

# System-wide lean implementation in health care: a multiple case study

# Abstract

## **Background**

Lean practices have been widely used by health care organizations to meet efficiency, performance and quality improvement needs. The lean health care literature shows that the effective implementation of lean requires a holistic system-wide approach. However, there is still limited evidence on what drives effective system-wide lean implementation in health care. The existing literature suggests that a deeper understanding of how lean interventions interact with the organizational context is necessary to identify the critical variables to successfully sustain system-wide lean strategies.

## **Purpose and methodology**

A multiple case study of three Italian hospitals is conducted with the aim to explore the organizational conditions that are relevant for an effective system-wide lean implementation. A conceptual framework, built on socio-technical system (STS) schemas, is used to guide data collection and analysis.

## **Findings**

The analysis points out the importance to support lean implementation with an integrated and coordinated strategy involving the social, technical, and external components of the overall hospital system.

## **Practice implication**

The study offers useful insights on the dimensions that both managers and policy makers need to invest on when implementing lean as an organizational-wide improvement initiative:

- clear and decentralized responsibilities for the lean implementation;
- commitment and stable guidance from the top-management;
- continuous improvement through pervasive training programs and external networking;
- redesign of healthcare delivery model in a process perspective;
- alignment of the lean strategy with the hospital planning and control system;
- direct involvement of healthcare professionals in lean projects.

Finally, the findings outline the importance of the interplay between the different system components, i.e. social, technical and external.

## **Keywords**

Lean, health care, system-wide, implementation process, socio-technical system, multiple case study

# 1.Introduction

In recent years, the health care sector has used quality improvement approaches and methodologies as an effort to meet efficiency, performance and quality improvement needs (Walshe, 2009). Among these practices, lean has stood out in terms of diffusion in many hospitals (D'Andreamatteo et al., 2015; Mazzocato et al., 2010; Carbone et al., 2013). Lean is a strategy that focuses on meeting customer needs (i.e. patient, internal staff, organization) and continuously improving processes by optimizing flows, reducing waste and creating value with the direct involvement of the organization's personnel (Ohno, 1988; Womack and Jones, 1996; Hines et al., 2004; Holweg, 2007). The adoption of lean requires the full awareness of the organization as a series of activities and processes that need to be streamlined to add value to the customer while activities that do not add value (i.e. waste) need to be removed (Womack et al., 1990; Waring and Bishop, 2010).

Literature on lean in health care shows that the effective implementation of lean requires a holistic system-wide approach (Brandao de Souza, 2009; Andersen et al., 2014). A holistic approach entails an organizational-wide application of lean, in which long-term improvement goals are aligned to the overall organizational strategy, which in turn leads to lean practices to be broadly embraced at all levels of the organizations (Radnor and Walley, 2008; Radnor, 2011). Nonetheless, most of the published lean studies have narrowed their focus to single technical applications or short-term improvements resulting in small pockets of best practices, with limited evidence on what drives effective system-wide lean implementation (Brandao de Souza, 2009; Radnor et al., 2012; Andersen, 2015). In order to understand the variation in how and when lean works in health care organizations, it is of a paramount importance to examine the organizational patterns that play a relevant role for the integration and the internalization of the change process (Waring and Bishop, 2010; Brandao and Pidd, 2011; Andersen, 2015).

A recent comprehensive review on the organizational factors that enable effective use of lean practices in health care has been conducted by the authors (Centauri et al., 2016). Findings showed that literature on lean in health care has mainly investigated single organizational factors (see Table 1), lacking insight on how these elements are influencing each other and how lean change management strategies can be developed across the organization as a whole.

Table 1. Relevant organizational factors to manage when implementing lean change initiatives in health care

<b>DIMENSIONS</b>	<b>MAIN REFERENCES</b>
Change management and organizational culture	Al-Balushi et al., 2014; Aherne, 2007; Barlow, 2009b; Bliss, 2009; Fillingham, 2007; Graban and Swartz, 2012; Holden, 2011; Kim et al., 2006; Lodge and Bamford, 2007; Mazzocato et al., 2010; Pedersen and Huniche, 2011; Radnor et al., 2006; Radnor

	and Bucci, 2007; Radnor and Bucci, 2010; Radnor, 2011; Radnor et al., 2012; Radnor and Osborne, 2013
Integration within the organizational strategy	Aherne, 2007; Al-Balushi et al., 2014; Holden, 2011; Radnor et al., 2006; Radnor and Bucci., 2007; Radnor and Bucci, 2010; Radnor, 2011
Process-driven organization	Al-Balushi et al., 2014; Barlow, 2009a; Barlow, 2009b; Bliss, 2009; Brandao de Souza. 2009; Fillingham, 2007; Graban and Swartz, 2012; Grant and Wilcox, 2008; Joosten et al., 2009; Nicosia and Nicosia, 2008; Radnor et al., 2006; Radnor and Bucci, 2007; Radnor and Walley, 2008; Radnor, 2011; Spear, 2005; Stroupe, 2012
Physical lay-out and spaces	Chan et al., 2014; Dickson et al., 2009; Nicosia, 2008; Nicosia, 2010; Noble and Lee., 2010; Soriano-Meier et al., 2011; Stroupe, 2012
Engagement of staff and management commitment	Aherne, 2007; Al-Balushi et al., 2014; Barlow, 2009a; Barlow, 2009b; Benneyan, 2011; Bliss, 2009; Dickson et al., 2009; Graban and Swartz, 2012; Grunden, 2009; Holden, 2011; Joosten et al., 2009; Pedersen and Huniche, 2011; Poksinska, 2010; Radnor et al., 2006; Radnor and Bucci, 2007; Radnor and Bucci, 2010; Radnor et al., 2012; Toussaint, 2009; Towne, 2010; Westwood et al., 2007
Availability of resource and organizational set-up	Aherne, 2007; Al-Balushi et al., 2014; Benneyan, 2011; Fillingham, 2007; Holden, 2011; Kollberg et al., 2007; Pedersen and Huniche, 2011; Radnor et al., 2006; Radnor and Bucci, 2007; Radnor and Bucci, 2010, Radnor, 2011
Information system and technology	Benneyan, 2011; Graban and Swartz, 2012; Grant and Wilcox, 2008; Pedersen and Huniche, 2011; Radnor and Bucci, 2007; Radnor and Bucci, 2010; Towne, 2010

(Adapted from Centauri et al., 2016)

To narrow this knowledge gap, the authors developed a modified socio-technical system model (STS) and use it to investigate how lean interact with the internal and external organizational context through the empirical analysis of lean change programs in healthcare organizations. A description of this conceptual framework is given in the following section. The article then presents a multiple-case study analysis to identify: i) which of the model's social, technical and environmental elements are critical in promoting and supporting lean change program; and ii) how the social, technical and external factors interrelate and interact to implement the organization work system. The final sections discuss the findings of the analysis, inform practicing healthcare administrators and hospital managers about how to operationally apply the modified STS

model, strengthen the extant knowledge of the lean change management approach, and point the way forward for future research.

## 2. Conceptual framework

The socio-technical system (STS) model was deemed appropriate to analyze the organizational system in which lean is implemented (Trist and Bamforth, 1951; Leavitt, 1965; Keating et al., 2001; Davis et al., 2014). The STS model embraces a system perspective (Boulding, 1956; Von Bertalanffy, 1969) on organizations, and thus allowed to identify the organizational factors that influence a change process. The original STS model considers each organization to be composed of (i) a social subsystem of people and structure components and (ii) a technical sub-system of technology and production process elements. The central premise of the STS approach is the joint optimization of these two subsystems that define the entire work system in relation to the external environment; indeed, these organizational systems are open to their environments (Keating et al., 2001). The consideration of this interrelatedness is needed when seeking to promote change within an organization, due to, for instance, the introduction of a new change program (Cherns, 1976). In health care, too many quality improvement interventions are seen as ‘magic bullets’ that will produce improvement in any situation, regardless of context (Dixon-Woods and Martin, 2016). Assuming the STS approach, health care organizations can be defined as work systems with a set of strategic goals and cultural assumptions, in which professionals (with different attitudes and skills) perform multiple tasks, use tools and technologies in a physical space, to deliver clinical and administrative processes (Marsilio et al., 2016).

We built our framework (Figure 1) on a robust stream of scientific works that have applied the socio-technical model to a variety of different domains (Leavitt, 1965; Davis et al., 2014) including hospitals (Marsilio et al., 2016). In particular, in our work we have stressed the importance of the interdependence of the different components and the role played by the external environment that influences, but it is also influenced, by the internal organizational dynamics (Lega, 2005; Leatt and Mapa, 2003; Moseley, 2008; Rivers and Glover, 2008).

We considered

- **the social sub-system** composed by the following themes and sub-themes:

### **STRUCTURE**

- **Strategic planning and control system**– encompass the planned system objectives and policies that hospital sets, at different levels, in delivering care and meeting performance goals with the aim of clarifying the relevant and sustainable direction and translating that direction into operational action;
- **Organizational structure** – refers to the formal assignment of roles and functions, the division of work among the different units and all the mechanisms to make the hospital work;

## PEOPLE

- **Human resources** – refer to the mechanisms by which hospital generates and spread commitment and knowledge to develop specific skills, competencies, attitudes (e.g. leadership, team working, training);
- **Working culture** – refers to people motivations, beliefs, ideas, principles, ideological assumptions associated with the hospital itself and their work.

- **the technical sub-system** composed by the following themes and sub-themes:

## TECHNOLOGY

- **Tools** – refer to the various types of operative tools and techniques that hospital uses to improve care quality or reduce costs;
- **Layout** – refers to the different spaces where hospital production processes are carried out (e.g. operating rooms, hospital wards, outpatient clinics).

**PRODUCTION PROCESSES**– refer to the three different categories of processes taking place within hospitals: (i) clinical processes (i.e. all medical and care activities directly performed on patients, such as diagnosis, treatment, etc.), (ii) ancillary clinical processes (i.e. all activities involving clinical professions but not directly patients, such as drug logistic or laboratory testing, etc.) and (iii) administrative processes (e.g. all non-clinical activities that make the hospital works, such as finance and purchasing, etc.);

- **the external environment** in which the hospital is embedded; this is made up of different sub-environments, such as: institutional (e.g. expectations from external relevant stakeholders, such as Regions or Local Health Authorities for public hospitals), socio-demographic (e.g. trends and behaviors of population and customers), economic (e.g. recession or expansion period, financial resources availability), political (e.g. prevalent ideology that shapes the policy making process), competitive (e.g. level of competition), etc.

This STS framework helped to embrace a system-wide approach to study how lean efforts are grounded into the organizational context (Mazzocato et al. 2014; Holden, 2011; Poksinska, 2010). As the context and the lean intervention interact, they reciprocally influence each other and this interaction can influence the adoption of lean as well as the organizational performance (Eriksson et al., 2016); under this assumption, the context should be considered as all interacting surrounding factors that characterize the intervention itself and make it work (Andersen et al., 2014). A deeper understanding of how lean interventions interact with the organizational context of application is needed in order to make lean spread and stay as an organizational-wide approach (Radnor et al., 2006).

Figure 1. A system wide framework for investigating lean in healthcare

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Insert Figure 1 about here

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### 3. Research design

To answer to the research question, we adopted a multiple case study approach (Yin, 2003). Case study is well suited to capture context-specific perceptions of organizational reality and to provide simultaneous assessment of organizational dynamics at multiple levels within each setting and across settings.

In recent years, lean interventions have become widely adopted by Italian health care organizations to optimize and better use available resources. In 2012, two members of the research group (MM, PM) conducted a survey on trends in the diffusion of lean management into the Italian health care sector including public providers (local health authorities – LHAs – or hospitals) and private accredited providers. The study showed a high diffusion of lean practices, but only six cases reached a significant level of integration of lean within the organizational context (high number of improvement projects, stable interventions in the organizational structure, multi-dimensional performance evaluation system) (Carbone et al., 2013). We started from the results of this study to identify, among these cases, the hospitals that were expected to produce similar results in terms of the mechanisms explaining effective lean implementation (i.e. literal replication) (Yin, 2003). Particularly, we found that only three hospitals maintained a stable and mature comprehensive lean approach over time. Two of those hospitals are public, while one is private.

In Italy, the 21 different regional governments are responsible for the organization and provision of healthcare services through public providers (local health authorities – LHAs – or hospitals) and private accredited providers (Anessi et al, 2001). Public and private providers play according to the same rules; the regional accreditation system sets requirements that a healthcare provider need to satisfy in terms of quality standards (e.g. clinical appropriateness and safety of patients, improvement and innovation processes, etc.). Patient can choose among accredited providers the one that better fits its need.

### 4. Data collection

In order to first familiarize with the cases under investigation, we collected several internal documents (official organizational strategic/management documents, budget sheets, etc.), three articles in specialized periodicals and published academic literature (four books). We then conducted 18 interviews to get an in-depth understanding of the implemented lean programs and of the organizational context (see table 2). We developed a semi-structured interview with open-ended questions based on the key organizational factors enabling effective lean practices reported in the literature (Centauri et al., 2016). The interview protocol was approved by the CEOs of the three hospitals. We intentionally selected the people to be interview according to their key role in the lean program. Through a snowballing approach, we asked these participants to suggest health care professionals who had an active role in the lean program (top managers, program leaders, lean team/office members). Most of the interviews took place during office hours

at the workplace of the interviewee, whereas others were performed through Skype or over the phone. The interviews were conducted by FC, MM, SV and lasted between 60 and 120 minutes. Informed consent was obtained by all study participants. Study visits were also performed in conjunction with the interview situations to familiarize with the organizational context. The visit to the case study sites were made in teams so that each case could be viewed from different perspectives of multiple observers; also, interviews most of the times were conducted by a three-person team, with one researcher guiding the interview, while the others recording notes (Eisenhardt, 1989).

Table 2. Overview of the main population's characteristics and of interviews performed and documents collected for each site

	<b>HOSPITAL 1</b>	<b>HOSPITAL 2</b>	<b>HOSPITAL 3</b>
<b>Ownership</b>	Public (legal autonomy)	Public	Private (main hospital of a group of private health care providers)
<b>Size (no. of beds)</b>	449	753	747
<b>Inpatient admissions/year</b>	17.000	35.000	50.000
<b>No. of employees</b>	1.810	2.700	2.100
<b>Start of the lean journey (year)</b>	2009	2012	2012
<b>Employees who have attended (at least) a lean training course (%)</b>	75	88	40
<b>Lean program coordinator</b>	Internal clinician	Lean office	Lean team
<b>Interviews performed</b>	8  CEO	6  Medical CO	4  Operations manager director



	ICU head and change program coordinator	Lean office responsible (industrial engineer)	Lean team member 1 (industrial engineer)
	ICU clinician and medical tutor	Lean office member 1 (industrial engineer)	Lean team member 2 (clinician)
	Medical department head	Lean office member 2 (clinician)	ICU clinician and lean champion
	Medical department head nurse and lean facilitator	Surgical area nurse and annual lean contest winner	
	Infectious disease ward head nurse lean facilitator	Anesthesiologist unit head and annual lean contest winner	
	ICU head nurse and lean facilitator		
	Lab technician and lean facilitator		
<b>Documents collected</b>	Three-year strategic planning  Internal regulation on organizational levels and departments  3 articles in specialized periodicals  2 books	Three-year strategic planning  Internal regulation on Lean office  2 budget sheets  Training courses catalogue  book	1 book

## 5. Data analysis

Interviews were transcribed *verbatim* and a qualitative content analysis was performed (Hsieh and Shannon, 2005). We followed a two-step process: first we followed an inductive approach to develop categories and then a deductive approach to refer the categories emerged to the theoretical framework. FC read through the transcripts to become familiar with the data and the information. For each case, FC extracted from the transcripts the meaning units that were relevant for our purposes and coded them inductively using NVivo 11 qualitative software (QSR International Pty Ltd. Version 11, 2015). FC categorized inductively (Pope et al., 2000) all the meaning units that related to the research question. The manifest meaning of the text was captured (Graneheim and Lundman, 2004). PM and FC categorized the inductively derived codes together for one of the cases; the authors worked independently on this initial and preliminary categorization in order to strengthen the trustworthiness of the findings. FC then conducted the categorization for the other two cases. Then, FC, PM, and MM discussed together the categorization, created final categories and sub-categories, and finally related them to the deductive themes in the theoretical framework, i.e. social (S), technical (T), external environment (EE), and to the sub-themes that are included in the framework. All the inductively emerged categories and sub-categories fitted into the framework's dimensions.

## 6. Findings

In this section, the most relevant categories and sub-categories emerged from the analysis of the interviews are presented, classified according to the three framework's themes (social, technical, external environment) and sub-themes.

### Social factors

#### Structure

##### Strategic planning and control system

In all cases, the top management shared similar goals for the launch of the lean initiatives: the need to improve staff well-being, patients' satisfaction and process efficiency.

*“We have always seen lean and quality as two strictly related concepts: the main program objectives were, and actually are, about quality but then pursuing quality has led to achieve also efficiency gains”* (Operation manager director – Hospital 3)

At the time of the launch of lean program, Hospital 1 approved the relocation of the existing hospital to a new hospital site. The idea was to develop and structure an innovative managerial approach before moving to the new building (now under construction) designed around patient centeredness. This circumstance facilitated the

launch of the lean change program and its promotion over time; indeed, it contributed to strengthening organizational efforts towards continuous improvement.

*“We aimed to create a new hospital in a hospital new, that is a new way of working for the new future building”* (CEO – Hospital 1)

Lean was integrated into the organizational long-term strategic planning from the beginning. Lean-related goals were step-wise included in the annual budget. In this way, the organizations strategy was translated into operational actions and professionals’ efforts could be better coordinated towards the identified goals.

*“Lean projects’ objectives, that are often related to flows optimization, patient centeredness, professionals’ empowerment, have soon been included in the budget sheets for professionals”* (ICU clinician and lean champion – Hospital 3)

### Organizational structure

New lean roles were developed to support and facilitate lean implementation. Initially, all three hospitals created central lean roles to develop strategic top-down projects, coordinate and provide internal training, and support bottom-up projects development. In Hospital 1 the lean program was launched and set-up by an internal clinician; his function and competency, were acknowledged by professionals:

*“They call him Dr. Lean or Dr. Flow”* (CEO – Hospital 1)

The lean office in Hospital 2 (that reported to the CEO and was composed of full-time industrial engineers, clinician, nurse, radiologist) and the lean team in Hospital 3 (that reported to the Quality office and was composed of a full-time industrial engineer and an internal clinician who was fully dedicated to lean one day a week) led and coordinated the lean efforts.

*“The lean office is the glue of the hospital”* (Anesthesiologist unit head and annual lean contest winner – Hospital 2).

After the initial implementation phase, physician and nurses (eight lean facilitators in Hospital 1, five process nurses in Hospital 2, and 15 lean champions in Hospital 3) were involved to deliver training activities and support other professionals in their local improvement projects.

*“They are the first lean professionals to interact with staff working on projects”* (Surgical area nurse and annual lean contest winner – Hospital 2)

*“A lean champion does for his area what the lean team does for the entire hospital; it is an extension of the lean team”* (ICU clinician and lean champion – Hospital 3)

These decentralized lean facilitator roles were formalized by internal regulation and in two cases (in Hospital 2 process nurses were fully dedicated to lean, whereas in Hospital 3 lean champions spent one day a week for lean) they had time allocated to lean efforts by contract. The introduction of these roles was important to engage professionals and helped them to understand that lean was in fact in their hands.

*“We use our relational and persuasion skills to foster a good team working environment and guide professionals to identify and address organizational problems emerging from daily work”* (Medical department head nurse and lean facilitator – Hospital 1)

Several channels were used to promote lean throughout the organization, e.g. information on intranet and word of mouth). These activities provided visibility to the lean program, and made professionals aware of the need to change and how lean could support this change.

*“Every professional in the hospital knows that lean exists and what is about”*  
(Lean team member 1 – Hospital 3).

The introduction of lean roles helped to maintain a bidirectional communication between the top management and professionals who worked on projects. This helped to align local improvement efforts with the overall goals in a cohesive way. Moreover, at all three hospitals, the annual lean contest provided a forum for all employees to acquaint themselves with ongoing lean projects and to know the strategic direction chosen by top management.

## People

### Human resources

Since the beginning, top management was strongly committed and engaged in the lean change program. They were also directly involved in the development of top-down strategic improvement projects. Their previous knowledge and experience in lean implementation (also in other production settings) made them believe in the benefits of adopting lean. In Hospital 2, the Administrative CO came from a global management consulting firm, and Hospital 3 was built and managed by a global engineering firm. In both case, the CEO involved industrial engineers to run and coordinate the lean implementation. In Hospital 1, the CEO had already begun an ambitious project to develop a process-oriented organization. He appointed a clinician, with a deep knowledge on lean implementation in health care, to lead the change.

In all three hospitals, the top management guidance and support of the change program was visible and stable over time (in Hospital 1 the CEO has held his position for more than ten years, in Hospital 2, for five years, and in Hospital 3, the Executive team has remained composed of almost the same professionals). The long-run sponsorship was the *conditio sine qua non* for lean efforts could be continuously strengthened and sustained.

*“CEO, Medical CO, Administrative CEO use every occasion to talk about lean and explain why it is the right approach to follow” (Surgical area nurse and annual lean contest winner – Hospital 2).*

In all three hospitals, a multi-level training program was launched with a similar general structure: the first level on lean principles and tools; the second level on the practical development of improvement projects; other courses on specific tools or techniques to use for improvement activities. The lean training program, open to all staff, enhanced professionals’ commitment and enabled the extensive use of lean in everyday work. The continuous and pervasive lean training (“train the trainers”) facilitated the integration of lean work practices in the organization. Professionals were trained to work in team and to develop improvement projects independently.

Different forms of intrinsic and extrinsic motivation toward lean program were mentioned in the interviews. Intrinsic motivation was linked to professionals’ empowerment to drive change, the positive effects they perceived in their work following lean changes, and the visibility they gained in doing so. Professionals involved in lean work gained visibility as their improvement projects competed in the annual lean contest attended by the top management and opened to all staff, and were presented at external events or international conferences. In Hospital 2, visibility was also gained as the Medical CO had the habit to do *gemba* walks inside hospital areas to observe the improvements realized in the workplace.

In Hospital 1 professionals were extrinsically motivated to get involved because working on lean projects was a requirement to obtain a promotion or reach budget objectives.

The whole change initiative was almost entirely self-sustained through the direct engagement and empowerment of internal professionals to manage and develop improvement projects and to coordinate and provide training activities. External support was only used to run specific training sessions. As true actors of change, they wore “lean glasses”, acquired a proactive approach to identify, in the daily work, problems to solve by developing bottom-up improvement projects; the number of projects launched and run by teams of professionals increased significantly over the years.

*“Most of the projects now – indicatively 90% - are promoted by professionals and only a small part – 10% - by the top management; this is a natural consequence of adopting and spreading an improvement initiative where the role of professionals is central: they are close to processes and to clinical and organizational dynamics, so they are in the best position to find problems and think for solutions” (Lean team responsible – Hospital 2)*

### Working culture

All three hospitals aimed at integrating lean into professionals’ thinking and action. All the improvement initiatives needed to be developed starting from daily practice.

In this light, the hospitals' strong vocation towards innovation (Hospital 3) and previous experience to work process-oriented (Hospital 1) were favorable conditions for the initial lean implementation. In fact, many professionals were already used to think and act according to innovative managerial concepts.

*“Over the years, we developed different organizational innovations and most of the times the hospital successfully changed itself to implement specific change processes”* (Operation manager director – Hospital 3)

Over time lean contributed to the development of multi-professional and multi-disciplinary team work which influenced the work culture. Health care professionals (also from different hospital areas) learnt how to coordinate their efforts and work together, and thereby collaboration, reciprocal support and trust were enhanced.

*“There is a lot of enthusiasm and most of clinicians, including the heads of units, are willing to participate to daily multi-disciplinary briefings”* (Surgical area nurse and annual lean contest winner – Hospital 2)

Professionals' positive attitudes towards the change - especially of those in managerial positions - influenced other colleagues' perceptions. A “no imposition” approach was followed with a strong focus on sharing and disseminating. Furthermore, surveys were conducted to assess the perceptions of those directly involved in improvement activities. The following table (Table 3) presents an overview of the main categories that relate to the social factors of the STS model.

Table 3 – Overview of categories related to the social sub-system

Deductive themes and sub-themes		Inductive categories
STRUCTURE	Strategic planning and control system	Embrace multiple goals in the lean transformation, i.e. improving staff well-being, patients' satisfaction, and internal processes.
		Integrate lean into the organizational strategic planning, e.g. into the annual budget.
	Organizational structure	Develop new (centralized and decentralized) organizational roles to support and facilitate lean efforts.
		Promote lean throughout the organization through multiple activities, e.g. information channels, lean contest.
PEOPLE	Human resources	Top management expertise, commitment, and involvement.
		Develop multi-level lean training.
		Experience intrinsic (e.g. gain empowerment and visibility, perceive a positive effect of lean on daily work) and extrinsic motivation (e.g. obtain a promotion)
		Use of internal human resources to run the change
	Support the development of bottom-up projects based on professionals' improvement ideas.	
	Working culture	Previous organizational experiences in change initiatives
Lean contributes to the development of multi-professional and multi-disciplinary team work.		

Technical factors

Technology

Tools

Several lean tools were routinely used in multiple hospital areas in all three hospitals. Visual management<sup>1</sup>, pull approach<sup>2</sup>, 5S<sup>3</sup>, and process analysis tools (mainly Value Stream Map<sup>4</sup>) were the most commonly used. A3 report<sup>5</sup> technique guided the development of each improvement project.

None of the three hospitals made significant investments in new technologies or IT solutions (e.g. almost all visual management systems were managed manually). In Hospital 1, the use of an *ad hoc* software was seen as a threat to building capacity to develop a critical understanding of the lean approach. Efforts were instead focused on the direct and active involvement of professionals in processes analysis and optimization.

*“To be optimized, processes require professionals working in teams rather than IT interventions; never automating a bad process: first, fix the process and then automate it”* (ICU head and change program coordinator – Hospital 1)

## Layout

In all cases, the ongoing application of lean techniques led to the repositioning of materials and equipment to support efficient processes.

Significant changes to the physical space were introduced to optimize and standardize flows. In Hospital 1, a recovery room was opened in the corridor next to the central operating room to improve its occupation rate. All hospitals physically separated the emergency and the elective surgical flows.

## Production processes

Lean programs supported a patient-centered and a process-based organizational model in all the cases. Hospital 2 started to re-organize its activities in the surgical area around homogeneous flows to overcome the barriers among hospital units and create multi-disciplinary and horizontal clinical settings (some projects were also launched in the medical area). Hospital 3 adopted a matrix organizational model with multidisciplinary care centers (cardio, neuro, ortho, and cancer) on one axis and production assets on the other axis to ensure the continuity of flows and processes (e.g. operating rooms, beds, technologies). In Hospital 1, since the very beginning, lean and the intensity of care model were parts of a single system-wide redesign project. Lean was considered suitable to support the transition towards a process-oriented organizational model.

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<sup>1</sup> Visual management approach uses visual tools to convey information on the state of the process clearly and concisely or to provide an immediate representation of the correct way to do something.

<sup>2</sup> The pull system requires that the previous process (upstream) produces a good or service only when the following process (downstream) demands it. Kanban and Just in Time tools are widely used to manage pull.

<sup>3</sup> The 5S process (Sort, Straighten, Shine, Standardize, Sustain) is about organizing the workplace in order to create a safe and clean environment where “everything has its place and everything is in its place”.

<sup>4</sup> Value stream mapping is a technique used to visualize the current state of the process, so that the team is able to see where the waste in the process is and define a future desired state.

<sup>5</sup> The A3 report is a tool that facilitates the activities of problem solving and decision-making as it implies a simple way of identifying, contextualizing, analyzing a problem and elaborating a corrective action plan.



*“Our patient-centered organizational model increases flows throughout the hospital and lean is the better approach to manage these flows and make the model works” (ICU head and change program coordinator – Hospital 1)*

In all cases lean was gradually combined with clinical pathways to streamline hospital primary care processes. Hospital 1 and Hospital 3 developed a comprehensive approach that merged the clinical (e.g. evidence-based clinical pathways) and the organizational dimensions (e.g. lead time) in the management of care processes.

*“Clinical pathways identify the patient flow from a clinical point of view, whereas lean practices contextualize clinical pathways into the specific organizational context” (Medical department head nurse and lean facilitator – Hospital 1)*

Even before the beginning of the lean change program, the Operations management unit in Hospital 3 had launched a systematic focus on the continuous redesign and optimization of clinical processes. Lean was considered the best approach to strengthen and integrate these ongoing change efforts.

The following table (Table 4) presents an overview of the main categories that relate to the technical factors of the STS model.

Table 4 – Overview of categories related to the technical sub-system

<b>Deductive themes and sub-themes</b>		<b>Inductive categories</b>
TECHNOLOGY	Tools	Extensive use of lean tools
		No investments for technologies or IT solutions to support the change
	Layout	Repositioning of hospital materials and equipment and reorganization of physical space to optimize patient flows
PRODUCTION PROCESSES	Clinical processes	Develop lean into a patient-centered hospital model

## External environment

At the beginning, external factors influenced the choice to implement lean. New regional normative that mandated the adoption of patient-centred organizational models (Hospital 1) and innovation to optimize the patient flows (Hospital 2) played a pivotal role in triggering lean implementation.

All hospitals were inspired by international cases that had previously adopted lean. At the same time, other national hospitals that had started to adopt lean were seen as competitors. This further accelerated and maintained the impetus for the change project.

*“We strive for being more efficient than other hospitals and, above all, the best lean practice in Italian health care”* (ICU head and change program coordinator - Hospital 1)

Once the change program started to be developed, all three hospitals exploited different opportunities arising from the external environment that fostered the continuous improvement and learning process. Hospital 2 and Hospital 3 were involved in national networks with the aim to exchange knowledge and experience about the improvement efforts. Networking was also used to spread and disseminate the lean culture in health care. Professionals in Hospital 2 started to offer their support and guidance to other hospitals interested in starting a lean journey. Hospital 2 took advantage of the external recognition for the achievements obtained; in fact, in its regional context, the legislator had continuously promoted and supported the spread of lean.

Table 5 presents an overview of the main categories that relate to the external environment component of the STS model.

Table 5 – Overview of categories related to the external environment

<b>Deductive themes and sub-themes</b>	<b>Inductive categories</b>
EXTERNAL ENVIRONMENT	Regional normative (H 1 and H2)
	Knowledge of international and national hospitals that had previously adopted lean triggered the lean initiatives
	Exploit opportunities that supported continual improvement and learning, e.g. networking among “lean hospitals” (H2 and H3)

## 7. Discussion

The analysis showed that several organizational and external factors played a relevant role in letting the change program be implemented. But no specific factor was sufficient by itself to explain the outcomes of the lean change programs. Through the adoption of a system integrated perspective, we found that the implementation of a system-wide lean intervention was fostered by interrelated changes across the STS framework’s dimensions adopted in this study.

## Lean needs to be absorbed into the organizational strategy

As stated in the literature, when lean implementation is clearly communicated as a long-term policy in the organizational strategic agenda, health care professionals are more willing to accept the re-organization and be involved (Al-Balushi et al., 2014). Our empirical data confirmed that the introduction and the maintenance of lean as a strategic pillar were essential to continually foster and address the hospital staff efforts towards the change. All three cases analyzed have, first, included, with the full commitment and approval of the top management, lean goals in the strategic planning process and, then, they have gradually declined lean related goals into the annual budget planning.

## Lean requires leaders

Literature claims that when lean is introduced as an organizational strategy, a proper leadership function need to be established at all levels of the organization to make the improvement efforts maintained (Waring and Bishop, 2010; Al-Balushi et al., 2014; Eriksson et al., 2016). In all the analyzed hospitals, the top management interest, engagement and support to the change program have always constituted an essential condition for continuously working on improvement and structuring lean into the organization. During the implementation process, the gap between the strategic and the operative levels within hospitals, that has been documented in the literature as a barrier when implementing models as decided on by the top management (Andreasson et al., 2016), was overcome by the introduction of central lean roles fully dedicated to lean. In fact, Hospital 1 opted for the appointment of a single lean coordinator, Hospital 2 opted for the construction of a lean office while Hospital 3 created a more agile lean team. Regardless of its form, the creation of an intermediate level between the top management and professionals ensured that the improvement efforts could be aligned and the impetus for the change sustained. At organizational unit and department levels, the creation of decentralized lean roles (fulfilled by clinicians, nurses and other health care professionals), together with the commitment of key actors (i.e. middle managers), contributed to make other hospital colleagues enrolled into lean thinking, so that a sustainable participation in lean could be obtained (Eriksson et al., 2016).

## Lean meant as a professional and a cultural approach

While the top-down dimension encompassed the input for launching the systematic change program and the continuous support to improvement efforts, the bottom-up flow of ideas was the core of lean implementation (Brandao de Souza and Pidd, 2011). Hospital professionals were responsible for carrying out the change in practice, in their daily work, working in multi-disciplinary and multi-professional teams to developing specific projects and spreading the new way of working throughout the hospital. This was coherent with the assumptions of lean as (i) a professional approach aiming at being integrated into the organizational working culture (Radnor et al., 2012) and (ii) an employee-driven system (Drotz and Poksinska, 2014). Furthermore, our empirical analysis indicated that the hospitals' preexisting experience in innovative managerial

initiatives, together with the leading roles' knowledge and skills in lean implementation, were both essential to sustain improvement efforts (Eriksson et al., 2016). A great emphasis was also placed on “soft drivers”, implying the primary role of motivation: various forms of moral rewards – i.e. gaining empowerment and visibility – made professionals feel their efforts were recognized and praised (Radnor et al., 2006).

## Lean implies a continuous learning process

As a cultural change, the ongoing implementation of lean required a continuous improvement and learning process to be carried out. The cultural change was reliant on the continuous education in the lean principles and methods within the organization (Fillingham, 2007; Al-Balushi et al., 2014). In all three hospitals, the pervasive multi-level training program became central to the hospital training activities and education efforts, enabling an extensive use of lean tools and techniques in everyday clinical practice. However, this continuous improvement and learning process was further enhanced by exchanging knowledge and experience on lean initiatives, or disseminating good practices, within networks of hospitals.

## Lean builds on a process-system view of the organization

In order to uncover all forms of waste and value, an end-to-end process view has to be undertaken and maintained (Fillingham, 2007; Brandao de Souza and Pidd, 2011). As lean health care principles aim to improve the complete care process, the hospital organizational model needs to be reshaped around patients' pathways and away from the traditional silo approach (Al-Balushi et al., 2014). All three hospitals invested a lot in innovating the organization of care delivery. Hospital 1 adopted the intensity care model (Villa et al., 2009), Hospital 2 introduced a patient-centered model for reorganizing patient flows at the wards (Lega and Calciolari, 2012; Gabutti et al., 2017) while Hospital 3 was widely recognized as process-based organization (Bohmer, 2005). Secondly in all three hospitals healthcare professionals have worked in multidisciplinary teams for the definition of integrated clinical pathways for several clinical conditions. In this perspective, lean has been perceived, by many clinicians, as a tool to facilitate the implementation of clinical pathways in the daily clinical operations.

## 8. Relevance and contribution to practice

The analysis of the three cases offers to managers and policy makers useful indications on the critical organizational variables that are relevant when implementing a hospital-wide lean implementation strategy:

- the stable guidance, sponsorship and support, at all organizational levels, with the top management launching and sustaining lean as a strategic pillar, and first-line managers influencing other colleagues to be involved;
- the introduction of a new role (i.e. lean roles), with the direct involvement of internal professionals, to lead improvement efforts towards the intended direction;
- the involvement of healthcare professionals in the overall lean implementation process with physicians and nurses, working on the shop floor, responsible to

- carry out specific lean projects within multidisciplinary teams;
- the process of continuous improvement and learning, that starts with the launch of the pervasive training program and is further sustained through external networking to disseminate knowledge and experience;
- the introduction of lean methodology in contexts where there is an ongoing process to overcome the vertical traditional organization with the introduction of integrated and multidisciplinary clinical pathways and the adoption of more patients-centered healthcare delivery models;
- the inclusion, in the strategic planning process, of lean goals that, subsequently, have been translated into measurable objectives comprised in the annual budget planning.

These findings clearly showed that, often, managers and policy makers, striving to understand which are the critical organizational conditions to implement lean, pose themselves the wrong questions likewise: (i) which is the best organizational structure to support lean strategy or (ii) what type of ICT investment is required to implement lean.

The successful cases analyzed in the present paper showed, first, that it does not exist a best one-fits-all organizational structure to support lean; in fact Hospital 1 opted for the appointment of a single lean coordinator, Hospital 2 opted for the construction of a lean office while Hospital 3 has created a more agile lean team. Secondly, none of the hospitals analyzed has judged ICT as a key driver in the lean implementation strategy.

As said, the secret for a successful lean implementation is the ability to integrate the different organizational and external described in the STS model. Some key findings described in the previous sessions support this thesis.

All three hospitals have invested a lot in strategies aiming to lead the organization of care towards more process-oriented models capable of overcoming the traditional vertical organization based on clinical specialties. These changes in the technical component have triggered in clinicians a different attitude and a new approach to the daily work (social element) that have eventually facilitated the lean implementation.

All the three hospitals have worked a lot in the area of clinical pathways (technical component) as a way to standardize the clinical decision-making process and the delivery process. In this sense, as illustrated also by some quotations reported in this paper, lean methodology has been considered as a very powerful and useful tool to make clinical pathways – designed on the paper – actually work in the real practice.

Another robust finding of the study is that it is important to align the hospital planning and control system (social element) with the lean management strategy; a current mistake in healthcare organizations is saying to aim for “A” while measuring and rewarding for “B”. All the three cases analyzed have actually behaved differently; they have, first, included, with the full commitment and approval of the top management, lean goals in the strategic planning process and, then, they have gradually declined lean related goals into the annual budget planning. The effort to include, in the budgeting process, not only efficiency/productivity goals but also quality and process performance indicators have facilitated a change in clinicians’ approach towards lean tools and methodologies (social component).

Finally, it is important to stress the different role played by the external environment in the three cases analyzed. For Hospital 2 the Region has played a significant and direct

role since it has set aside a specific budget to fund lean projects. In the case of Hospital 1 the link is not so direct but the Region has given mandate to the hospital to move towards a process-based and patients-centered organization and the CEO has chosen the lean approach to facilitate this change. For Hospital 3 (a private for-profit hospital) the adoption of lean has been an autonomy strategy to improve quality and efficiency for better dealing with the growing pressures posed by the external competitive forces (e.g. new players and merge and consolidation of other hospitals). Furthermore, all three hospitals started to share and disseminate knowledge and experience on lean implementation within networks of hospitals.

As represented in Figure 2, a key element in the lean strategy implementation is the interplay between the different technical, social and external components of the STS model. In all cases hospitals have done considerable efforts in redesigning the production processes through the introduction of clinical pathways and new process-based models of healthcare delivery (technical component - production processes). The ongoing application of lean techniques led to the revision of the space and equipment layout to support efficient processes (technical component – lay out). This circumstance has prompted a change in the cultural attitude and a more direct involvement of clinical professionals (social component – human resources). Furthermore, the lean model has been perceived by nurses and clinicians as a facilitating tool to realize the expected changes in the organization of production processes. The all change process has been sustained by consistent intervention in the organizational context (social component - human resources and strategic planning and control system) and it has been continuously sustained and supported by a strong and committed leadership. Finally, regional funding and mandate, together with networking and knowledge sharing, enhanced and strengthened the process of continuous improvement.

Figure 2. The relevant social, technical and external environment factors for system-wide lean implementation

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Insert Figure 2 about here  
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## 9. Relevance and contribution to theory

Our study confirms that the organizational and external context matters and may lead to more enhanced research on how lean is implemented and on its impact on health care organizations. In fact, we aimed at providing a snapshot of the dimensions that are relevant for effective and stable system-wide lean implementation in health care. Further research could address the influence of the dynamics of the implementation process on sustainability, investigating how these organizational dimensions behave and fit each other (Chamber et al., 2013). Future research could also explore the impact of the relevant dimensions on organizational performance, including the analysis of quantitative performance data.

In this study, we drew on the lean health care and system-organization literature to propose a theoretical framework that provides highly useful insights to researchers and practitioners to guide and deal with the implementation of holistic quality improvement interventions in health care; we believe this is true for two main reasons: (i) it recognizes the need to take a system-wide perspective to organizational change and (ii) it is useful to identify the relevant variables to be acted on when fostering improvement efforts within health care organizations. Thus, the framework could be used to prepare more in-depth research that investigate the implementation issues in more comprehensive ways.

In fact, in this study we did interview only people who were directly involved in the lean transformation management, reporting their perspectives and point of views on the lean change process; furthermore, we only focused on hospitals where organizational-wide improvement programs have been maintained over time. A suggestion for future research is to further test the framework by investigating other hospitals where system-wide lean implementations have not been sustained, also including professionals not actively involved in lean; in fact, comparing polar types – clearly successful hospitals and unsuccessful ones – could allow to capture the differences in the dynamics taking place and influencing the outcomes of lean interventions (Eisenhardt, 1989). Future research on lean in health care should also focus on hospitals, or other health care settings, from different national contexts, so that the conditions and constraints under which they are implementing lean could be addressed in a more rigorous way.

## Acknowledgements

The authors are grateful to the hospitals employees who participated with enthusiasm in the study. The authors also thank the participants, and especially the chair of the PhD session, of the annual European Health Management Association Conference (Milan, June 2017) for their invaluable comments on earlier draft of this paper. Finally, the authors would like to thank the editor and three anonymous referees for their valuable suggestions and comments.

The authors have no competing interests.

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