of the methodology, climate and culture	Obstacles	Inexperienced operators, limited time, cultural aspects, no perception of the importance of support processes, difficulties to identify the patient and the value of activities	

of this unit is supplied, and drug is stored before its preparation. Solving the research objective, the key characteristics of the analyzed project are summed up in Table 2 and described in the following.

5.1. Triggers and objectives

In the interested hospital, HLM project is usually implemented in four circumstances. The first one occurs after a future state value stream map. The second one regards an auto evaluation: after that, if the requested improvement actions are complex and involved different processes and figures, the guide of the HLM unit is considered fundamental. HLM projects can be also implemented following a 5S audit, executing actions similar to those of the previous point. In this hospital, an HLM project can also start after the analysis of process incidents or adverse events, which are eradicated in complex causes and which cannot be solved with a daily kaizen

(Hamel, 2010). The analyzed project started in this last circumstance where a high error percentage in the drug administration process was reported. The intervention was required by the person in charge of patient safety. Thus, the first objective of the project was the reduction of adverse events. In particular, the team aimed to reduce them by 80%. Moreover, other secondary objectives concerned cost reduction of 5% for drug supplying, drug stock optimization, reduction of expired and wasted material, increase of the trust to the provider and of the collaboration between pharmacy and inpatient unit, and methodology learning.

5.2. Organizational aspects

In the analyzed organization, with more than 350 people trained in HLM, an external support for this project was considered not useful. They started to adopt HLM in 2008, with the help of a consulting company for two years and then they have continued

to apply HLM by themselves. However, in the first day of the kaizen realized for the project, one-hour lesson was provided by the HLM manager. A full-time multidisciplinary team was built for the project, engaging a mechanic engineer, a management engineer, two nurses, a person of patient safety unit, a pharmacy technician, a pharmacist and the responsible of the inpatient unit. The CRM manager was the propeller of the project, thus he was involved from the beginning. According to the usual Omega kaizen procedure, the role of tutor has to be assigned to who raised the issue; nevertheless, for this project instead of attributing this role to the CRM manager, it was assigned to the person responsible of the inpatient unit, who was also the project leader, while the project referent was the HLM manager.

Four weeks before starting the project, the tutor informed all the involved operators about the motivation and the objectives of the project, and he sent a written communication to each member about his specific assigned role. People that work in the field were not only informed, but also consulted before the implementation: suggestions and opinions of employees were gathered in an initial brainstorming, and coordination meetings were executed. At the beginning of the project implementation the engineers, the patient safety manager and the inpatient unit manager met together. During the kaizen, lasted three days, all the team took part in a daily meeting. A final meeting was executed to approve the improvement actions and to present what had been implemented. The same presentation was repeated with the top management. A closure meeting was carried out involving the leader, the tutor, the referent of the project and the person responsible for economics and finance of the hospital in order to verify whether the objectives of the project were achieved or not.

5.3. Phases and tools implemented

Through the analysis of the errors, it was discovered the highest percentage of notifications came from the process of drug administration: 49% of them caused patient damages, 19% did not cause patient injuries and the 32% were near miss events. After the identification of these errors, an HLM project was required; therefore, objectives were defined and activities planned. First of all, the project was presented to motivate the team to the achievement of its objectives. A short lecture about the project and HLM was provided, data were gathered and elaborated and the possible causes of problems were identified through problem analysis, adopting brainstorming, 5 Whys and Ishikawa chart. The main sources of the adverse events regarded the lack of adequate procedures, the presence of not followed procedures, the lack of tasks distribution and responsibilities definition, no communication channel between the pharmacy and the inpatient unit. Another brainstorming was executed, generating 52 ideas for the process improvement. The created post-its were imported in an impact–effort matrix, in order to identify the interventions to be carried out. The implemented actions concerned: firstly the definition of new safety rules, which imposed to write any treatment variations in the medical records, secondly the preparation and administration of medicines one by one, according to the one-piece-flow logic, and finally a double check of their name. Procedures for the requirement of urgent and not-urgent drugs were also defined, in addition to the delineation of methods for consumption and reposition, using Kanban system and other visual management tools (shadowing, visual signals and illustrative procedures). Other activities carried out regarded the determination of roles and responsibilities for: management of the labels, revision of the amount and cleanness of the medicines stock, revision of the loop to return medicines to the pharmacy, management and adoption of new and expired drugs, revision and updating of the existing procedures. Moreover, the stock had to be adequate to the actual

consumption, defining the current codes and the respected quantities, identifying medicines at risk and similar ones. Supporting this intervention, Pareto analysis was conducted to identify the most used codes and the safety coefficient was calculated (1.2 = medicine not indispensable; 1.6 = medicine not replaceable, but that stops patient assistance; 1.4 = other cases) to eliminate medicines not necessary and never required; moreover, visual signs were created to recognize the risky medicines. Quantitative and qualitative tools supported the phase of monitoring and evaluation of the adverse events through also the submission of questionnaires to the personnel.

5.4. Outcomes and tools for assuring continuity

Of course, the implemented actions have led to efficiency improvements, eliminating activities and costly and not necessary materials, but especially they provoked positive results in terms of patient safety. An incidents-causes matrix was created, reporting the percentage of each incident that was prevented eliminating a specific cause in the kaizen event. Applying this computation for all the eliminated causes, adverse events, near miss events and errors were totally reduced by 84.38%. Through a better identification of medicines and new procedures for drugs administration, patient safety improvements were achieved. With the new methods for consumption and reposition of medicines, irregularities of the flow have been also reduced. Staff involved were satisfied, and their expectations were met. From the questionnaires, it emerges they have appreciated in particular time management, the approach adopted for problem solving and the active participation of all the people. Time constraints were notified as a project limit. However, an increase of the participation and motivation has been reported in addition to a more proactive use of HLM tools.

The implemented project could be a reference point for others. Its replication has been planned for other similar processes, but potentialities for different processes have been also recognized. In order to guarantee the continuity of HLM adoption, it is fundamental to share the achieved improvements, whereby all the personnel has to be involved, aligned and updated about all the procedures, through training sessions, documentation sharing in the intranet, information panels and illustrative procedures. It is important to share all the results of the project, as they are feedbacks about HLM effectiveness. After this project, plenty of ideas have been generated and will be considered for future implementations, according to PDCA (Plan Do Check Act) logic.

5.5. Enablers and obstacles

The first project enabler regards the inpatient unit manager that was already trained about HLM philosophy and tools; he had already taken part in other kaizen projects, besides being respected and esteemed by his collaborators. Other key elements for the successful implementation of the project are: the creation of a multidisciplinary team, the search of continuous improvement and the constant application of the methodology in a favorable climate where the culture of HLM is spreading.

On the front of the hindering factors, the first was the lack of importance perception of the alignment between the core processes and the support ones. Other obstacles were recognized in the inexperience of some operators, little time for the implementation of the project and the difficulties to identify the patient and what is valuable for him.

6. Discussion and lessons learned from the analyzed case

After the project analysis, it is possible to grasp significant evidences.

Firstly, in this case the linkages between HLM and CRM appear at institutional level from the organizational chart, as their organizational units are inside the same department, and this peculiarity facilitates their interaction. Moreover, HLM is normally adopted in this hospital to solve complex problems connected to CRM, as HLM is the key methodology indicated in the strategic plan for the improvement and innovation of all the processes. These are the peculiar characteristics of this hospital that aims to be aligned with the patient needs and expectations, assuring the use of the best practices. There are circumstances linked to clinical risks that are usually solved adopting HLM in this hospital. For this reason, clinical risk manager should be involved especially when the HLM project is promoted to solve CRM issues. In this particular organization, the key trigger of the examined project is the requirement of the person responsible for patient safety and the first objective of the project is errors reduction, while efficiency improvements are secondary objectives. In this case, therefore, the linkage between HLM and CRM starts before the project implementation.

Based on these considerations, lessons learned regard the project triggers (LL1 in Table 3) and the organizational aspects (LL2 in Table 3).

This hospital, supported by a consulting company during the implementation of its first HLM projects, now is independent. Inside its organizational structure, there are plenty of people already trained and, in particular, the health lean manager has gained a lot of experience in implementing lean management projects, firstly in industrial sector and after in Omega. For this reason, the short lecture about HLM for the untrained staff of the inpatient

unit was provided by the HLM manager without needing external support (LL 3 in Table 3).

Looking at Table 2, tools and practices of HLM can be identified pursuing CRM objectives. Risks are identified using incident reporting and analyzed investigating the causes of the reported adverse events. In addition to typical CRM tools, others of HLM are used to support these phases (e.g. brainstorming, 5 Whys, Ishikawa chart). Clinical risks are treated defining new safety rules, determining new procedures and double checks, but also adopting HLM principles and tools (e.g. visual management, Kanban, one-piece flow). The monitoring phase is also interested by the application of tools from different approaches (e.g. incident-cause matrix, meetings, questionnaire for feedbacks from staff). The phases of ISO 31000 for CRM are recognized in this L&S project, suggesting LL 4 (Table 3). The adoption of tools from both the approaches leads to the LL5 (Table 3), supporting the possibility and the value to develop a synergic methodology.

Discussing the causes of the reported adverse events, errors in this case are due to procedures, tasks, responsibilities and staff communication. Therefore, according to Reason (1990), they can be prevented improving organizational aspects, instead of identifying individual and personal faults that need to be punished and better trained (LL 6 in Table 3). In this way, the working of the physicians is guaranteed and protected against mistakes, slips and lapses (Reason, 1990; Ferner and Aronson, 2006), as synthesized in LL7 (Table 3).

Besides the use of hospital intranet and basic tools, no other particular types of ICT have been adopted. ICT seems not strictly indispensable for the adoption of the analyzed “system approach” to avoid human errors.

The key project enablers highlight the importance of the “soft” aspects (Shah and Ward, 2003, 2007) for a good implementation of L&S projects.

The collaboration of people with different backgrounds and points of view is considered fundamental for the success of the project implementation, as emphasized in the “enablers” (Table 2) and reported in LL10 (Table 3).

Besides the high multidisciplinary of the team, the definition of key roles has to be highlighted, in addition to the selection of the inpatient unit manager as tutor of the project, exploiting his leadership and his HLM knowledge. This element has been identified as an “enabler” by the interviewees (LL11 in Table 3). Thus, cultural features and the involvement of people already trained result fundamental.

However, according to Radnor and Walley (2008), all the staff should be involved and consulted. Increasing staff motivation and satisfaction with continuous improvement, valorizing their human rather than technical characteristics, can create conditions for a sustainable implementation (Yang et al., 2012; Radnor and Walley, 2008). In the analyzed project, the staff involvement has been identified as a tool for assuring the continuity of the implemented changes, leading to LL9 (Table 3).

Moreover, archival documentation is considered relevant to assure the continuity of the adoption of these managerial approaches. This aspect contributes to the organizational learning, providing formalized guidelines that could be adopted by other units to replicate the project. As emerged from the project analysis, for an organization that intends to develop the “Omega production system”, the capture and dissemination of the knowledge created during the project are vital (LL8 in Table 3). This ensures the execution of the last phase of the knowledge management process that comprises generation, codification, application, storing, mapping, sharing, and transfer of knowledge (Carlucci et al., 2004; Wiig, 1997). Also Dombrowski et al. (2012) underline that lean management is not simply a process redesigning; in order to create sustainable changes people’s knowledge has to be modified.

Table 3
Lessons learned from the analyzed case.

Dimensions of L&S projects	Lessons learned from the case
Triggers and objectives	LL1 – To pursue CRM objectives the person in charge of patient safety is involved from the beginning of the project implementation
Organizational aspects	LL2 – An integration between HLM and CRM units encourages the realization of L&S projects LL3 – When inside the organization there are people already trained in HLM, external support is not necessary and a short lesson for all the staff about the main principles and tools is sufficient before starting a L&S project
Phases and tools implemented	LL4 – Pursuing safety improvements, risks are identified, analyzed, treated and monitored LL5 – Besides specific CRM tools and practices, also HLM tools can be implemented for risk analysis, treatment and monitoring when patient safety improvements are pursued LL6 – The main factors that cause clinical errors in drug administration process are organizational and managerial ones linked to procedures, tasks, responsibilities and staff communication
Outcomes and tools for assuring continuity	LL7 – L&S projects allow creating an environment where trained physicians are more protected against mistakes LL8 – To assure replication and continuity to the adoption of the new implemented solutions, knowledge capture and dissemination are relevant LL9 – Staff involvement from the beginning of the project contributes to sustain the implemented changes
Key factors	LL10 – A multidisciplinary team where people with different backgrounds collaborate enable L&S projects implementation LL11 – The identification of the right leader and a pre-existent culture and experience about HLM facilitate the implementation of L&S projects

Moreover, the definition of key roles and the contribution of experts, who provide their experience in the project implementation, emphasized by Dombrowski et al. (2012), have been found also in the examined project.

7. Conclusion

The connection between HLM and CRM is not properly studied in the literature yet, as this research stream is still at its early stage and requires extensive investigations. Giving a contribution to fill in this gap, context of application, organizational aspects, phases, tools, practices and key factors for a successful L&S project implementation have been described in this paper. In addition, the studied case is particularly relevant because it allows investigating the characteristics of a HLM project adopted to solve CRM issues. The integration between HLM and CRM starts at institutional level in this hospital and is evident from the beginning of the investigated project realization. The significant obtained results confirm that HLM and CRM should be considered and usefully developed in an integrated methodology.

One of the most important contribution of this paper is the development of first indications to be followed for a successful adoption of HLM to achieve CRM results. Moreover, the lessons learned defined in the previous section constitute a base and a stimulus for future research.

These first indications about how developing L&S projects should be tested and exploited, also in other contexts, such as different hospital units inside the same hospital, or other health-care organizations that need to achieve efficiency enhancement, improving quality and, in particular, patient safety at the same time. The second contribution of this study is the creation of a research framework, which could be considered to analyze other cases, in order to carry out a comparison and multiple case study and to extend and generalize the obtained results. Moreover, further monitoring and evaluation of the first obtained results could be useful to refine the present research. Elements of knowledge management have emerged as enablers of the examined project. Creating a model of knowledge flows and studying the knowledge management tools helpful for this kind of projects could be an opportunity for further research, to study in more details how it is possible to implement sustainable L&S projects.

The indications provided in this research contribute to the definition of guidelines useful for practitioners. Hospital managers, who are usually not accustomed to methodologies coming from industrial sector, need to know the instructions and the directions of these emerging managerial approaches. The results of this paper constitute part of the guidelines that, once refined and contextualized, should conduct anyone during the application of a synergic methodology. This will permit to pursue multiple objectives in a challenging environment and foster the development of more safe and sustainable health care systems for the benefit of the entire community.

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