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Lean in Healthcare: a comprehensive review

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Lean in Healthcare: a comprehensive review

Abstract

Background: In the last fifteen years Lean has been increasingly adapted and adopted in healthcare. Accordingly, Lean healthcare has been developing into a major strand of research since the early 2000s. The aim of this study is to present a comprehensive overview of the main issues highlighted by research on implementation of Lean in a complex context such as the healthcare one.

Method: Comprehensive literature review was conducted in order to identify empirical and theoretical articles published up to September 2013. Thematic analysis was performed in order to extract and synthesis data.

Findings: 243 articles were selected for analysis. Lean is best understood as a means to increase productivity. Hospital is the more explored setting, with Emergency and Surgery as the pioneer departments. USA appear to be the leading country for number of applications. The theoretical works has been focused mainly on barriers, challenges and success factors. Sustainability, framework for measurement and critical appraisal remain underestimated themes. Evaluations of "system wide approach" are still low in number.

Conclusion: Even though Lean results appear to be promising, findings so far do not allow to draw a final word on its positive impacts or challenges when introduced in the healthcare sector. Scholars are called to explore further the potentiality and the weaknesses of Lean, above all as for the magnitude of investments required and for the engagement of the whole organization it represents increasingly strategic choice, whilst health professionals, managers and policy makers could and should learn from research how to play a pivotal role for a more effective implementation of lean in different health contexts.

Keywords: Lean; Lean Six Sigma; Lean thinking; healthcare; operational excellence; Continuous Quality Improvement; review

1. Introduction

The investigation of Lean healthcare has been developing into a major strand of research since the early 2000s (e.g., [1-3]), attracting many researchers worldwide. Accordingly, a growing number of books (e.g., [4,5]), well-known and oft-quoted papers (e.g., [2, 3, 6]) and grey literature (e.g., [7, 8]) have been disseminated, highlighting different cases, topics, methodologies, countries, etc.

Organizations in the United States, such as the Institute for Healthcare Improvement, and the United Kingdom, such as the NHS Confederation and the Institution for Innovation and Improvement, advocated the use of Lean in 2005, 2006 and 2007, respectively, as Lean had proved itself useful in other sectors and began to show promising results in healthcare [7]–[9]. These organizations recognized the contribution of Lean in both maximizing value and eliminating waste [7] and suggested it as a possible answer to the need for change perceived in the sector [9].

One of the first papers published about Lean in healthcare, the study by Young, T. P. et al. [2] addresses the use of industrial processes to improve patient care. Fundamentally, the authors describe three established industrial approaches, i.e., Lean thinking, the theory of constraints and Six Sigma, and explore how the concepts underlying each relate to healthcare. These authors conclude that the three methodologies have common features, as each emphasizes the concept of production as a complex interaction of individual activities, and each recognizes that for production to be efficient and effective, it is fundamental to identify weak links or bottlenecks and take appropriate remedial action. However, in order for them to work, all approaches would require strong leadership, the adoption of algorithmic methods to problem solving based on iterative improvement, and employee participation in all components of the system.

Widely cited is the study by Spear [3] published in the Harvard Business Review in 2005 in which the author discussed how health professionals could ensure that the quality of their service matched their knowledge and aspirations. Spear claims that learning how to improve the work one does while actually doing it can deliver extraordinary savings in lives and dollars. According to Spear, some hospitals are making enormous short-term improvements that are not based on legislation or market reconfiguration and with little or no capital investment. Instead of waiting for sweeping changes in market mechanisms, these institutions take an operations approach to patient care. Spear describes how doctors, nurses, technicians, and managers radically increase the effectiveness of patient care and dramatically lower its costs by applying the same capabilities in operations design and improvement as those that drive the famous Toyota Production System.

In 2006, Kim et al. [10] claimed that the readiness to act by hospitalists that use the new principles of Lean within hospitals can deliver high-quality and efficient care to patients. The authors also underlined the cultural and practical barriers to overcome to spread the use of Lean techniques. Among these barriers is the suspicion against management tools imported from a context other than healthcare, a misunderstanding of what Lean aims to achieve by cuts and layoffs, and the difficulty to act as a whole by units that are accustomed to functioning as autonomous "silos."

The flourishing [11] of this new area of study has also prompted the publication of several literature reviews. For example, de Souza [12] sought to illuminate general emerging trends in and approaches to Lean healthcare and evaluate the research status quo by proposing a taxonomy primarily based on differentiating between theoretical papers and case studies. Poksinska [13] provided a portrait of how Lean has been implemented in healthcare, simultaneously presenting barriers, challenges and outcomes. Mazzocato et al. [14] produced a "realist review" that

emphasizes the general mechanisms involved in the application of Lean. Conversely, Holden [15] crafted a critical review that deployed an analytical framework to focus on emergency care settings.

Other literature reviews ([15-16]) evaluate Lean applications in specific settings or compare various process improvement approaches, analyzing the academic, the practitioner and the grey literature. Radnor et al. [16] highlighted some critical features of Lean in the public sector that remain sparsely investigated (i.e., how it works, its outcomes, barriers to change, and success factors for sustainability), highlighting that Lean principles were adapted for its application. Boaden et al. [17] demonstrated an increasing emphasis on Lean in healthcare, with Lean sometimes being integrated within the Six Sigma framework. The report also indicates that there are some difficulties in identifying guidelines for the implementation of Lean and in identifying additional studies with findings that are more comparative, independent, or critical.

Although all the precedents reviews offers important insights on the topic, they are based on narrow research questions (e.g. [18], [19]) and inclusion criteria (e.g. [20–24]). Some of them need to be updated (e.g. [12,13]), as well. Consequently, the aim of the current paper is to present a comprehensive overview of Lean in healthcare as well as describing emerging important issues about its implementation. Accordingly, this work focuses on two main research questions: *which is the diffusion of Lean in healthcare, so far? which are areas in need of further research?*

The paper is organized as follows. The next section shows the methodological approach to the review; section three synthesizes the principal themes drawn from the body of research reviewed; and section four discusses the main issues to future research on Lean healthcare and challenges in its implementation.

2. Methods

A thematic analysis [25] was conducted to identify the main themes and concepts of the selected literature. The process followed the guidelines proposed by the Centre for Reviews and Dissemination [26], with some exceptions detailed in the following subparagraphs to take account of the variety of research approaches (quantitative or qualitative) and consequent methodologies as well as different traditions of research (social sciences and health sciences). The review protocol was designed around the intent to gain a wide comprehension of the phenomenon of Lean, where Lean has been applied in healthcare, in which countries and with which outcomes, and what issues are inherent to its implementation. The protocol includes sources of data, criteria for inclusion and the organization of the results.

2.1. Data sources, inclusion/exclusion criteria and data extraction

Papers published in peer-reviewed journals up to September 2013 were selected by exploring the Scopus and Pubmed databases, which are two platforms relevant to the social sciences (primarily the Scopus database), and the life and health sciences database (mainly the Pubmed database). Papers were searched in the databases by combining the following keywords: "Lean approach", "Lean process", "Lean methodology", "Lean method", "Lean transformation", "Lean philosophy", "Lean principles", "Lean practices", "Lean process improvement", "Lean management", "Lean healthcare", "Lean thinking", "Lean production", "Lean six sigma", "Toyota management system", "Kaizen", "Rapid improvement event", "Rapid improvement workshop", "health system", "hospital", "acute care", "primary care", "secondary care", "tertiary care", "rehabilitation", "home care", and "community care". Articles were included if they were published in the English language and contained the search terms in the title, abstract or keywords when available. Furthermore, they must be published in peer-review journals. Accordingly, books, reports, proceedings and grey literature were excluded. Journals should not be report, magazine or trade publications. The potentially relevant records were scrutinized independently by two of the authors to eliminate

duplicates, errors and to ensure the retention of peer-reviewed papers. The only exception was Spear's article [3], which was published in the *Harvard Business Review* in 2005. This paper is one of the first and most cited of all selected publications, and it was included because the journal is a widely respected resource in the academic and practitioner community. Additional papers were identified by reading the papers included in the review.

Next, according to the method chosen for the review -- the thematic analysis -- the papers were scrutinized to bring out the main concepts. To facilitate the full-text analysis process, each paper was examined using a data extraction sheet. The data extraction sheet contained the following items: title; author(s); year of publication and journal details; abstract; key words; type of paper (theoretical and empirical); significant details about each type of article (healthcare setting; outcome data; issues about lean implementation); reasons for exclusion from the review; and space for possible comments and notes. A paper was excluded if, contrary to indications in the title or the abstract, it did not address the topic. Furthermore, editorials and letters to the editor were excluded from the review along with papers aimed to educational use or facility management. Each author examined a group of papers, and two of them checked all of the data added in the sheets. Doubts regarding any features noted in the sheet were resolved by discussions among all the authors. A graphical word-processing and an electronic spreadsheet program were used to collect and analyze the data.

2.2. Cluster of works

Studies were clustered into two main groups depending on the type of paper: empirical or theoretical. The categories were borrowed from de Souza [12], who distinguished the Lean healthcare literature among theoretical and case studies, with the former based on methodological and speculative works and the latter on practice-based discussion. In this work, the empirical cluster included papers reporting documented data on the process of implementation and its outcomes, and the theoretical cluster included more conceptual reflections about specific issues related to Lean. Accordingly, in the first group, data were gathered with regard the effects of Lean on healthcare performance; cross-comparative analyses between organizations within a country or between different countries; types of clinical specialty, auxiliary services or support activities; joint or parallel implementation with other quality-improvement approaches and techniques; and the extent of the Lean implementation (if systematic – at an organizational or cross-organizational level – compared to a micro-context focus). For all empirical papers, the country of implementation was recorded. The second group (theoretical papers) focused on theoretical reflections on specific issues within Lean healthcare. Drawing on Radnor et al.'s report "Evaluation of the Lean approach to business management and its use in the public sector" [16], key areas were identified: barriers and challenges to Lean implementation; organizational readiness to implement Lean (i.e., the required state of an organization to introduce Lean) [16]; the implementation process itself; the factors of success; the outcomes of Lean; and discussions of Lean or related techniques, tools and approaches. Narrative reports regarding Lean projects lacking an in-depth explanation of the aim, context, rationale, methods and findings as well as papers with the first aim to explain Lean and spread its use were included in the theoretical group and referred to as speculative. Papers with empirical contents, but at the same time with a focus on frameworks, definitions and conceptual discussion were included in the theoretical cluster. The following table (Table 1) summarizes the organization of findings concerning key aspects from the empirical and theoretical papers, as they emerged at the end of the full-text review. The following section shows the main themes that stemmed from the literature.

Table 1

(about here)

3. Results

Following the method underlined in the previous section, 622 potentially relevant records were identified by searching in the databases. 40 papers were added subsequently after reading the full text of selected papers (e.g. reference lists of studies included). Next, by excluding some records, 306 articles were assessed for eligibility. Finally, by excluding some papers, 243 articles were included in the thematic analysis. Figure 1 shows the selection process of the studies [27].

Figure 1

(about here)

The findings were organized as follows: a) a cumulative frequency analysis of included papers intended to show the trend of publications since the first studies on Lean healthcare up to September 2013 (Figure 2); b) an analysis of the empirical and theoretical literature according to the dimensions depicted in the second stage.

Table 2

(about here)

Figure 2

(about here)

Beyond the possible “bandwagon effect,” this result most likely means that various journals (especially medical and nursing journals) show an increased interest in the Lean approach as a means of improving operational efficiency, the clinical outcomes of care processes and well-being at work, even though criticalities remain in its implementation

3.1. Empirical works

A total of 109 papers of the 243 were categorized as empirical and contained an in-depth description of Lean interventions and documented outcomes. Table 3 summarizes the primary results from the review in a data matrix. The papers were further grouped according to their discussion of Lean’s levels of care, joint implementation with other techniques, effect on performance and the activity involved. All of these features were also related to the country of implementation; the US had the highest number of interventions, likely because only English language literature was considered.

Table 3

(about here)

3.1.1. Whole or partial approach

Despite the rich literature, only a few papers addressed an entire organizational approach. Examples were identified in the Netherlands, Australia, the US and the UK, with the US accounting for the majority of the cases [20–26]. When Lean was implemented within a plan of actions aimed to improve the whole organization performance, the organizations appeared to become more

process-oriented, reduce costs and increase quality [23,25]. One major effect was that employees were stimulated to become change agents and work using a team-based approach [24, 26]. Important outcomes were also achieved in the areas of safety and the accessibility of care [29]. On a smaller scale, similar results were achieved with projects implemented in a single ward, in other specific units or addressing only one organizational process, even though these results does not allow to appreciate improvement of the overall organizational performance.

3.1.2. *Levels of care, countries and other improvement techniques*

With regard to the *level of care* and countries among the empirical papers, nearly all (more than 90%) were concerned with projects implemented in a hospital, with a few exceptions for primary care. Only eleven papers were grounded on cross-comparative analyses, four of which were between different countries [e.g. 27,28] and the others within the same country [e.g. 29–31]. The US and the UK saw the majority of interventions (33 and 18 cases, respectively), whereas in the rest of Europe, the Netherlands was second in the number of cases studied (eight papers) [25, 26, 30, 32–36]. Furthermore, projects were identified in Canada [36,37], Taiwan [47], and New Zealand [48].

In terms of the *joint implementation* of different *improvement techniques*, Lean and Six Sigma were the approaches most often combined, with advocates primarily in the US (e.g., [23,40,41]) and in the rest of Europe (i.e., Germany, Sweden, Italy and the Netherlands) (e.g., [32,42,43]), where particular attention was also paid to benchmarking, Queuing Theory and the Theory of Constraints (4 cases) [30,33,42, 44].

3.1.3. *Impacts on performance*

With reference to the *impacts on performance*, different documented outcomes were observed, both tangible and intangible, which demonstrated the positive influence of Lean on performance. In particular, positive outcomes were observed related to productivity, cost efficiency, clinical quality, patient and staff safety, patient and staff satisfaction, and financial result. A total of 167 findings were documented, and over 50% referred to increased productivity and cost efficiency. Broadly speaking, the results suggested a reduction in different categories of waste, one of the fundamental features of Lean. The other two principal outcomes were patient safety (18 cases) and financial outcomes (19 cases). Only a few papers [46–48] documented an increase in staff satisfaction, and only two papers demonstrated an improvement in staff safety [43-49]. No negative effects were reported, except for some cases in the emergency department (e.g. [58]).

3.1.4. *Core (clinical specialties and ancillary services) or support services*

Finally, in terms of which services applied Lean projects, the healthcare community, clinicians and especially nurses were particularly proactive in experimenting with Lean projects within the sector. Nearly all of the clinical specialties tried to implement Lean and analyze the corresponding results. Surgery (e.g., [22,32,50]) and emergency care (e.g., [6,32,51]) accounted for more than half of the included studies. Among ancillary services, hospital pharmacies and laboratories were the principal contexts for experimentation, followed by radiology (four cases). Only nine empirical papers showed that the application of Lean improved support activities such as information technology processes, meal delivery and supply chain management [20, 21, 40, 51–56].

3.2. *Theoretical papers*

A total of 134 of the 243 papers were considered theoretical according to the criteria highlighted in the previous section. Of these, 62 were classified as speculative, because narrative reports concerning Lean without a complete and well explanation of projects or intended to just disseminate the related concepts and ideas in different settings. Among the remaining papers, 13 were literature reviews. 63 articles addressed crucial elements of Lean, such as barriers and challenges, success factors, outcomes and conditions of organizational readiness. Only 8 theoretical studies were based on a cross-comparative analysis [9,56–62]. 26 papers concerned other specific features related to Lean implementation. Overall, three main themes were identified that can represent the field: (i) *Lean and the change process*, (ii) *Lean and other process improvement techniques* and (iii) *critical assessment*. Within the first group the following sub-themes, among others, were acknowledged: barriers and challenges, success factors, implementation process, sustainability and measurement framework. This section examines each perspective.

3.2.1. *Lean and the change process*

Barrier and challenges

Many included studies highlighted specific critical features that affect the Lean journey, i.e., barriers, challenges and success factors. The existence of barriers in the healthcare setting may explain the slower adoption of Lean in this context [75]; some obstacles would be evident in specific sectors of healthcare and must be appropriately managed, such as obstacles to mental health services [76]. Accordingly, there would be varied challenges that affect its successful implementation, such as the receptivity of staff, the complexity of the adoption process, the evidence of innovation sharing and the embedding of change [77] as well as high process variability, a lack of understanding of Lean, problems in defining waste [12] and a poorly defined focus [78]. Some of these challenges are triggered by a narrowly focused Lean approach that causes or shifts problems to other parts of the organization [13]. Sustaining momentum once the program begins and initial enthusiasm wanes would be critical [79]. A more significant issue is posed by the adaptation of Lean from the private to the public sector, requiring that specific managerial and organizational “breaches” be addressed [73]. Furthermore, a paradigm shift would be necessary in public services reform to establish Lean within a “public service-dominant business logic”, where the focus is the end-user, rather than internal efficiency [80]. Simultaneously, especially in hospital environments, key sources of tension must be resolved when implementing service improvements; i.e., as the NHS would show, tensions might arise between the need to demonstrate efficiency and achieve performance targets (derived from governmental financial pressure) and the need to invest time and resources in embedding a culture of continuous improvement [81].

Success factors

To address these barriers and challenges, the literature stresses a number of factors. Support from managers at each level would be required [13], and leadership should be secured [15]. However, scholars advocate framing Lean in a manner that creates an emotional connection between the program and the people by including central resourcing (also at a national level), senior executive- and board-level backing and support from external change agencies [77]. Significantly, creating cultural change, adapting Lean to the local context, learning from previous experiences [15], fostering a long-term view of continuous improvement [14], arranging high-impact training courses and providing rewards and incentives to achieve greater involvement at all levels [82] would be further key suggestions for Lean implementation. In addition, in several instances, it is possible to observe how the “industrial” concept of “Lean thinking” is applicable to a healthcare setting, thereby identifying key performance indicators that measure change toward the “conceptual framework” in this context. Hence, Lean thinking should be perceived as a component of “the

larger management shift to plan for changes in mindset and in the workplace” [83]. The quality of project definitions would be another critical success factor in pursuing improvements in healthcare delivery; project definitions should be related, for instance, to patient safety, patient satisfaction, and the business-economic performance of the hospital [84].

Strictly linked to success factors, *organizational readiness conditions* are prerequisites of the launch of the project and its subsequent implementation. For Lean to be successful, the following should be present: a clear definition of the quality targets, an increase in the availability of data, an understanding of customers and what they value, the knowledge of processes and stakeholder involvement before initiating the change [77]. Furthermore, key enablers of the implementation process are the presence of an information-led organizational design [72], the basic stability of the organization [85] and links between implementation attempts and an improvement strategy [71].

Implementation process

The implementation patterns highlighted in the literature include key steps such as conducting Lean training, initiating pilot projects and implementing changes [13]. A standard Lean transformation process should proceed through understanding the current state, defining the future state, implementing Lean and sustaining the implementation [87]. Essentially, one could distinguish the Lean implementation (as experimented by the NHS) as “tentative,” “productive ward only”, “few projects”, “program” or “systemic” [88]. To achieve Lean’s potential, a full implementation approach would be recommended [68]: “full implementation” - or systemic - would be an approach that embeds Lean in the organization's strategic vision for the long term; this model would prefer employee development, continuous process improvement and sustainability of change over short gain through cost savings. Accordingly, a learning environment should be developed for both staff and management to address the delivery of care, and Lean would be powerful to build such a context [85]. External pressure to improve the care process, the staff’s willingness to accept change, and changes in patient volume appear to influence which Lean tools are implemented and how changes are sustainable over time [86]. One fundamental lesson that should be learned is that Lean is a “translated” idea when adopted in contexts other than manufacturing [67]. Furthermore, when implementing Lean, an awareness of the dynamic association of actors would be critical to the design of the process if the intervention is challenged [76,77]. Further, the processes and outcomes of Lean would depend not only on the technology itself but also on the negotiation context in which the planning and implementation of the Lean project occur, especially when the context is the public sector. Consequently, Lean is not a neutral and value-free activity, but it is fluid and open to multiple interpretations, interests and logics [70]. Many outcomes of the implementation process have been reported in the literature [14]. Briefly, Lean has been shown to affect patient care indirectly and employees both directly and indirectly, improving or worsening care processes and patient outcomes [15]. Attention should be paid to leadership and management tasks in leading the process of change (e.g. [83, 84]).

Sustainability

Another critical theme mentioned by nearly all studies but explicitly addressed only in a few is the *sustainability* of improvements over the long term. Generally, there is a lack of evidence of sustained results, i.e. improvements that maintain the achieved level over the time [22]. Linking together approach, readiness and sustainability, a healthcare organization might progress towards a 'generative' state, one in which it promotes an organization wide, self-sustaining approach, with improvement as a continuous condition [71].

Measurement framework

The literature reports attempts to elaborate upon the *measurement frameworks* to assess the implementation of Lean. The implementation scheme may concern the approach or the definition of Lean itself and permits an evaluation of where shortcomings exist. In the first case, organizations may evaluate their implementation process as ‘tentative,’ ‘productive ward only,’ ‘few projects,’ ‘program’ or ‘systemic’ and track the Lean journey over time, monitoring changes from one approach to another [88]. In the second case, one should consider Lean as an attitude of continuous improvement that creates value, organizations clarify priorities and guide staff accordingly, enhances respect for the people who do the work, is ‘visual’ and creates flexible regimentation [74]. The distance from these poles can measure the gap toward a ‘full’ Lean implementation. When adopting Lean thinking principles, it is important to design a measurement system that reflects the initiatives taken and also reflects the efficiency and effectiveness of healthcare performance. A comparison shows [83] that the flow model, which is a rather simple process model that measures time parameters, is an appropriate model for indicating changes toward Lean thinking, although the flow model must be balanced by other measurements to provide a complete picture of Lean performance (e.g., patient satisfaction, referral management, process mapping and fulfillment of targets and policies).

3.2.2. *Lean and other process improvement techniques*

Other papers address using Lean in combination with other techniques and provide a deeper understanding of some of the tools of interest, implying that some techniques may work better than others in specific healthcare organizations [93]. More broadly, some authors suggest that interest should be focused on bringing Lean and Six Sigma together, giving rise to the Lean Six Sigma approach [94]. In addition, when Lean and Six Sigma are blended, it appears that statistical tools are used less often than they are in other contexts [95]. In this respect, some works demonstrate the benefit of using the Healthcare Lean Six Sigma System model, combining the two approaches. This combination would fill the service gap between healthcare providers and patients, balance the requirements of healthcare managers, and deliver healthcare services to patients by combining the benefits of Lean’s speed and Six Sigma’s high-quality principles [96]. Notably, Aleem’s paper [97] focuses on primary care and the existing challenge to providing high-value care along with improved consistency and reduced waste to reap financial benefits in increasingly popular patient-centered medical homes and in an Accountable Care Organization model of care. Aleem observes that the transfer of various quality-improvement techniques such as Lean Six Sigma from the manufacturing industry to a service industry such as healthcare would provide an opportunity for healthcare organizational systems and practices to objectively improve the value of the care they provide.

3.2.3. *Critical assessment*

Finally, in terms of *critical assessment*, there was a claim of methodological development stemming from a problematic definition of an important driver of Lean implementation, i.e., the understanding of customer value in healthcare [98]. Although different areas of improvement, such as time savings and the timeliness of service, cost reduction or productivity enhancement, the reduction in errors or mistakes, staff and patient satisfaction, mortality, and intermediate outputs (i.e., reduction of steps in a process), were observed [14], some papers also confirm a gap in the literature, which offers evidence of the poor quality in reporting the outcomes of business-process improvement methodologies, thus stipulating more rigorous studies to spread evidence-based management practices (e.g. [84,86–88]).

Furthermore, there is some discussion regarding the risks of an uncritical adoption of Lean thinking into work-design processes in hospitals, whose effect would be the creation of a

fundamental tension between the production of healthcare and the protection of the patient [99]. Besides, Lean should not be regarded as a cornerstone of NHS policy without a deeper preliminary understanding of how to balance utilization and waste when matching demand with the capacity of healthcare services [100].

4. Discussion

Drawing upon the themes underlined in the previous sections, this section highlights the main challenges and issues about Lean in healthcare, identifies possible future strands of research and notes the limitations of the current review.

First of all, it appears in literature to exist a lack of uniformity in the theoretical conceptualization of Lean. By reviewing the literature, it seems that everything may be Lean; on the contrary, a common definition should be established to distinguish what Lean is and what Lean is not to properly analyze future projects and to strengthen both research and practice. Other terms for Lean used in the healthcare sector, such as "The Henry Ford Production System" [101], the "ThedaCare Improvement System" [102], and the "Virginia Mason Production System" [103] for health system and "The productive ward" and "The productive operating theatre" [104] for specific programs, while anchored to Lean principles, might be confusing as well.

The term Lean, first introduced in 1988 by Krafcik [105] to explain the Japanese system of success, was later spread by Womak, Jones and Ross in their leading book *The Machine that changed the world* [106] and by Womak and Jones through *Lean thinking: banish waste and create wealth in your corporation* [107]. Lean is currently understood [108] as a combination of basic principles (specify value; identify the value stream; avoid interruption in value flow; let customers pull value; start pursuing perfection again) and other principles such as committed management, respect for people and the involvement of supply chain management. At a more abstract level, Lean could be conceptualized as "an operation strategy that prioritizes flow efficiency over resource efficiency" [109].

Accordingly, a critical issue that emerged by reviewing the literature is the prevailing focus on single processes, units or departments as well as specific principles or tools of Lean. To the contrary, Lean should be viewed and applied as a strategy to reach a holistic transformation and 360° efficiency (e.g. [110]). Despite the usefulness of an in-depth comprehension of specific aspects of the phenomenon, this state of art impedes the generalizations of the results that have emerged so far. Indeed, the inability to evaluate more cases of the system-wide implementation of Lean in healthcare settings with a great deal of experience allows only quasi-anecdotal appreciations of Lean's goals and results. However, it should be recognized that Lean is a dynamic state [109] characterized by a continuous improvement approach, and an a priori rejection of earlier or narrower experiences might lead researchers and practitioners to lose useful insights. Creating a shared framework or protocol for research would be rather important for the development of the field, with a primary focus on clarifying what is being investigated in accordance with the concept of "Lean healthcare". According to the authors of the paper, this is especially important to allow future systematic and sound evaluations of the evidence about Lean programs. This lack of a definition is reflected in the quality of the reported evidence. Indeed, several authors call for a better assessment of Lean's outcomes (e.g., [14, 87–89]). For Lean to obtain the commitment of healthcare professionals beyond a "bandwagon effect," its effects must be shown by improved studies in terms of its design, analysis of results and, in particular, assessments of clinical outcomes and other overlooked benefits (i.e., financial results and staff and patient satisfaction and safety).

Furthermore, the analysis of the benefits and the criticality of a joint implementation with other techniques remain undervalued. In this work, the most important and cited process improvement techniques for evaluating public services [111] were searched when proposed in combination or the

concurrent implementation of Lean, including Six Sigma, benchmarking, business re-engineering, Total Quality Management and the European Foundation Quality Model. To date, it has not been determined whether Lean has been implemented because of a new "bandwagon effect" or because of a disappointment with the previous process improvement techniques. Consequently, before rejecting other approaches, more in-depth research is needed about the relationships among the different techniques in the healthcare setting. In the reviewed literature, it seems that the most often experimented way is the Lean Six Sigma (e.g., [113]), in which it is shown that a joint implementation could overcome each system's respective points of weakness [82-104]. It would be useful to deepen the intrinsic nature of Lean Six Sigma in relation to both Lean and Six Sigma and analyze the appropriate ways to integrate them.

Drawing upon "empirical cluster" papers in particular, it can be stated that more healthcare settings require investigation. The acute level of care is the most investigated, but more analyses are required for home care and community and primary points of care as well as throughout the healthcare supply chain. Furthermore, there exist few cross-comparative and multi-site analyses. New cases – especially concerning different countries – would allow for an appreciation of the extent of the phenomenon and, simultaneously, a better evaluation of the possible cultural influences on the choice to adopt and adapt Lean. A promising subfield of research may be the analysis of the similarities and differences between the implementation of Lean in private healthcare organizations and in the public sector. As Radnor and Osborne state, the "genealogy for Lean raises [...] important challenges for its implementation in public services" [80]; therefore, it would be worthwhile to better understand the way to overcome these challenges and the specific features of the implementation of Lean in the private compared to in the public sector.

The implementation process itself and sustainability remain key and underinvestigated issues. With reference to the first issue, as suggested by Hoss and ten Caten, it would be interesting to know more about the influence of roles, rules and values as well as how Lean practices are structured by social actors [114]. For sustainability, more longitudinal studies regarding new or well-known programs would be useful (e.g., [58]), especially those characterized by a holistic approach.

Despite the many recognized and well-proven benefits of Lean, a few papers are critical of using Lean in healthcare or of the manner in which Lean is used. In fact, we know more regarding the drivers of success than the causes of failure. Indeed, many scholars assert that the literature is specifically built on positive cases (e.g., [15]). In reality, a few cases in the literature reviewed showed impacts other than positive [58]. On the contrary, it would be important to learn from unsuccessful projects and, generally, to apply a more critical view to evaluate Lean in healthcare.

Eventually, the cost effectiveness of Lean interventions must be shown. An evaluation framework for measuring Lean healthcare performance should be developed to compare the amount of resources invested (often described as null) and financial and non-financial benefits that result from its the implementation.

The current study has various limitations. Despite the different degrees of methodological rigor among the studies reviewed, the papers were intentionally not assessed for their quality. The aim of the authors was to avoid excluding papers for which not relevant mistakes could have affected the overall quality of the articles despite their important findings [115]. Indeed, with reference to the general scope and related research questions for the current review, a conventional method of systematic review could not have allowed the authors to catch all of the significant issues related to the implementation of complex quality improvement programs [116]. The exclusion of papers for their low quality could have resulted in ruling out themes that are potentially good and relevant. On the contrary, a low threshold might be set to "maximize the inclusion and contribution of a wide range of papers at the level of concepts" [117]. Furthermore, the study characteristics (principally the study design) varied significantly according to different traditions of research, namely, the life and health sciences compared to social sciences, with the latter having a different tradition of evidence-based research (e.g., in the management literature [118]). Hence, the exclusion of some of

the papers by using assessment criteria that are fairly general for all papers but do not fit the purpose with reference to a specific group could have affected the completeness of the review. Nevertheless, we mitigated this criterion by acknowledging the existence of a specific category (conceptual/speculative) in which we grouped papers with a low quality of reporting about any aspect of the research (i.e. its aim, context, rationale, methods and findings) and/or with a principal aim to explain Lean and spread its use in healthcare. These criteria allowed the authors to extract meaningful concepts from this group of papers.

Another limitation of the study is that it examines only English-language studies, although relevant insights may stem from papers published in languages other than English. In addition, there may be influential books by scholars or practitioners that may provide a sound understanding of the phenomenon but that did not meet the inclusion. Finally, although a careful search approach was deployed, some papers from journals not indexed in the searched databases may have been overlooked.

5. Conclusion

Lean is an improvement approach increasingly applied in the healthcare field. Healthcare professionals and managers in many countries are experimenting with Lean tools and techniques to improve efficiency, clinical outcomes, satisfaction and safety for both staff and patients and ultimately to enhance financial performance and sustainability. In the USA, Lean experiences seemed to have significantly increased over time, and the UK government has primarily chosen Lean as a means to reform its public sector [80]. Tough, despite the interesting results, only few organizations appear to have attempted to implement a system-wide approach. Furthermore, notwithstanding the great number of publications in peer-reviewed journals, the research and implementation in the field appears to be at an early stage of development if a system wide view of Lean is to be acknowledged.

Therefore, even if we now know much more regarding Lean in healthcare than we did at the beginning of this century - particularly regarding its underlying principles and tools, enablers, barriers and outcomes, as described in the previous sections - there is nevertheless much to learn regarding some under-investigated or overlooked issues. Particularly, the following could be some directions for future investigations:

- a) a common definition should be established to distinguish what is Lean and what is not in order to properly analyze future attempts to introduce Lean in healthcare and to strengthen the literature;
- b) the analysis of benefits and challenges or drawbacks of a joint implementation with other techniques remain undervalued; it would be useful to analyze future trends utilizing blended approaches such as Lean Six Sigma;
- c) to obtain the commitment and engagement of healthcare professionals beyond a “bandwagon effect” Lean impacts and consequences must be the focus of more robust studies in terms of design, methods and analysis of findings. In particular, specific attention should also be paid to the assessments of clinical outcomes and other overlooked benefits (i.e., financial results and staff and patient satisfaction and safety);
- d) more settings require investigation. The acute level of care is the most investigated. Further research is required for Lean introduction in home care and community and primary care contexts as well as throughout the whole healthcare supply chain.

- e) there are few cross-comparative and multi-site analyses. New cases – especially concerning different countries – would allow an appreciation of the extent of the phenomenon and, simultaneously, a better evaluation of possible cultural influences on the choice to adopt and adapt Lean.
- f) the implementation process and sustainability remain key issues. More longitudinal studies regarding new or well-known programs would be useful, especially those characterized by a systematic approach.
- g) the literature is specifically built on cases of success. Many scholars advocate learning from both positive and negative cases; generally, it is important to apply a more critical view to evaluate Lean in healthcare.
- h) the cost-effectiveness of Lean interventions must be addressed. An evaluation framework for measuring Lean healthcare performance must be developed.

These unexplored issues imply it is difficult to draw a last word or unquestionable implications. Nevertheless, some preliminary insights emerge. First, findings show that Lean, no matter if implemented with a 'system wide approach' or not, would ensure a range of benefits. When managers are committed and secure leadership and enhance organizational readiness conditions, changes towards a 'leaner healthcare organization' would be more likely. Furthermore, in sector as complex as the healthcare one, policy makers should play a pivotal role in allowing a more precise implementations of this strategy, through the adoption of guidelines and frameworks that help professionals to be more comfortable with 'industrial' process improvement techniques. Also, other policy-making implications stem from this review. They have no claim to be exhaustive, still provide some interesting directions for future policies, such as:

- provide stronger incentives to spread Lean initiatives outside the hospital setting. Assuming the scarcity of research so far conducted in settings different than hospital it's an index of the relative low development of Lean projects in community and other healthcare settings. Therefore, much more can be done to spread the Lean approach toward those contexts;
- given the magnitude of the phenomenon, an higher priority in terms of funding could be allocated to research project that address issues connected with Lean introduction in healthcare, further with the aim of making easier cross-national learning and dissemination of findings;
- competences and skills on Lean health could be introduced - obviously with different intensity - in executive management training initiatives dedicated to health professionals, in study curricula of doctors and nurses, in training schemes for health organizations administrators and managers.

Finally, as experiences such as the NHS one highlight, to introduce Lean in national plans for development and improvement and sustain it with central sourcing could be an advisable (or necessary) - even though not sufficient - condition to foster the use the spread of the Lean approach. Certainly, to avoid just a 'bandwagon effect', evidence to advocate for national plans should be based on evaluation of 'system wide approach' cases, in which Lean is implemented as an overall organizational strategy, rather than a means to reach short gains in limited areas. Especially this last issue should receive more attention from the academic community in the near future.

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Tables

Table 1 – Organizations of findings from analysis

Empirical applications papers	Theoretical papers
Whole or partial approach Levels of care, countries and other improvement techniques Impacts on performance Core or support services	Lean and the change process Lean and other process improvement techniques Critical assessment

Table 2 – Accumulated frequency analysis of the papers included in the review

Year	Frequency	Accumulated Frequency
2003	1	1
2004	3	4
2005	6	10
2006	11	21
2007	13	34
2008	15	49
2009	32	81
2010	36	117
2011	39	156
2012	51	207
2013	36	243
Total	243	

Figures

Figure 1 – Selection process of studies - Source: Adapted from Moher et al. [19]

(see attached file)

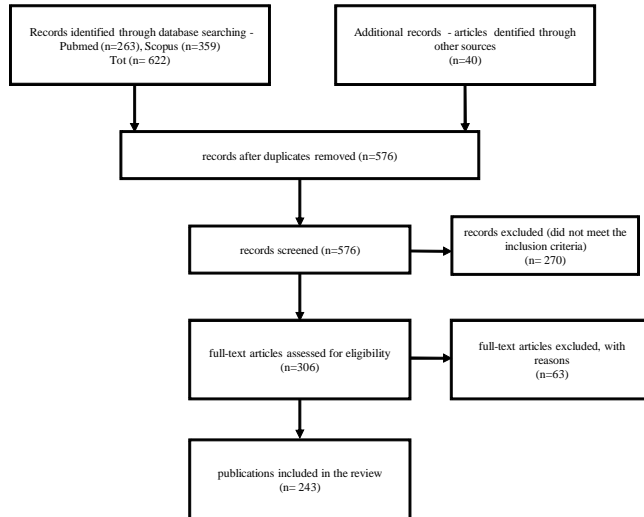


Figure 2 – Accumulated frequency analysis of the papers included in the review

(see attached file)

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Table 3 – Data matrix analysis of empirical papers

<i>Focus/Countries</i>		<i>Rest of the World (or not well-specified Country)</i>	<i>Rest of Europe</i>	<i>Australia</i>	<i>USA</i>	<i>UK</i>	<i>Total</i>
Levels of care	Secondary and Tertiary point of care	10	25	6	54	13	106
	Disease Prevention and Control and other settings	1			1		2
	Home, community and Primary point of care				3	3	6
	Subtotal	11	25	6	58	16	116
Cross Comparative Analysis	Within Countries		2		5		7
	Between Countries	1	3	1	3	2	10
	Subtotal	1	5	1	8	2	17
Lean and other technique	Six Sigma	2	7		12	1	22
	Other process improvement techniques , theory or approaches	1	4	1	2	1	9
	Subtotal	3	11	1	14	2	31
Documented impacts on performance	Productivity and Cost efficiency	9	17	5	50	13	94
	Clinical quality		4	1	6	3	14
	Patient Safety	2	2	1	12	1	18
	Staff Safety		1			1	2
	Staff Satisfaction			2	1		3
	Patient Satisfaction	1	2	4	8	2	17
	Financial outcomes	1	5		13		19
Subtotal	13	31	13	90	20	167	
Approach	Several projects or Systemic implementation		2	2	9	2	15
Basic medical or surgical	Surgery	1	8	1	7	5	22
	Emergency	4	3	3	5	2	17
	Other specialties	1	5	1	16	4	27

	<i>Subtotal</i>	6	16	5	28	11	66
Ancillary services	Hospital Pharmacy	1	1		5		7
	Laboratory (Pathology)	1	2		7		10
	Other AS	1			5	3	9
	<i>Subtotal</i>	3	3	0	17	4	26
Support activities	Support activities	1		1	7		9

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Lean in Healthcare: a comprehensive review

Highlights

- We aim to provide a comprehensive review of Lean in Healthcare.
- Notwithstanding the growing body of knowledge some issues remain underexplored.
- We investigate the existing literature in order to underline the main themes and settings of implementation .
- Lean is an improvement approach increasingly applied in healthcare.
- Nevertheless, the research in the field appears to be at an early stage of development and a more system wide approach in implementation is needed.

