Can lean reduce infections? A systematic review and meta-analysis of prospective studies

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Abstract

Background: Lean is largely applied to the health sector and on the healthcare-associated infections (HAI). The latter are a plague for our society. However, a few results on the improvement of the outcome have been reported in literature. The purpose of this study is to analyze if the lean application can reduce the healthcare-associated infections rate.

Methods: A comprehensive search was performed on PubMed/Medline, Scopus, CINAHL, Cochrane, Embase, and Google Scholar databases using various combinations of the following keywords: "lean" and "infection" from August to December 2019. Inclusion criteria were: 1) research articles with quantitative data and relevant information on lean methodology and its impact on healthcare infections; 2) prospective studies. The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines has been used.

Results: 22 studies were included in the present meta-analysis. Lean application demonstrated a significant protective role on healthcare-associated infections rate (RR 0.50 [0.38-0.66]) with significant impact on central line-associated bloodstream infections (CLABSIs) (RR 0.47 [0.28-0.82]). There was a significant correlation between lean application and healthcare worker satisfaction and compliance, but no significant decrease of mortality has been reported.

Conclusions: Lean has a positive impact on the decreasing of HAIs and on the improvement of compliance and satisfaction of the staff.

Contributions To The Literature

- Lean method has several purposes and there is a growing interest on its application in healthcare processes.
- Healthcare associated infections (HAIs) are the most common adverse events affecting millions of patients annually worldwide and recent evidences suggest that lean application may decrease HAIs incidence.
- Although several research articles support the Lean applications to decrease healthcare-associated infections rate, no literature review with analytic purpose of the efficacy aspect is available.
- This study provides high level evidence that critically analyse the impact of lean on HAIs.
- The direct consequence of lean application could be a direct improve in compliance and staff satisfaction.

Background

“Lean thinking” words appeared for the first time in 1988 after a MIT comparative research of the automotive industry.[1, 2] This term is based on the innovative production model called Toyota Production System (TPS).[1, 2]. TPS focused the attention of the entire production on the value for the

customer.[3] “Just in time” and “jidoka” are the two main pillars of TPS. The first one ensure to product “what is needed, when it is needed, and in the amount needed” whereas the latter is “the automation with a human touch”. These principles help the organization to detect, prevent and consequently solve problems.[4] Liker[5] highlighted that the lean enterprise is simply “the end result of applying the Toyota Production System to all areas of your business”.

In other words Radnor et al. defined the “Lean as a management practice based on the philosophy of continuously improving processes by either increasing customer value or reducing non-value adding activities (muda), process variation (mura), and poor work conditions (muri)”.[6]

Ohno[3] identified seven kind of muda categorized in transportation, inventory, motion, waiting, overproduction, overprocessing and defects. These muda are present also in the healthcare sector.[7] Subsequently, Lean management has been exported to this sector.[8, 9] This application has been described in so many different ways such as strategy, philosophy or way of working[10] and several efficiency results (i.e. time saving or cost reduction) have been achieved over time.[11–15] However, few results on the improvement of the outcome have been published.[16]

Although, a protocol for a Cochrane Review on the effect of lean on the patient outcomes has been reported,[17] the specific impact of LEAN application on healthcare-associated infections (HAIs) has not still extensively investigated.

Lean and Six Sigma can be applied to several aspects of health care including finance, inventory management, information processing, outpatient clinics, and inpatient setting.[18]

HAIs are recognized worldwide as an important public health problem, and they are of increasing interest to politicians, patients, and the public.[19]

Up to 2,609,911 new cases of HAIs occur every year in the European Union and European Economic Area (EU/EEA).[20] Multiple research studies report that in Europe hospital-wide prevalence rates of HAIs range from 4.6–9.3%. In particular HAIs have impact on critically ill patients with around 0.5 million episodes of HAIs being diagnosed every year in intensive care units (ICUs) alone, including central line-associated bloodstream infections (CLABSIs), catheter-associated urinary tract infections (CAUTIs), and ventilator-associated pneumonia (VAP).[21]

The problem of nosocomial infection is increased by the spread of multiresistant microorganisms.[22–28] Since the 1970s, the selective pressure exerted by antibiotics has given rise to bacterial species that are increasingly resistant, and the last 20 years have seen a dramatic rise in the number of multi-resistant pathogenic strains;[29] the attributable deaths in the EU due to antimicrobial resistant microorganisms were estimated to be 33,110 per year.

At present, the monitoring and prevention of HAIs is a priority for the healthcare sector, and reducing the incidence of HAIs is used as an indicator of the quality of service provided.[19]

Several identified causes of HAIs have been identified[30] such as the lack of standardized procedures[31–34] or inadequate sanitation procedures that can contribute to the spread of cross-infections.[35]

Some estimate that 20–30% of HAIs are preventable through an extensive infection prevention and control programme.[36]

The reduction of HAIs is considered a quality indicator of the healthcare provided.[37] Lean and six sigma supported by change management are important tools, renamed Robust Process Improvement (RPI), to address those problems by the Joint Commission Center for Transforming Healthcare.[38] In fact, The Joint Commission reported one example of reduction or Surgical Site Infection through RPI.[38] In 2012 a review of the literature focused on the quality improvement in the surgical healthcare showed how different tools (lean, six sigma and statistical process control or PDCA) can decrease the infection rate.[39]

Several lean applications have been described over the years with the purpose of improving healthcare quality,[8, 40–43] nonetheless, to the best of our knowledge, no systematic reviews and meta-analysis have been selectively focused on the lean application for reduction of HAIs.

The aim of this systematic review and meta-analysis of prospective studies is to provide high-level evidences about the lean application for HAIs reduction. The purpose of this study is to analyze if the lean application can reduce the healthcare-associated infections rate.

Methods

The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines[44] has been used as a guide to ensure that the current standard for meta-analysis methodology were met (PRISMA Checklist Additional file 1).

A comprehensive search on PubMed/Medline, Scopus, CINAHL, Cochrane, Embase, and Google Scholar databases was performed using various combinations of the following keywords: "lean" and "infection" from August to December 2019 using Medical Subject Headings (MeSH) terms as vocabulary.

Inclusion criteria were: 1) research articles with quantitative data and relevant information on lean methodology and its impact on healthcare infections 2) prospective design studies. Exclusion criteria were: 1) articles not strictly related to the research query; 2) items without enough information on the sample size or on the population; 3) research works not matching the PICOS criteria (Table 1 Additional file 2); all those articles were therefore excluded. No time filter or language filter was applied.

Table 1
RR and 95% CI for all meta-analyses carried out. The table should be placed at Page 9 line 196

outcome	**HAI SUBGROUP**	**RR [IC95%]** **N**	**p**
hEATHCARE ASSOCIATED INFECTION	HAI (NO CLABSI)	0.51 [0.36–0.71] 16	**< 0.001**
	CLABSI	0.47 [0.28–0.82] 7	**< 0.01**
	ALL	0.50 [0.38–0.66] 23	**< 0.001**
UNEXPECTED DEATH		0.71 [0.42–1.18] 5	n.s.
HEALTHCARE WORKERS SATISFACTION		1.24 [1.08–1.42] 3	**< 0.001**
HAND HYGIENE AND ALL COMPLIANCE	HAND HYGIENE COMPLIANCE	1.42 [1.15–1.76] 3	**< 0.01**
	COMPLIANCE (NO HAND HYGIENE)	1.98 [1.50–2.63] 14	**< 0.001**
	ALL	1.86 [1.47–2.34] 17	**< 0.001**

Two authors (C.P. and M.S.) were involved during the screening of the literature. One of them were an industrial engineer and a black belt in lean and six sigma while the other one was a biologist with a postgraduate course on Systematic review and meta-analysis Cochrane. A complete consensus was achieved through discussion for the texts included in this study.

Articles were firstly selected based on title and abstract. The full text of relevant researches was then acquired and assessed. Each reference of the selected articles was checked in order not to miss any relevant article. The authors independently read all the papers and they implemented a database for the

meta-analysis including the surname of the first author, the year and country of publication, the site of infection and the pre- and post-intervention outcome measure. Studies have been classified depending on the used method within the following six categories: “LEAN”, “LEAN/PDSA (Plan, Do, Study, Act)”, “LEAN/TPS (Toyota Production System)”, “LSS (Lean Six Sigma)”, “RPI (Robust Process Improvement)” and “TPS” (Table 2 Additional file 2). “LEAN/TPS” included all the paper where lean and TPS were used as synonymous. Any disagreement was solved by meeting consensus.

Table 2
RR and 95% CI of all outcome measures stratified for each lean method. The table should be placed at Page 10 line 202

	HEALTHCARE ASSOCIATED INFECTION	**UNEXPECTED DEATH**	**HEALTHCARE WORKERS SATISFACTION**	**COMPLIANCE (without HAND HYGIENE)**	**HAND HYGIENE COMPLIANCE**
METHODS					
LEAN	0.80 [0.36–1.74] 4	1.17 [0.66–2.05] 1	1.24 [1.08–1.42]** 3	8.75 [4.45–17.22] 1	-
LEAN/PDSA	0.50 [0.09–2.72] 1	0.53 [0.36–0.77] 1	-	1.34 [0.92–1.94] 3	-
LEAN/TPS	0.30 [0.11–0.86]** 4	0.31 [0.19–0.51] 1	-	1.99 [1.43–2.76]*** 10	1.35 [0.85–2.14] 1
LSS	0.46 [0.23–0.93]* 5	1.17 [0.77–1.79] 1	-	-	1.26 [1.06–1.50] 1
RPI	0.75 [0.43–1.34] 2	0.81 [0.41–1.60] 1	-	-	1.69 [1.35–2.11] 1
TPS	0.49 [0.23–1.07] 7	-	-	-	-
OVERALL	**0.55 [0.41–0.74]***** **23**	**0.71 [0.42–1.17]** **5**	**1.24 [1.08–1.42]**** **3**	**1.98 [1.50–2.63]***** **14**	**1.42 [1.15–1.77]***** **3**

The following subgroups of HAIs have been identified among the included studies: central line associated blood stream infections (CLABSI), surgical site infections (SSI), Methicillin-resistant *Staphylococcus Aureus* (MRSA) infections, *Clostridium difficilis* (CD) infections, Ventilator-associated pneumonia (VAP), catheter associated urinary tract infections (CAUTI).

The infection rate before and after Lean application was considered as the effect size (ES) of primary outcome measure. The ES of the secondary outcome measures was considered as the percentage of satisfied healthcare workers, the healthcare workers' compliance to procedures, the hand hygiene compliance and the unexpected death.

A meta-regression was conducted to verify the effect of different infection sub-categories on relative risk (RR). As no significant impact was detected, all the infection categories were considered for primary analysis followed by a secondary sub-group (CLABSI) analysis.

The risk of bias and the study quality was independently assessed by two researchers using the "Quality assessment tool for before-after studies with no control group".[45] Results were matched and disagree were solved by meeting consensus. Fifteen studies were classified as "good",[19, 47, 49–50, 52–55, 57–61, 63–64] 5 as "fair"[38, 46, 51, 62, 65] and 2 as "poor".[48, 56]

Statistical heterogeneity was evaluated with I^2 statistics and Heterogeneity chi-square test. Heterogeneity was supposed to be significant with P values (χ^2) < 0.1. The values of 25%, 50% and 75% in the I^2 test corresponded to low, moderate and high levels of heterogeneity, respectively. In case of moderate or high heterogeneity among the studies, a random-effects model was used for the meta-analysis. The RR was calculated as effect estimates, with their 95% confidence intervals (CIs). The RR of the meta-analyses were supposed to be significant if the confidence intervals did not enclose the value "1". If the confidence interval enclosed the value "1", the absence of an association between exposure and disease cannot be excluded. A smaller confidence interval than value of the individual studies indicated less inaccuracy.

The meta-analysis was performed by means of the STATA SE14® (StataCorp LP, College Station, TX, USA) software and the funnel plot was used to assess the risk of bias. If asymmetry was detected by visual assessment, exploratory analyses using trim and/or fill analysis were performed with investigating and adjusting purpose. The probability of publication bias was tested by means of Egger's linear regression and a value of $p < 0.05$ was considered as indicative of publication bias.

Further stratification was performed with respect to study quality to identify sources of variation. Finally, the stability of the pooled estimate regarding each study was assessed in the setting of sensitivity analyses with exclusion of individual studies from the analysis.

Results

Concerning the systematic review, our initial query resulted in 648 hits (specifically, 600 articles from PubMed/MEDLINE and Scopus, and 48 from other sources); after removal of duplicated items, the

resulting list comprised 615 non-redundant articles. Forty-six studies were retained in the qualitative synthesis, and 22 were finally considered in our systematic review and meta-analysis (544 articles were discarded as not being directly pertinent to the topic under investigation and 25 as not meeting the inclusion criteria). Six studies reported more data inherent to infections and were all considered for the meta-analysis. Further details are reported within the Fig. 1 Additional file 3.

The full list of studies included[19, 38, 46–65] and their main characteristics are shown in Table 2 Additional file 2.

Three studies were performed in European countries, 1 in UK and the others in America (1 in Canada and 17 in USA).

Among 22 studies finally included for meta-analysis fourteen studies[19, 38, 46, 47, 49, 54–57, 60, 61, 63–65] measured the HAI as primary outcome measure and 8 studies[50–53, 57–59, 64] the healthcare worker compliance. Five studies[38, 47, 52, 60, 62] included relevant data on unexpected mortality and 2 studies [48, 59] on healthcare workers satisfaction".

Meta-analysis on 14 prospective studies measuring the reduction of healthcare-associated infections rate showed that lean have a significant protective role (RR 0.50 [0.38–0.66]). Moreover, meta-analysis showed that lean application significantly decreased incidence of CLABSI (RR 0.47 [0.28–0.82]). The results showed a positive effect of lean application on healthcare worker satisfaction and compliance, but no significant decrease of mortality has been reported (Table 1).

The adjusted rank correction test (Begger test) and the regression asymmetry test (Egger test) were used to evaluate the risk of bias. The studies evaluating the compliance had high risk of biases ($p < 0.001$).

A stratified meta-analysis for different lean methods has been conduct to assess for the impact of each method to the final outcome measure (Table 2).

Healthcare associated infections

The meta-analysis showed that application of LEAN/TPS (RR 0.30 [0.11–0.86]) and LSS (RR 0.46 [0.23–0.93]) had significant impact on HAIs. The application of LEAN, LEAN/PDSA, RPI and TPS showed no significant impact on HAIs (Fig. 1).

More than 30% of included studies were focused on sub-group of CLABSI with overall significant data for all applied methods (RR 0.54 [0.31–0.95]) (Fig. 2). However, no significant data have been obtained with analysis of each method applied, due to few studies for each method. Data on other HAIs confirmed that LEAN/TPS and LSS had significant results on other HAIs (Table 3).

Table 3
RR and 95% CI for HAI stratified for LEAN methods. The table should be placed at Page 10 line 211

	HEALTHCARE ASSOCIATED INFECTION	
	OTHER HAIs	**ONLY CLABSI**
METHODS		
LEAN	0.77 [0.34–1.77] 3	1.00 [0.06–15.96] 1
LEAN/PDSA	-	0.50 [0.09–2.72] 1
LEAN/TPS	0.14 [0.04–0.47] 1	0.53 [0.23–1.06] 3
LSS	0.45 [0.22–0.95]* 4	0.50 [0.04–5.51] 1
RPI	0.75 [0.43–1.34] 2	-
TPS	0.49 [0.21–1.17] 6	0.50 [0.09–2.72] 1
OVERALL	**0.55 [0.39–0.78]**** **16**	**0.54 [0.31–0.95]*** **7**

Unexpected death

Only one study demonstrated that the application of LEAN/PDSA had significant influence on unexpected death (RR 0.53 [0.36–0.77]). One other study showed that LEAN/TPS significantly decreased the unexpected death (RR 0.31 [0.19–0.51]).

Healthcare workers satisfaction

All studies evaluated the LEAN application impact on healthcare workers satisfaction with significant results (RR 1.24 [1.08–1.42]).

Compliance

Only one study measured the compliance with application of the LEAN method with a significant influence (RR 8.75 [4.45–17.22]).

Three studies, reporting a total of ten outcomes, used the lean and the TPS and measured the pre- and post-intervention compliance. The stratified analysis showed that “LEAN/TPS” significantly increased the compliance of healthcare workers (RR 1.99 [1.43–2.76]). Nonetheless, two studies including three outcomes used the lean and PDSA. The application of “LEAN/PDSA” method showed no significant influence on compliance of healthcare workers.

Hand Hygiene Compliance

Only one study measured the hand hygiene compliance with application of the LEAN/TPS, one study measured the hand hygiene compliance with application of the LSS and one with application of RPI.

The overall analysis highlighted a significant correlation between LEAN (all methodologies) and hand hygiene compliance (Table 2).

Discussion

The most important finding of this study is the significant protective impact of lean strategies on HAIs, compliance and staff satisfaction.

Healthcare associated infections (HAIs) are the most common adverse events that afflict millions of patients annually around the world.[21] The reduction of HAIs is considered a quality indicator of the healthcare provided.[37] Over the years different strategies and preventions measures have been applied against infections.[39]

Several studies described the lean as affective method to prevent infections, however literature is surprising lacking of quantitative and measurable results on outcome measures. Johnson et al[66] proposed an example of lean method to reduce the readmission for patients with community acquired pneumonia without providing data of outcome. Simons et al[67] proposed the lean method to decrease the SSI rate through the reduction of the door movement. Nonetheless authors measured only the number of door movement without assess the SSI rate in their research.

To the best of our knowledge, this is the first systematic review and meta-analysis of prospective studies focused on lean application and their relative impact on HAIs.

Due to lack of high-quality evidence data Vest et al[68] raised doubts about the efficacy of the application of lean method on several clinical outcomes. Moraros et al[69] in a systematic review of the literature reported conflicting results on reduction of MRSA infection and lean application with significant data in only three out on twenty-two included studies.

In the present meta-analysis, the overall lean application demonstrated a significant impact on HAIs reduction. The subgroup analysis showed that LEAN/TPS and LSS had significant impact on HAIs reduction on nine studies. Moreover, the lean application showed significant impact on CLABSI and all subcategories of HAIs.

There is uncertain evidence of statistical reduction of mortality with the lean application. Mason et al[70] reported only one study with significant reduction of mortality in patients with proximal femoral fractures with lean application. This finding could be explained considering the lack of data of other factors influencing death. In the present meta-analysis, the lean application seems to have a protective role on unexpected death although with inconclusive data. Only two studies showed a significant reduction of mortality with "LEAN/PDSA"[52] and "LEAN/TPS"[47] methods. Certainly, further studies are required to definitively ascertain this aspect.

The purpose of this research is to answer to a very actual question: "Is lean efficacy in the healthcare sector?". Several studies are available without measurable data supporting this affirmation.[69]

The strength of this work is the detailed meta-analysis on prospective studies. However, this study presents some limitations: there are several independent factors influencing the healthcare-associated infections rate that were not measured in the included studies. Patients and pathogens features were not detailed reported and precluded a detailed analysis of potential confounding factors. Data of infection reduction were calculated measuring the infection rate before and after a period of Lean application in the same hospital ward and assume that the characteristics of patients don't substantially change. Nevertheless, no detailed population analysis before and after the intervention has been reported. Further potential weakness of this research is the limited number of available articles as consequence of novelty of the research area. Finally, there was high heterogeneity of HAIs spectrum among the published studies.

Conclusions

HAIs are a plague for the healthcare sector. Lean seems to be an important method to decrease infection rate and to achieve improvement in compliance and staff satisfaction. However, little is known about the unexpected death and lean. Furthermore, given the above-mentioned limitations, further research in the field is warranted.

List Of Abbreviations

CD: Clostridium difficilis

CI: Confidence Intervals

CLABSI: Central Line-Associated Bloodstream Infection

ES: Effect Size

HAI: Healthcare-Associated Infections

ICU: Intensive Care Unit

LSS: Lean Six Sigma

MeSH: Medical Subject Headings

MRSA: Methicillin-resistant Staphylococcus Aureus

PDCA: Plan Do Check Act

PDSA: Plan Do Study Act

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

RPI: Robust Process Improvement

RR: Relative Risk

SSI: Surgical Site Infections,

TPS: Toyota Production System

VAP: Ventilator-Associated Pneumonia

Declarations

Ethics approval and consent to participate: Not applicable.

Consent for publication: Not applicable.

Available of data and materials: The dataset used and analysed during the current study are available from corresponding author on reasonable request.

Competing of Interest: The authors declare that they have no competing interests.

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Authors' contribution: Data curation, AMS, ES and GO; Formal analysis, MS; Investigation, MS, MLC and CP; Methodology, MS and CP; Project administration, MS and MLC; Software, ES, GO and CD; Writing – original draft, MS, CP and MLC; Writing – review & editing, MS, AMS, ES, GO, CD, MAM, CP and MLC.

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Additional File Legend

Additional file 1 – PRISMA Checklist

Additional file 2 – Supplementary materials – in this file there are 2 tables: 1. Search strategy; 2. List and features of studies included

Additional file 3 - FIGURE 1 SUPPLEMENTARY MATERIAL – This file reports the PRISMA 2009 Flow Diagram

Figures

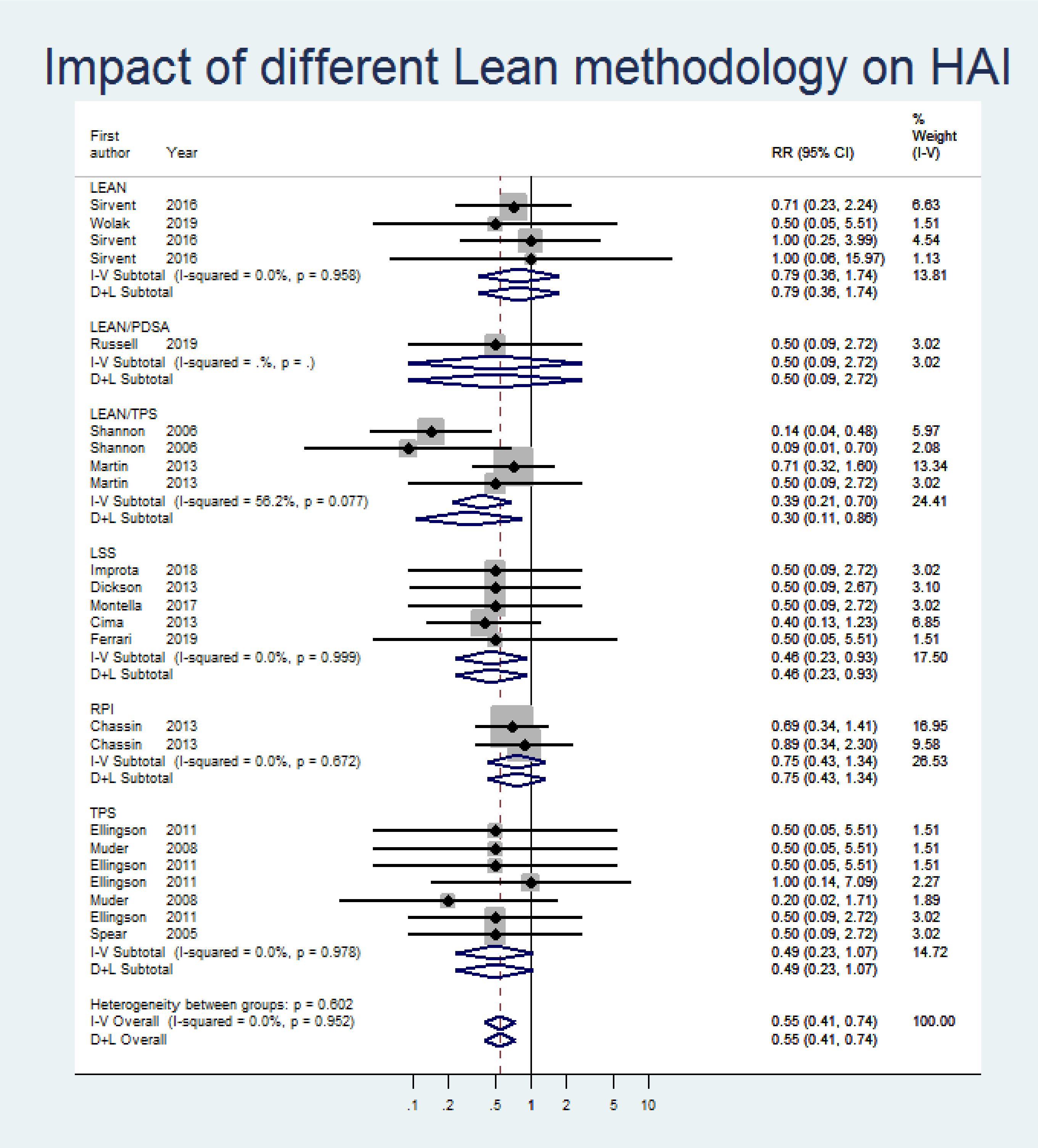

Figure 1

Forest plot of Impact of different Lean methodology on HAI

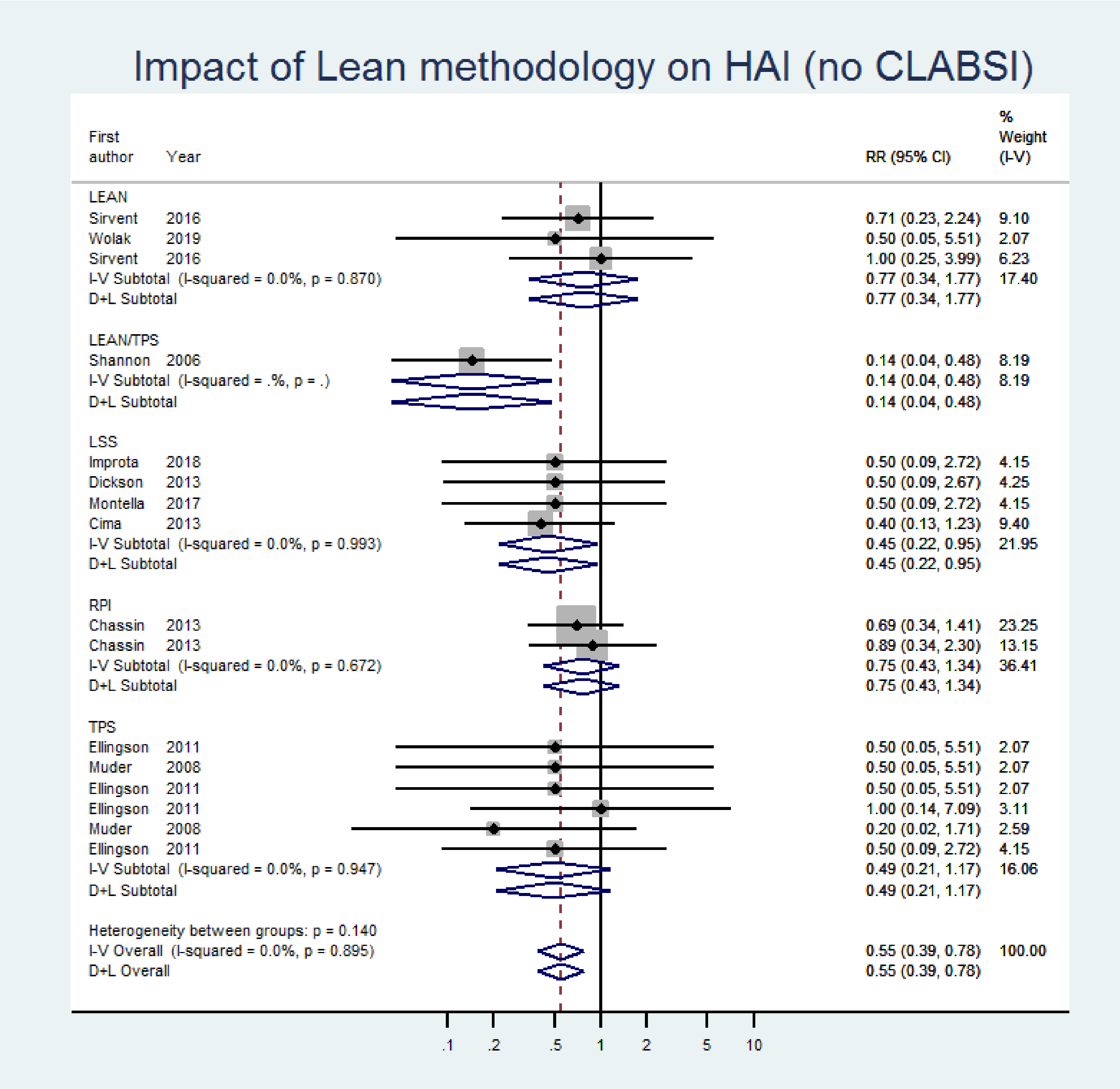

Figure 2

Forest plot of Impact of different Lean methodology on HAI (without CLABSI)

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Additionalfile1PRISMA2009Checklist.docx

- Additionalfile2Supplementarymaterials.docx
- Additionalfile3FIGURE1SUPPLEMENTARYMATERIAL.tif