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Il "Lean thinking" in ambito ospedaliero - Risultati di una revisione sistematica di letteratura

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Parole chiave: *Metodo Lean, Assistenza sanitaria, Valore.*
Riassunto:
Obiettivi: L'obiettivo principale di questo lavoro è stato esaminare le esperienze applicative della metodologia Lean e valutarne l'impatto in termini di: tempo di processi, produttività, effetti sul personale sanitario e sull'esperienza/soddisfazione dei pazienti.
Metodi. Per la revisione sistematica della letteratura sono stati consultati tre database (PubMed, Scopus e CINAHL) al fine di identificare studi che valutassero l'implementazione della metodologia Lean in ambito ospedaliero. La selezione degli studi è stata effettuata da due ricercatori senior e i dati sono stati estratti secondo il PRISMA statement.
Risultati. Su 635 articoli identificati, 27 sono stati inclusi nella revisione. La maggior parte degli studi ha mostrato esiti positivi relativi all'implementazione della metodologia e degli strumenti Lean.

Lean thinking in the hospital setting - Results of a systematic review of literature

Key words: Lean, Healthcare, Value.
Summary: Aim: The aim of this study was to review experiences of use of the Lean methodology in the hospital setting and assess the impact of the interventions in terms of time of processes, productivity, effects on staff and patientd satisfaction. Methods: PubMed, Scopus and CINAHL databases were searched to identify studies evaluating the lean methodology. Two reviewers screened the citations identified and extracted data according to the PRISMA methodology. Results: In total, 635 citations were identified, of which 27 were included in the present review. Most studies showed a positive outcome related to the implementation of the Lean methodology and tools.

Introduction

Lean Thinking is a methodology originated from the Toyota Production Systems (TPS), attributed to Taiichi Ohno, father of the Lean manufacturing (1912-1990) [(1)]. Lean production is a business model and collection of tactical methods aimed to produce a high-level output whilst minimizing the use of resources and activities which do not add value (waste), delivering quality products on time at least cost with greater efficiency. According to Lean Thinking, production process should be treated in a comprehensive way to reduce the complexity of production, focusing on

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its flexibility involving all business functions [1].

Lean methodology is aimed to redefine the production process through different principles: accurately defining the value of each product from the perspective of the customer; analyzing the various steps of the process in order to eliminate the ones which do not add value; minimizing the time between those value-adding steps; repeating the cycle until waste has been eliminated. The goal of Lean thinking, in summary, is to make the best use of the lowest amount of resources to create just what is needed in just the required time, just where it is needed and just when it is needed. For the past years, the Lean approach has been adapted to be suitable for different sectors and expanded by a wide range of industries and institutions, among which healthcare providers. In healthcare, the Lean methodology has been focused on patient-centered care, aimed to provide higher quality and safety services to patients. The evidence supporting the Lean approach in healthcare is rapidly expanding in current economic situation, where increasing costs and long waiting lists have made necessary to implement an innovative approach to simplify processes, increase efficiency and generate quality improvement. The implementation of the Lean principles in healthcare has become popular in the USA, which seems to be the leading country along with England, Australia and Nordic countries, since the early 1960s. In recent years, publications about Lean application have been increasing and disseminated [2].

The areas of greater Lean implementation in health include the functions oriented to the process, in which the most important goal is to save time and queuing [3]. Several studies [4–8] showed that Lean implementation in health results in important outcomes, some of which are directly measurable as reduced time for the execution of specific processes with the same volumes of activity, cost reduction, increased productivity, decreased mortality rate; other outcomes are more qualitative, such as a reduced probability of making mistakes, an improvement in the organizational structure, an increase in patient satisfaction. As an example, King et al. explained this concept, since the application of Lean Thinking in the emergency department can help to address the patient flow and thereby decrease the potential for overcrowding and blocking access [9]. Moreover, Holden examined the Lean implementation in fifteen Emergency Departments in the United States, Australia and Canada, reporting both positive and negative effects on patient care [10]. The aim of this project was to conduct a review of the applicative experiences of Lean methodology and assess their impact in terms of production capacity, time, staff productivity and patient satisfaction.

Methods

A systematic review has been carried out according to PRISMA methodology for meta-analyses and systematic reviews [11].

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1.1 Search strategy and study selection

A search protocol on study describing or evaluating Lean implementation was developed, and a literature search was conducted using Pubmed, Scopus, and CINAHL databases; grey literature was analyzed through Google and the websites of Health Ministries or National Institutes.

The search strategy was based on the combination of the following keywords:

("lean thinking" OR "lean healthcare" OR "lean methodology" OR "lean implementation" OR "lean management" OR "lean principles" OR "lean model" OR (lean AND ("Models, Organizational"[MESH] OR "Organizational Innovation"[MESH] OR "hospital restructuring"[MESH] OR "organizational model" OR "organizational models" OR "hospital organization" OR "hospital reorganization" OR "hospital redesign" OR "patient focused hospital" OR "patient centered hospital"))). Our search was restricted to studies in English and Italian published from 1st January 2000 to 31st December 2016. Studies were considered eligible if they investigated active experiences where an effective implementation of the Lean methodology was conducted, regardless of settings, health operators, patients and families involved in the process. Studies not reporting original data as well as editorials, comments, letters, methodological studies or studies not focusing exclusively on the impact of Lean methodology were excluded. Two reviewers independently screened titles and identified abstracts of relevant titles. Full texts of potential citations were subsequently obtained and independently screened by the two reviewers for inclusion. Disagreements were resolved through discussion.

1.2 Quality assessment

A critical appraisal checklist (the Newcastle-Ottawa Scale) [12] was used to assess the methodological quality of included studies, using a 'star system', where high quality papers were identified with a 'star'. Each study was evaluated on the basis of three categories: "Selection", "Comparability" and "Exposure" (for case-control studies) and "Outcome" (for cohort studies). One star was given for each item, with a maximum score of 4 stars for the "Selection" category, 3 stars for the "Exposure/Outcome" categories and 1 star for the "Comparability" category. Two reviewers assessed quality of the included studies independently and disagreements were resolved through discussion.

1.3 Data extraction

From each study data about first author's last name, year of publication, study period, country, study design, study aims, setting and evaluated outcome were extracted. Evaluated outcomes were subsequently classified according to four macro-dimensions related to time of processes,

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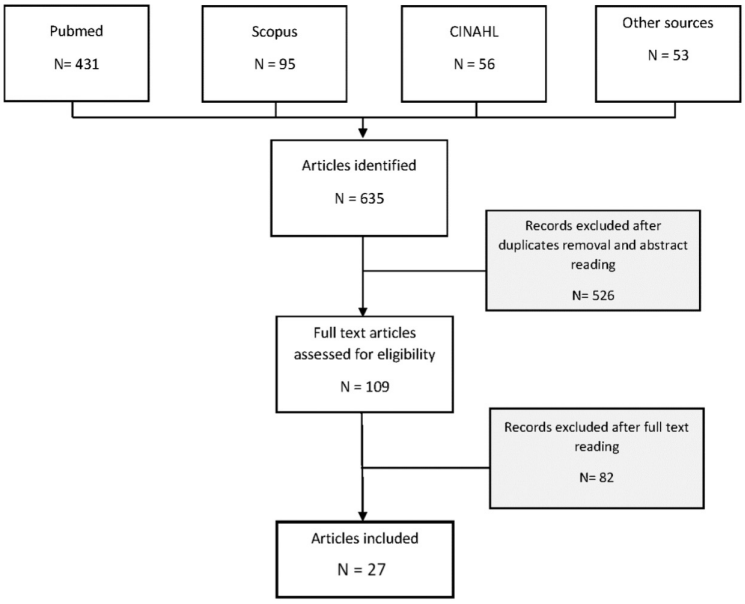
productivity, effects on staff and patients' satisfaction/experience. Two reviewers conducted all data extraction independently and disagreements were resolved through discussion.

Results

We identified 635 articles through PubMed, Scopus and CINHAL online databases and 53 additional records through other sources in grey literature. After removing duplicate records, 223 studies were left, of which 109 full text articles were selected after screening by abstract. Among them, 78 articles were excluded after full-text reading because they did not meet the inclusion criteria and 4 because full text was not available. Twenty-seven studies were left for final analysis (Figure 1). A summary of selected studies is reported in Table 1. The publication years of the included studies ranged from 2007 to 2016 [13–39].

Figure 1. *Literature search and study selection process*



Most of the included studies 41% (n=11) of our review were carried out in Europe [13–23]; 37%

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Table 1. *Summary of selected studies and quality assessment*

Summary of the results of the review

Article	First author and year	Country	Study design	Setting	Objectives	Methods and instruments	Main results	Quality
Improving emergency department efficiency by patient streaming to outcomes-based teams	Kelly et al., 2007	Australia	Pre-post	Hospital, Emergency Department	To improve admitted and discharged patients flow. To improve emergency department (ED) efficiency.	Processes redesign and implementation; patients streaming. Results evaluation. Staff satisfaction survey.	Increasing in proportion of discharged patients. Improvement in bed requests within 4 hours of presentation. Episodes of ambulance bypasses decreased. Reduction in waiting time. Increase in total ED time for triage category 3 (median increase 7 min) and a decrease for categories 4 and 5 (median reduction 14 and 18 min, respectively).	Selection* Comparability* Outcome*
Improving the efficiency of a chemotherapy day unit: Applying a business approach to oncology	van Lent et al.,2008	Netherlands	Pre-post	hospital-based chemotherapy day unit	To improve the efficiency of a hospital-based chemotherapy day unit (CDU).	Business approach structured into a Plan-Do-Check-Act phases.	24% growth of treatments and bed utilization. 12–14% increase of staff productivity and 81% overtime reduction.	Selection *** Comparability * Outcome *
Use of lean in the emergency department a case series of 4 hospitals.	Dickson et al., 2009	USA	Pre-post	2 community hospitals	To reduce the global patient length of stay. To dicrease numbers of patients who left ED without being seen by a physician. Rise in patients satisfaction.	Observation and thorough documentation of the existing process. Value analysis and process redesign. Testing ideas generated by frontline workers. .	Reduced length of stay in 3 of the EDs despite an increase in patient volume in all 4. Increased patient satisfaction. Immediate results greater in the EDs in which the frontline workers were actively involved.	Selection*** Comparability* Outcome**

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Lean thinking: can it improve the outcome of fracture neck of femur patients in a district general hospital?	Yousri et al., 2010	UK	Pre-post test	Hospital	To evaluate the impact of Lean thinking on the outcome of fracture neck of femur patients.	Split of patients into two groups before and after applying the Lean thinking model. Set of a value-stream model (Lean thinking) to improve the outcome of fracture neck of femur patients. Mapping patients' journey from admission to discharge to plan smoothening the 'patients' flow'.	Statistically significant reduction of the overall mortality from 20.7% (pre-Lean) to 11.4% (post-Lean). Statistically significant reduction of 30-days overall mortality from 11.7% (pre-Lean) to 6.7% (post-Lean). "Not statistically significant" outcomes: • Door-to-theatre time • Admission to a trauma ward • Length of hospital stay.	Selection**** Comparability* Outcome**
Exploring the relation between process design and efficiency in high-volume cataract pathways from a lean thinking perspective	Van Vliet et al., 2011	UK, USA and Netherlands	Retrospective comparative study	Three eye hospitals in the UK, the USA and the Netherlands (1207 patients)	To compare process designs of three high-volume cataract pathways in a lean thinking framework. To explore the relation between efficiency, in terms of lead times, hospital visits and costs, and process design.	International retrospective comparative benchmark study with a mixed-method design. Comparison of cataract's pathways of three eye hospitals. Data analysis of all patients who underwent first eye cataract surgery in 2006.	Reduced wastes. Reduced number of hospital visits and costs. Short lead times associated with the use of a general outpatient clinic and a high-volume cataract surgery clinic.	Selection**** Comparability* Outcome**
Thinking lean: implementing DMAIC methods to improve efficiency within a cystic fibrosis clinic.	Smith et al., 2011	USA	Case study	Cystic Fibrosis Clinic	To assess the effectiveness of Lean methods in creating efficiencies when applied to a cystic fibrosis (CF) clinic.	Data collection through the use of single automated time stamp, after a specific staff training. Data collection for 171 visits, and development of a	Completion of 41.5% of patient visits in 60 min or less, 23% greater than the baseline capability. Reduced mean and median visit times by 10 min per visit.	Selection** Comparability* Outcome*

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						baseline capability analysis. Collection of a second set of measures to determine the visits length.	Increased research efforts by 500 patient visits per year, representing additional revenue of over US$165,000 annually with no additional administrative costs incurred.	
Application of Lean principles to improve early cardiac care in the emergency department.	Piggott et al., 2011	Canada	Pre-post test	Hospital, Emergency Department	To evaluate the specific outcomes of the process Lean in the Emergency Department, particularly the outcomes of the clinical management of suspected acute coronary syndrome (ACS).	Processes re-design: "ACS Patient Flow from Presentation to ECG Interpreted" "Lead Time from Triage to Treatment for ACS Patients" "Sustainment: Triage to First MD Assessment" Summary and re-analysis of performance data on a monthly basis.	Statistically significant increase of proportion of physician assessments completed within 60 minutes by 12.1% (35.1% to 47.3 %,). No change in the rapidity of ASA administration found. Statistically significant and continued improvement over time, with increasing proportions of ECG times ≤ 10 minutes, MD-A times ≤ 60 minutes, and ASA administration within 3 hours. Post-Lean average delay from ECG performance to physician interpretation (ECG-I) of only 5 minutes (median 3 minutes).	Selection**** Comparability* Outcome**
Lean processes for optimizing OR capacity utilization prospective analysis before and after implementation of value stream mapping.	Schwarz et al., 2011	Luxembour g	Pre -post	Hospital, Operating Room (OR)	To increase the number of operations. To reduce patient throughput time. To increase capacities to optimize patient monitoring, improving safety and quality, and additional operations. To increase patients satisfaction.	Value stream analysis and design (value stream mapping, VSM). Switch from a Push system to a Pull system.	Decrease in waiting time per patient in total of 23%.	Selection**** Comparability* Outcome**
Applying Lean Implementation of a		USA	re/Post	Hospital,	To evaluate a Rapid Triage and Treatment (RTT)	Application of Lean principles.	Reduced mean ED length of stay after RTT from 4.2 hours (95% CI = 4.2-4.3;	Selection*** Comparability* Outcome*

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Rapid Triage and Treatment System.	Murrell et al., 2011			Emergency Department (ED)	system to decrease waiting time.	Visit and treatment of low-acuity patients by a physician in the triage area. No changes in staffing, physical space or hospital resources during the study period.	SD = 3.9) to 3.6 hours (95% CI = 3.6-3.7; SD =3.7). Reduced mean ED arrival to physician start time after RTT from 62.2 minutes (95% CI = 61.5-63.0; SD = 58.9) to 41.9 minutes (95% CI = 41.5-42.4; SD = 30.9). Reduced leaving the ED without being seen by a doctor (LWBS) rate after RTT from 4.5% (95% CI = 3.1-5.5) to 1.5% (95% CI = 0.6-1.8).	
Nursing works: the application of lean thinking to nursing processes.	O'Neill et al.,2011	Australia	Cohort study	Teaching general hospital	To make nurses focusing on adding value to the patient journey. To move from reactive work processes.	Processes re-design. Evaluation by direct observation and recording of nurses activities taking greater than 15 seconds in duration. Data collection describing the primary nursing processes that were undertaken, why they were required, how long they took to complete, and where they occurred. Mapping and tracking nursing activities and issues across the day.	Increased time spent by nurses in delivering direct patient care from 35% (2.8 hours) to up to 60% (4.8 hours) of shift time (8 hours). More than 80% of care planned and delivered appropriately to patients. Reduced length of medications rounds by 50% (from 120 to 64 minutes) with interruptions decreased from the average of 15 to 20 to less than 2 per round. Reduced time spent in communicating information by 40% (from 15 hours of total nursing time across 3 shifts to 7.5 hours).	Selection*** Comparability* Outcome**
The Lean method as a clinical pathway facilitator in patients with lung cancer.	Aasebø et al.,2012	Norway	Pre/Post	University Hospital	To improve quality and shorten the workup time for patients with lung cancer.	Introduction of diagnostic packet pathway for Lung Cancer. Definition of a set of indicators and their evaluation after the process implementation.	Reduced workup time for the diagnostic packet path from a median of 64 days to 16 days. Reduced median time from chest X-ray to CT scan from 10 to 5.5 days. CT scan performed within 24 h for 33% of the patients Reduced median time from diagnosis to surgery from 26.5 to 15 days.	Selection**** Comparability* Outcome***
Efficacy and efficiency of a lean cataract pathway: a comparative study	van Vliet et al., 2010	Europe	Cohort study	Eye Hospital, cataract surgery clinic	To analyse the efficacy and efficiency of a lean Cataract pathway.	Comparison of Lean care delivered to a prospective cohort with traditional care delivered to a historical cohort and with expected lean care in the	Reduced patient visits by 23% and increased access to the cataract pathway with 42% in the lean pathway Estimated reduction of patient visits by 40% and increase of access to the cataract pathway with a 76%, if healthcare staff	

						prospective cohort. Evaluation of efficacy (how many patients received care that adhered to the lean pathway's specifications). Evaluation of Efficiency (how often patients visited the hospital and how many additional patients could access the pathway).	would have adhered to the lean pathway's specifications.	
Lean thinking transformation of the unsedated upper gastrointestinal endoscopy pathway improves efficiency and is associated with high levels of patient satisfaction.	Hydes et al.,2012	UK	pre-/post-test	Hospital endoscopy unit	To redesign the patient pathway for unsedated UGI endoscopy using lean thinking transformation; to demonstrate the efficiency and quality of the redesigned service. To develop a pathway template transferrable to other healthcare environments; to demonstrate if it fulfilled patient's expectations after its implementation.	Literature search of patient expectations for UGI endoscopy. Creation of a value stream map of the current pathway. Service transformation using lean thinking. Creation and implementation of a patient pathway template into a secondary unit. Assessment of patient satisfaction through questionnaire studies.	Reduced patient pathway steps from 19 to 11 and maximum lead-time from 375 to 80 min following lean thinking transformation. Increased minimum value/lead time ratio from 24% to 49%. Minimised patient and staff travelling distances, waiting times, paperwork and handoffs. Reduced nursing staff requirements by 25%. Increased patient-endoscopist interaction time. Successful introduction of the template into a second unit with an overall positive patient satisfaction rating of 95%.	Selection*** Comparability* Outcome**
How does lean work in emergency care? A case study of a lean-inspired intervention at the Astrid Lindgren Children's hospital, Stockholm, Sweden.	Mazzocato et al.,2012	Sweden	Case study	Hospital, Pediatric Emergency Department	To improve care processes (i.e. increase patient value and decrease waste) and working conditions across Karolinska University Hospital	Collection of Hospital's weekly averages data of: a) the proportion of patients leaving the A&E within 4 hours; b) the waiting time from triage to first A&E physician consultation; c) the patient volume Collection of data on the intervention planning phase. Institution of improvement team meetings.	Increased percentage of patients completing their visit and leaving the A&E within four hours from 67% pre-lean [95% CI 65,5-69,7] to 80% in the first year post-lean [95% CI 78,2-82,4]. Decreased average time to first physician consultation from 67 minutes pre-lean [95% CI 61,7-71,5] to 51 minutes in the first year post-lean [95% CI 46,5-56,3] and to 54 minutes in the second year post-lean [95% CI 49,4 - 59,2].	Selection** Comparability* Outcome*

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							Increased patient volume from 24,4 [95% CI 23,1 -25,5] visits per day (between 08.00 and 16.00) to 26,5 [95% CI 25-27,9] in the second year post-lean.	
One-stop cholecystectomy clinic: an application of lean thinking–can it improve the outcomes?	Siddique et al., 2012	UK	Post-test Cohort study	Hospital, surgery department	To reduce the number of patient hospital visits, preoperative admissions and the waiting time to surgery.	Comparative cohort study based on the type of clinic attended (onestop clinic or the routine care).	Number of hospital visits and preoperative admissions much lower amongst patients who attended one-stop clinics. Length of waiting time to surgery significantly shorter in one-stop clinic patients as compared to the routine care.	Selection**** Comparability* Outcome***
The Positive Impact of Simultaneous Implementation of the BD FocalPoint GS Imaging System and Lean Principles on the Operation of Gynecologic Cytology	Wong et al., 2012	USA(Connecticut)	Pre-/post-test	Cytology laboratory	To determine the combined impact of the Focal Point Guided Screener (GS) Imaging System (BD Diagnostics–TriPath) and lean manufacturing principles on the turnaround time (TAT) and productivity of the gynecologic cytology operation.	Definition of a baseline measure of the TAT for Papanicolaou tests; pre-post comparison after implementing the Focal Point GS Imaging System and lean principles (including value-stream mapping, workflow modification, first in–first out policy).	Statistically significant improvement (27%) in the average TAT after the implementation of Focal Point GS Imaging System and lean principles. Improved productivity of staff (17%). Decreased false-negative fraction, from 1.4% to 0.9%, with a 36% improvement.	Selection**** Comparability* Outcome**
Lean principles optimize on-time vascular surgery operating room starts and decrease resident work hours	Warner et al., 2013	USA (New Hampshire)	Cohort study	Hospital, Vascular surgery unit	To facilitate the identification of inefficiencies and waste in preoperative process. To make rapid, high-yield modifications to process with real-time monitoring to create sustainable change.	Use of standard process improvement techniques (DMAIC methodology: define, measure, analyze, improve, control) to identify causes of delayed vascular surgery first case starts. Creation of value stream-maps and process flow diagrams. Analysis of process data with Pareto and control charts. Definition and analysis of outcomes measure.	Identification and change of resident rounding process inefficiencies. Implementation of process with statistically significant improvement of first case on-time starts at 6 weeks. Reduced resident rounding time by 33% (from 70 to 47 minutes).	Selection**** Comparability* Outcome**

						Comparison of data with existing benchmarks.		
Antecedents and Characteristics of LeanThinking Implementation in a Swedish Hospital: A Case Study	Ulhassan et al.,2013	Sweden	Pre-/post-test	Inpatients cardiology ward; ED Cardiology.	To illuminate how a department with a long quality improvement history arrived at the decision to introduce Lean and how Lean influenced employees' daily work.	Mapping of the existing care process. Use of a strategy to reduce the ED visit time, including, among other factors, that patients should meet an experienced physician earlier in the process. Training of all staff members on the ward in Lean concepts and tools. Redesign process with the staff as an active part.	Increased proportion of patients discharged within 4 hours (from 74% in 2008 to 83% in 2009 and 84% in 2010), despite an increasing volume of patients. Reduced average length of stay per patient in the cardiac ED (from 206 minutes in 2008 to 155 minutes in 2009 and 129 minutes in 2010). Reversed trend by 2011, as a consequence of patient volume increased even further.	Selection** Comparability* Outcome*
Lean techniques for the improvement of patients' flow in emergency department.	Chan et al.,2014	Hong Kong, China	Pre/post	Hospital, Emergency Department	To evaluate the current patient flow in emergency department. To identify and eliminate the non-value added process. To modify the existing process.	Performing of a preliminary assessment. Drawing of a process flow chart and a value-stream map to better analyze ongoing processes. Implementation of lean management works to improve services.	Significantly decreased triage waiting time and end waiting time for consultation by lean methodology application. Significantly decreased admission waiting time of emergency medical ward (EMW) from 54.76 minutes to 24.45 minutes after implementation of PAT program ($p < 0.05$).	Selection*** Comparability* Outcome
Application of Lean Six Sigma methodology to reduce the cycle time of out-patient department service in a rural hospital.	Bath et al, 2014	India	Pre-/post	Rural hospital	To reduce the average waiting time of patient.	Use of Six Sigma methodology, through the DMAIC approach with the use of statistical tools. Data collection through a detailed plan. Use of Lean methodology to locate the air of waste within the process.	Reduced average cycle time to 1.5 minutes from 4.27 minutes (65% improvement). Reduced average waiting time in system of 97% (from 32 minutes to 1 minute).	Selection*** Comparability* Outcome*
Evaluation of an Emergency Department Lean Process Improvement Program to Reduce Length of Stay	Vermeulen et al.,2014	Canada (Ontario)	Pre/post Retrospective cohort study	Ontario's Hospitals, Emergency Department	To determine the effect of a Lean Process Improvement Program on ED	Use of a lean improvement approach modeled on pilot programs in several Ontario hospitals.	Partially reduced ED length of stay after the Lean Process Improvement Program implementation.	Selection**** Comparability* Outcome***

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					waiting times and quality of care.	Identification of improvement opportunities in patient flow from arrival in the ED to discharge from inpatient units by dedicated hospital improvement teams composed of senior leaders, managers, and staff from a variety of departments within participating hospitals. Training and mentoring of improvement teams at each hospital by an external lean coach.	Partially decreased time to physician assessment.	
Improving Emergency Department Door to Doctor Time and Process Reliability: A Successful Implementation of Lean Methodology.	El Sayed et al.,2015	USA	Pre-/post Cohort study	Hospital, Emergency Department	To determine the effectiveness of using lean management methodology on improving door to doctor times at a tertiary care hospital.	Process mapping of the patient journey from arrival to being assessed. Application of improvement interventions based on the lean methodology to reduce delays in waiting times and more specifically door to doctor time.	Statistically significant decreased mean door to doctor time measure (40.0 minutes ± 53.44 vs 25.3 minutes ± 15.93; p <0.001). Reduced mean ED length of stay of both admitted and discharged patients (from 2.6 to 2.0 hours and 9.0 to 5.5 hours, respectively). Not statistically significant change in left without being seen rate.	Selection* Comparability* Outcome*
Ontario's emergency department process improvement program: the experience of implementation.	Rotteau et al.,2015	Canada	Cohort study	Hospital, Emergency Department	To describe the hospital-based teams' experiences during the ED process improvement program implementation. To assess the team's perceptions of the key factors that influenced the program's success or failure.	Performing of semi-structured interviews with hospital implementation team members (team leads, medical leads, and executive sponsors) at 10 purposively selected hospitals in Ontario.	Identification of four major themes as significantly affecting the implementation experience: local contextual factors, relationship between improvement team and support players, staff engagement, and success and sustainability.	Selection**** Comparability* Outcome
Effective management of patients with acute ischemic stroke based	Liang et al., 2016	China	Pre/Post	Hospital, Departments of Emergency,	To hasten the initiation of thrombolysis by	Organizing of a multidisciplinary team (Stroke Team)	Statistically significant decreased door-to-needle time (DNT) from 90 to 47 min (p < 0.001).	Selection**** Comparability* Outcome**

on lean production on thrombolytic flow optimization.				Neurology, Neurosurgery, Pharmacy, Laboratory and Radiology	pathways re-organisation.	to implement an ongoing, continuous loop of lean production. Evaluating the efficiency of flow optimization.	Statistically significant increased percentage of patients treated between 60 min after hospital arrival from 38.46% to 75.0 % ($p = 0.015$). Optimization on delay of tissue plasminogen activator (tPA) administration ($p < 0.001$). Statistically significant likelihood for patients to have a good prognosis (modified Rankin Scale_mRS ≤ 2 at 90 days) after the flow optimization (30.77–75.00 %, $p = 0.012$).	
Elimination of waste: creation of a successful Lean colonoscopy program at an academic medical center.	Damle et al.,2016	USA	Pre/post test	Hospital, Endoscopy Unit	To determine the feasibility and effectiveness of applying Lean principles to an Academic Medical Center colonoscopy Unit.	Improving the Lean process by training endoscopy personnel, observing patients, mapping the value stream, analyzing patient flow, designing and implementing new processes, and finally re-observing the process.	Statistically significant decreased mean colonoscopy time by 10 % to 121 min ($p = 0.01$). Decreased time to achieve adequate sedation, time to recovery, and time to discharge from 3.7 to 2.4 min ($p < 0.01$), 4.0 to 3.4 min ($p = 0.09$), and 41.2 to 35.4 min ($p = 0.05$), respectively. Increased overall unit capacity of colonoscopies from 39.6 per day to 43.6.	Selection*** Comparability* Outcome***
Using Lean Thinking at an Otorhinolaryngology Outpatient Clinic to Improve Quality of Care.	Van Leijen-Zeelenberg JE et al., 2016	Netherlands	Pre/Post	ORL clinic with an Academic and Regional function.	To evaluate improvements made by implementing Lean. To determine the effects on patient satisfaction, employee satisfaction, the amount of waste, and organizational culture.	Creating of a value stream map. Performing of semi-structured interviews and identification of waste also with the support of a Lean board.	Improvements of 36 inefficiency issues, not all concerning a specific type of waste. Not significant change in patient satisfaction (which was high both at baseline and follow-up). Improvements in transportation, motion, and waiting mentioned by employees. Slight effects on provider satisfaction; significantly decreased satisfaction with autonomy and participation; significantly increased satisfaction with communication.	Selection**** Comparability* Outcome**
Lean Principles in an Operating Room Environment.	Alves et al., 2016	Portugal	Pre/Post	Hospital	To implement the essential measures to improve the	Using of observation, interviews, document and video analysis as instruments to identify the wastes.	Development of an efficient work mode. Reduced material stocks (between 20% and 50%) with a reduced time spent by	Selection**** Comparability* Outcome**

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	operational efficiency. To increase staff motivation by improvement opportunities. To reach the full satisfaction of the clients' needs.	Value stream mapping (VSM) to map all activities involved in the OR and diagnose them. Summarizing of wastes and their sub-causes into a cause-effect diagram. Taking implementations according with 5S lean methodology.	nurses and assistants in the operating process of the order of the material (80%) and in the replacement of the material in warehouses (60%).

VSM: value stream mapping; SMED: single minute exchange of die; DMAIC: define, measure, analyse, improve, control; DNT: door to needle time; LWBS: left without being seen; PDCA: plan do check act.

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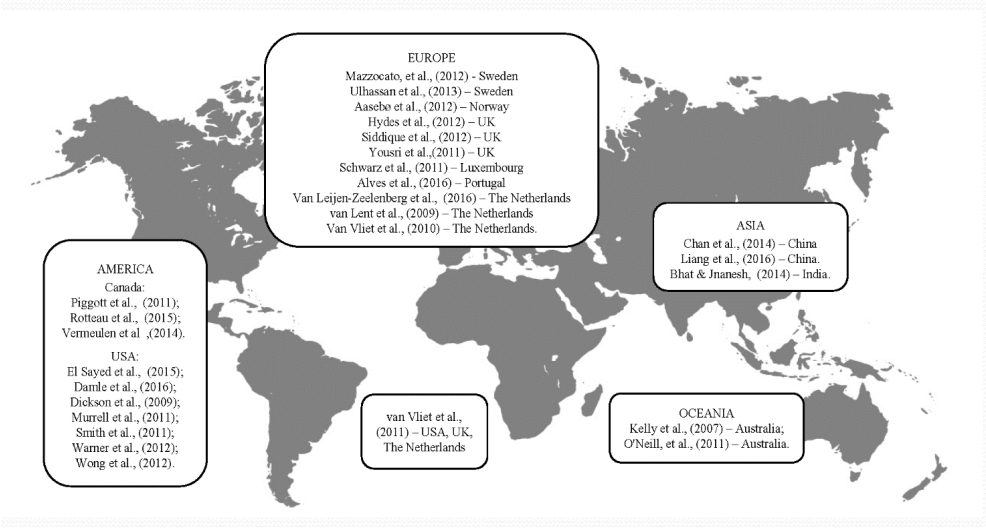
(n=10) were conducted in North America (7 in USA and 3 in Canada) [24–33], 11% (n=3) were carried out in Asia [34–36], 7% (n=2) in Oceania [37,38]; only 4% (1 study) was conducted in more than one country (UK, USA and The Netherlands) [39] (Figure 2). As for study design, 59% (n=16) of the included studies were based on a pre-post study design without a control group; 30% (n=8) were cohort studies while the remaining 3 studies were individually a case study, a case series and an action research.

Figure 2. Retrieved articles listed by country



1.4 *Quality assessment*

The overall quality of the analyzed studies was good for selection of the study groups and description of outcome or exposure. The median value for category "Selection" was 3,2 (maximum score in "stars" was 4), while the median value for category "Outcome" was 1,8 (maximum score in "stars" was 3). All the studies scored the maximum value (one star) for "Comparability" category (Table 1).

1.5 *Evaluated outcomes*

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All the selected studies described the aim to achieve improvement in healthcare delivery by applying Lean methodology tools; different outcomes were set and pursued. In order to describe the impact of Lean methodology on the analyzed setting, outcomes were divided into four categories and the results of the different studies included in the review linked accordingly to them:

- Time of processes;
- Productivity;
- Effects on staff;
- Patients' satisfaction/experience.

1.5.1 *Time of processes*

Sixteen studies (59%) analyzed the effects of Lean methodology on time processes [13, 17, 19, 23–25, 27, 29–31, 33–37, 39]. In 8 studies processes were redesigned to obtain a reduction in time wasting activities and a faster pathway of care in different clinical and operative areas [17,19,23,25,29,30,34,39]. Eight studies were set in emergency settings [13,24,27,31,33,35–37]; in six of them, the main aim was to reduce triage and intervention time, medical visits and discharge time within an Emergency Department [13,24,27,31,35,36]; ambulance bypass waiting time and number of patients who left the Department of Emergency without treatment were analyzed in the other two studies [33,37]. In three studies the described Lean methodology aimed to reduce required time for diagnostic procedures [25], time wasting activities, with consequent optimization of operating room utilization capacity, and nonvalue-added activities [19,29]. In addition, 11 studies showed that process redesign was found to be effective in improving the diagnostic-clinical pathway for patients, with time reduction from admission to the execution of diagnostic exam and faster access to the enunciation of the diagnosis [14–16, 21–23, 28–30, 34, 36]. Reduction of inpatient waiting time was settled as outcome in 4 studies: one analyzed reduction in order time and improvement in on-time delivery to customer [34]; 3 studies also described experiences in which the main goal was to achieve reduction in hospital visits and preoperative hospitalization time [17, 23, 39].

1.5.2 *Productivity*

Lean methodology showed: to be effective in the operating room management promoting better strategies for storage within the warehouse and reduction in inventories and time to process orders [20]; to have a positive impact on the capacity use of operating room with and allowed a larger number of operations to be performed [19]. Lean management was also shown to have an effect on surgical patients pathways, allowing a reduction in waiting time for surgery and preoperative hospitalization as well as, consequently, an increase in surgical volumes within the health facility [17, 39].

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1.5.3 *Effects on staff*

Lean implementation in personnel activity led to reallocation of staff, creating new operational standards with leadership supervision, determining an increase in employees' satisfaction [26, 33, 37]. This positively affected patient satisfaction [13, 26]. As for staff, the reorganization of the material and patient flow within a clinical pathway took place by inviting the current staff to increase efficiency by adopting simplified and standardized procedures [19,23,33], despite the staff resistance to change at the beginning of the optimization process [20,34]. Only one study [12] described as outcome the reduction in nursing personnel by 25% [16]. Staff satisfaction after process redesign led to improvement in communication and increased staff productivity [21, 22, 30]. According to O'Neil et al., Lean implementation led to improvement in the nursing work, increasing time for assistance, with a standardized work planning, and through efficient management of time for the preparation and administration of drugs [38]; Van Leijen-Zeelenberg et al. found a decrease in autonomy [21], while Kelly et al. did not find any significant difference in employee satisfaction after Lean implementation [37].

1.5.4 *Patient satisfaction/experience*

Some positive results were described about patient satisfaction [16, 25, 26]. Four studies focusing on patient satisfaction as an implementation area for Lean methodology [16, 21, 22, 25]. Three studies focused on clinical outcomes: Yousri and colleagues showed a statistically significant reduction, after Lean implementation, in overall-mortality and 30-day mortality for fracture neck of femur patients in a district general hospital [18], as well as a higher probability for patients to have a good prognosis [33,36].

Discussion

The results of this systematic review shows that experiences aiming to improve health services through a lean-thinking methodology could effectively reach this goal in many different areas of healthcare management: restructuring healthcare processes and reducing their time, developing more value-added time activities, promoting a patient-centered approach, adding value to the products or services provided and increasing staff and patients' satisfaction. This work highlighted that the application of Lean methodology, even if it takes place on individual basis from the facility taking care of clinical pathways and not within a Lean-management department, can result in a significant increase in efficiency.

The application of Lean methodology in the hospital setting is driven by the need to reduce waste and improve quality process through a proper management of patients and materials flow

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[1, 2]. As stated by Cendan & Good, assessment based on workflow allows to processes redesign to produce greater efficiency [40]. The work process rationalization allows greater system capacity and control and makes the staff more efficient and satisfied [38]. Indeed, positive outcomes have a direct correlation with clear decisional rules to reduce the gap between expected and effective service provision [21, 23, 32]. In this sense, both patient and staff satisfaction were shown to be a key element for the redesign of working paths and procedures. Several studies showed that reorganization could be successful with both use of personnel and resource materials through reallocation and creation of new working standards [26, 31, 32]. The reorganization of processes can lead to a clearer and simpler organization and consequently to an improvement in risk management [19]. The first principle of Lean is identifying the value for clients, in this case the patient [1, 2]. Few studies evaluated directly patients' satisfaction, though this represents a major asset in driving processes implementation since Lean methodology in health aims to identify and remove waste in order to create value for patients [16, 21, 25, 26].

Among other clinical outcomes, such as mortality, only one study [18] showed a statistically significant result after Lean Thinking based processes reorganization. This does not necessarily represent a negative result, as Lean methodology focuses on influencing processes and the flow of patients or materials, and its effects can be studied mainly over a long-term perspective.

The context of the implementation seems to play a key role for this approach to be successful; establishing strong relationships with clear communication strategies, preparing the staff for the implementation and assessing sustainability before the start, setting the focus on positive results that could be obtained thanks to Lean implementation have been described be seen as primary elements in process management [32]. Three key factors seem to contribute to success of Lean implementation: the first one is staff training, which helps to develop a critical perspective for the identification of waste and the reorganization of work processes [26] with the guidance and support of experts in Lean management. The second factor is to foster enthusiasm for change in the healthcare setting. A top-down approach to change without a thorough understanding of the working processes and staff time management creates an environment in which there is a tendency to resist to change because that could be seen as an imposed choice [26]. A passionate and motivated staff will be more likely to spend time for the scheduled activities and contribute to the improvement of working processes [41]. The studies focusing on employees satisfaction showed an overall positive effect of Lean implementation on personnel activity [17,19–21,26], with only one study not reporting any difference after Lean implementation [14]. Eventually, the third fundamental factor for success is leadership, which needs to be present at both the upper levels of the organizational hierarchy and at lower levels in clinical pathways, providing additional support to staff [8, 42].

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The strength of this systematic review consists in giving an international overview of the Lean implementation in the last two decades, in order to analyze the state of the art of Lean thinking in healthcare setting to promote supplementary comprehension and support the results of other recent studies on this matter. The selected studies allowed us to investigate the outcomes and the objectives according to the four set dimensions, and to evaluate the impact of Lean implementation on health organizations. The main limit of this systematic review is the analysis of studies on several ongoing experiences, not presenting the results of implementation. Another limitation is the lack of detailed description of the situation before implementation, the intervention that was effectuated and the situation after intervention. Moreover, it is well noticed that Lean implementation is well diffused inside of clinical pathways, while its application to the operating units or entire sanitary structures still represents a minority. Finally, all the majority of the studies presented positive outcomes related to the implementation of the Lean tools and methodology, but in some cases, it is unclear whether this change comes as a result of the implementation of Lean tools or as a result of previous improvements made [14,27].

Conclusion

In literature there is a wide and varied consensus about the adaptability of Lean methodology to health services reorganization and its utility in the patient care pathway, as Lean tools led to processes redesign and decisive improvement in clinical activities, patient and staff satisfaction/experience, and in some cases even in financial results. The success of the Lean methodology implementation depends on the level of adherence to its principles, considering the individual experiences in different settings, as each one requires a different approach to implementation [26]. Furthermore, Lean framework should also be considered as an educational tool for staff and leaders because it introduces themes of discipline and responsibility, since all professionals in the healthcare setting are motivated within an organizational strategy to improve performance. Lean methodology seems one of the most appropriate strategies to face and resolve critical situations in healthcare settings, mentioning also the influence of numerous external and internal variables that modify the outcome. For that reason, in the future a more rigorous research is required to definitively ascertain the impact and effectiveness of Lean in healthcare.

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