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Lean management in health care: effects on patient outcomes, professional practice, and healthcare systems (Protocol)

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[Intervention Protocol]

Lean management in health care: effects on patient outcomes, professional practice, and healthcare systems

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

- To assess effects of Lean management in health care on patient, professional, and systems outcomes by addressing the following question.

  - What are the effects of Lean management interventions in health care on patient outcomes, professional practice, and healthcare systems?

- What are the effects of Lean management interventions in health care on patient outcomes, professional practice, and healthcare systems?

- To answer the following questions in addressing secondary objectives:

  - What are the effects of Lean management interventions in combination with other management systems (e.g. Six Sigma) on patient outcomes, professional practice, and healthcare systems (utilisation and access, adverse effects, cost)?

  - Is the effectiveness of Lean interventions influenced by the setting (e.g. Emergency Department, Laboratory, Pharmacy) in which they are implemented?

- What are the effects of Lean management interventions in combination with other management systems (e.g. Six Sigma) on patient outcomes, professional practice, and healthcare systems (utilisation and access, adverse effects, cost)?

- Is the effectiveness of Lean interventions influenced by the setting (e.g. Emergency Department, Laboratory, Pharmacy) in which they are implemented?

BACKGROUND

Description of the condition

Healthcare systems are facing growing challenges as our aging society is increasing the demand for care (Al-Balushi 2014; Leggat 2015; Poksinska 2010). Healthcare systems are required to meet this growing demand, while increasing accountability and improving the quality of care (DelliFraine 2010; Leggat 2015; McIntosh 2014). The challenge of meeting these demands is complicated by the fact that financial conditions among healthcare systems are not improving and in some cases are even worsening (Al-Balushi 2014; Poksinska 2010).

In response to this phenomenon, healthcare providers are striving to improve outcomes while simultaneously achieving greater efficiency (Baker 2001; Fine 2009; Kohn 2000; McIntosh 2014). To meet these goals, many organisations have turned to industrial improvement approaches (Kaplan 2014). One prominent improvement method is the Lean management system (Lean); it has been estimated that this system has been adopted in some form by 53% of US hospitals (ASQ 2009). Lean management promises enhanced quality, capacity, and safety, while containing costs (Curatolo 2014; Kaplan 2014).

Description of the intervention

Lean management, originally termed the Toyota Production System (TPS), was developed in the auto industry by Taiichi Ohno (Black 2008; Radnor 2012). The original aim was to ensure defect-free manufacturing, while minimising waste and addressing customer needs (Andersen 2014; Black 2008; Curatolo 2014; Reijula 2014). Since it was developed, Lean has been applied to various industries and is now conceptually described as "an integrated socio-technical system whose main objective is to eliminate waste by concurrently reducing or minimizing supplier, customer, and internal variability" (Shah 2007).

When Lean was adopted into health care, numerous components were emphasised, and common foci include development of a culture of continuous improvement, empowerment of employees, and reduction of waste, with focus on improving the value of services received by patients (Andersen 2014; Casey 2009; Curatolo 2014; DelliFraine 2010; Holden 2011; Mann 2010; Mazzocato 2010; Poksinska 2010; Printezis 2007). Concentrating on these values is expected to result in decreased costs, enhanced safety, and improved quality of care (Casey 2009; D'Andreamatteo 2015; Mann 2010; Mazzocato 2010; Poksinska 2010). To achieve these goals, Lean management systems use several common activities. Table 1 depicts frequently used activities.

How the intervention might work

Various authors have proposed theories for how outcomes in health care could be improved through the application of Lean management systems. Spear has suggested that Lean should empower front-line employees, providing them with the tools necessary to make improvements, while simultaneously promoting a focus on the patient. This approach is intended to encourage staff to focus on caring for patients while simultaneously finding better ways to provide care (Spear 2005).

Similarly, Womack has proposed that Lean could be utilised in health care by focusing on ensuring value to the patient and including various measures of patient satisfaction such as comfort and wait times as key performance indicators (Womack 1996). In contrast, Young has recommended that Lean should be used to eliminate waste in the form of wait times, repeat visits, errors, and inappropriate procedures (Young 2004).

The current literature demonstrates that Young's theory provides the best description of how Lean has been utilized in healthcare to date. This is shown by work suggesting Lean organizations have done little to develop a better understanding of customer's value (Radnor 2012). Instead, most interventions have focused on implementing changes that reduce waste by standardising processes to bring them in line with best practices (DelliFraine 2010; Holden 2011). Additional evidence suggests that Lean is most commonly implemented as a set of individual interventions that use Lean tools to make improvements within specific departments or wards (Poksinska 2010; Radnor 2012).

Why it is important to do this review

Although Lean has been widely applied in healthcare systems in Canada, the United States, and the United Kingdom, patients, front-line staff, healthcare managers, and policy makers lack evidence-based information regarding the effectiveness of Lean management approaches in health care (ASQ 2009; Burgess 2013; Fine 2009; Hamilton 2014; Kaplan 2014; Mazzocato 2012). This is due in part to the fact that although the body of literature on Lean management in health care is slowly growing, most publications are case studies that present only anecdotal evidence, providing

weak empirical support (D'Andreamatteo 2015). Researchers attempting to synthesise data have noted significant gaps (Andersen 2014; DelliFraine 2010; Leggat 2015; McIntosh 2014). Studies report conflicting results regarding effects of Lean implementation in various health contexts (Leggat 2015; McIntosh 2014). Many studies have demonstrated various shortcomings such as failure to describe the implementation process and utilisation of suboptimal evaluation designs. This evidence gap, combined with the fact that costs of both implementation and failure are high, necessitates a thorough, high-quality evaluation of the management system (McIntosh 2014; Mann 2005; Mann 2009). This protocol outlines the research that must be conducted to address this need and advance our knowledge through a rigorous, systematic review of Lean management in health care with focus on its effects on healthcare systems, professional practice, and patient outcomes.

OBJECTIVES

- To assess effects of Lean management in health care on patient, professional, and systems outcomes by addressing the following question.

  - What are the effects of Lean management interventions in health care on patient outcomes, professional practice, and healthcare systems?

- To answer the following questions in addressing secondary objectives:

  - What are the effects of Lean management interventions in combination with other management systems (e.g. Six Sigma) on patient outcomes, professional practice, and healthcare systems (utilisation and access, adverse effects, cost)?

  - Is the effectiveness of Lean interventions influenced by the setting (e.g. Emergency Department, Laboratory, Pharmacy) in which they are implemented?

METHODS

Criteria for considering studies for this review

Types of studies

We expect few randomised trials, so we will also include non-randomised trials, controlled before-after studies, and interrupted time series studies that meet methodological quality criteria of the Effective Practice and Organisation of Care Group (EPOC) (EPOC 2017a). We will include full-text studies and will consider conference abstracts, as well as unpublished data.

Types of participants

This review will look at use of Lean management in the following healthcare settings.

- Hospital care.
- Primary care.
- Community or home care.
- Rehabilitation.

We will include all individuals impacted by implementation of Lean management, which we expect will include the following.

- All employees of the healthcare system, such as CEOs, healthcare professionals, administrative staff, and support staff.
- Patients and their families.
- Lean experts and key stakeholders.

However, because Lean impacts all individuals who interact with organisations that have adopted the management system, we will not exclude participants who are not listed. Instead, exclusion will be based on the focus of Lean implementation.
We will not include any studies focused on the following.

- Animal research.
- Drug discovery.
- Drug manufacturing.
- Medical device delivery.
- Medical device manufacturing.
- Software development.
- Teaching (e.g. techniques for teaching nursing).

Types of interventions

Despite increased use of Lean terminology and popularisation of Lean management approaches, especially in the hospital sector, little agreement has been reached regarding how Lean is described and defined in the literature (D'Andreamatteo 2015). In response to this shortcoming, we developed an operational definition of Lean management in health care (Rotter 2016). This definition requires that all included studies focus on interventions that (1) occurred in an organisation or a subunit of an organisation (e.g. department, ward) that has made a commitment to Lean philosophy (including a commitment to both Lean principles and continuous improvement); and (2) utilised at least one Lean assessment activity or Lean improvement activity whereby:

- **Lean philosophy** is a set of core ideas that make up Lean and include two components: a commitment to Lean principles and a commitment to continuous improvement;
- **Lean principles** refer to an overarching set of principles aimed at transforming workplace culture (Kruskal 2012). These

include focus on eliminating waste; improving the flow of patients, providers, and supplies; and ensuring that all processes add value to customers (Black 2008; DelliFraine 2010; Holden 2011; Kim 2006; Mazzocato 2010; Poksinska 2010). Further, Lean principles suggest that problems are identified and addressed by front-line staff members, as it is believed that the people doing the work are best suited to create solutions (Casey 2009; Holden 2011; Kruskal 2012);

- **Commitment to continuous improvement** refers to the acknowledgement that Lean does not occur as a single intervention but instead requires a commitment to continually improving the workplace (DelliFraine 2010; Holden 2011; Mazzocato 2010);
- **Lean activities** comprise a set of management practices, tools, or techniques that can be directly observed and are prescribed to improve the workplace (Shah 2007). Two types of Lean activities have been developed: assessment activities and improvement activities;
- **Lean assessment activities** work as analytical tools to identify waste and areas of possible improvement. These activities allow team members to see problems and identify opportunities to reduce waste and make improvements but do not prescribe specific solutions. Lean assessment activities include value stream mapping (VSM); spaghetti diagrams; rapid process improvement workshops (RPIWs); Gemba walks; and root cause analysis; and
- **Lean improvement activities** suggest specific ways to reduce waste and improve the workplace while setting up new working practices. These include actions and concepts such as 5S ('Sort, Sweep, Simplify, Standardise, Sustain/Self-Discipline') events; levelled production; daily visual management (DVM) (including Kanban supply management); standard work; and 'Stop the Line' techniques.

We will include studies that test multi-faceted Lean approaches (e.g. Lean management combined with the Six Sigma approach) if Lean components can be assessed separately from other process improvement techniques or tools used (e.g. Six Sigma).

Types of outcome measures

Primary outcomes

We will categorise all outcomes according to Cochrane EPOC guidance (EPOC 2017b). Primary outcomes for the review will include the following.

- Patient outcomes.
    - Patient satisfaction.
    - Length of stay (LOS).
    - Wait times.
- Healthcare provider outcomes.
    - Employee satisfaction.
- Utilisation and access.
- Adverse effects or harms.
    - Error rates related to patient safety.
- Resource use.
    - Cost.
    - Cycle time (amount of time required to complete a specified task).
    - Error rates related to resource use.

When possible, we will use satisfaction data from validated questionnaires (e.g. Patient Satisfaction Questionnaire (PSQ-III), Picker Patient Experience questionnaire (PPE-15) and directly observed measurements of length of stay, wait times, error rates, cycle time, and costs. However, as we anticipate a limited body of literature, we will also include less rigorous measures (e.g. surveys that have not been validated, cost estimates). We will consider the certainty of all measures when completing risk of bias assessments. Because Lean has the potential to reduce errors in both patient safety (e.g. infection rates, errors regarding drug administration) and resource utilisation (e.g. specimen labelling errors, culture contamination), we will include both types of error rates as primary outcomes.

Secondary outcomes

We expect a diverse range of outcomes to be reported. We will capture all outcomes not listed above that fall into one of the following EPOC categorisations and will consider them secondary outcomes: patient outcomes; utilisation, coverage, or access; quality of care; adverse effects or harms; resource use; and healthcare provider outcomes.

Search methods for identification of studies

Electronic searches

We will search the *Cochrane Database of Systematic Reviews* (CDSR) and the Database of Abstracts of Reviews of Effects (DARE) for primary studies included in related systematic reviews. For primary studies, we will search the following databases with neither date nor language limits. We will apply two methodological filters: the Cochrane Highly Sensitive Search Strategy (sensitivity- and precision-maximising version - 2008 revision) to identify randomised trials (Lefebvre 2011); and an EPOC methodology filter to identify non-randomised designs. See Appendix 1 for a draft strategy for OVID Medline.

- Cochrane Central Register of Controlled Trials (CENTRAL) (Wiley).

- MEDLINE, 1946 - In-Process and other non-indexed citations; Daily Update (OvidSP).
- Embase, 1947 - (OvidSP).
- Cumulative Index to Nursing and Allied Health Literature (CINAHL), 1980 - (EBSCO).
- Dissertations and Theses Database, 1861 (ProQuest).
- Web of Science.
    - Science Citation Index Expanded (1900-).
    - Social Sciences Citation Index (1900-).
    - Arts & Humanities Citation Index (1975-).
    - Conference Proceedings Citation Index - Science (1990-).
    - Conference Proceedings Citation Index - Social Science & Humanities (1990-).
- Business Source Premiere (EBSCO).
- EconLit (economics research database) (EBSCO).
- Public Affairs Information Service (PAIS) (ProQuest).
- Social Work Abstracts (EBSCO).

Searching other resources

Grey literature

We will conduct a grey literature search in an effort to identify studies not indexed in the databases listed above. Sources may include the following sites (we will document and present in our review actual sites searched).

- OpenGrey (http://www.opengrey.eu/).
- Grey Literature Report (New York Academy of Medicine) (http://www.nyam.org/library/online-resources/grey-literature-report/).
- Agency for Healthcare Research and Quality (AHRQ) (www.ahrq.gov/).
- National Institute for Health and Clinical Excellence (NICE) (www.nice.org.uk/).
- Institute of Healthcare Improvement (IHI) (www.ihi.org).

Trial registries

- International Clinical Trials Registry Platform (ICTRP), World Health Organization (WHO) (http://www.who.int/ictrp/en/).
- ClinicalTrials.gov, US National Institutes of Health (NIH) (http://clinicaltrials.gov/).

We will also:

- screen a selection of individual journals (e.g. handsearch);
- review the reference lists of relevant systematic reviews and/or studies;
- contact, if necessary, the authors of relevant studies and/or systematic reviews to clarify reported data or to inquire about the availability of unreported data;
- contact researchers with expertise relevant to the topic of our review; and
- conduct cited reference searches for studies identified for inclusion in our review using ISI Web of Knowledge Science and Social Sciences Citations Indices.

Data collection and analysis

Selection of studies

We will import into all titles and abstracts retrieved by electronic searching into EndNote x7 (EndNote 2016). We will break results into five groups for screening. Pairs of review authors (LA and CP, JC and CP, MF and CP, AK and LH, TR and LK) will independently screen titles and abstracts for inclusion. We will code all potentially eligible studies as 'retrieve' (eligible or potentially eligible/unclear) or 'exclude'. We will retrieve full-text study reports/publications for all studies coded as 'retrieve' by at least one review author. We will divide retrieved studies into three groups. Pairs of review authors (CP and MF, CP and AK, CP and LA) will independently screen the full-text reports, will identify studies for inclusion, and will identify and record reasons for exclusion of ineligible studies. We will resolve disagreements through discussion. If consensus cannot be reached, we will consult a third review author (TR). We will report the number of studies excluded upon title review and full-text review. We will report articles that appear relevant to the review question but were excluded from analysis along with reasons for exclusion as per the *Cochrane Handbook for Systematic Reviews of Interventions*, Section 7.2.5. (Higgins 2011). We will collate multiple reports of the same study so that each study, rather than each report, is the unit of interest in the review. We will provide any information we can obtain about ongoing studies. We will record the selection process in sufficient detail to complete a PRISMA flow diagram and 'Characteristics of excluded studies' tables (Liberati 2009).

Data extraction and management

Pairs of two review authors will independently extract data according to the double data entry method by using a standardised data extraction form developed in Microsoft Access (Microsoft 2016). We will pilot-test the data extraction form on three studies from the review and will extract all data directly from included studies. We will refer disagreements to a third review author. If necessary, we will contact authors of the primary studies for additional information. Areas of data extraction will include:

- study characteristics: author, publication year, healthcare setting (e.g. primary care, hospital, long-term care), location (urban vs rural), country;

- intervention: type of Lean intervention used, Lean vs Lean Six Sigma, theoretical background used in implementation, target population;
- population characteristics (participants): age, gender, number of participants;
- population characteristics (healthcare providers): types of healthcare professionals involved, number of healthcare professionals involved, types of additional personnel involved (e.g. senseis, continuous quality improvement (CQI) group), number of additional personnel involved; and
- outcomes: participant, healthcare provider, utilisation and access, adverse effects or harms, and resource use.

Assessment of risk of bias in included studies

Two review authors will independently assess risk of bias for each study using criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* and guidance from the EPOC group (EPOC 2017c; Higgins 2011). We will resolve disagreements by discussion and will refer the matter to a third review author if agreement cannot be reached. For randomised trials, non-randomised trials, and controlled before-after studies, we will assess risk of bias according to the following domains.

- Random sequence generation.
- Allocation concealment.
- Baseline outcomes measurement.
- Baseline characteristics.
- Incomplete outcome data.
- Knowledge of intervention allocation.
- Protection from contamination.
- Selective outcome reporting.
- Other bias.

For interrupted time series studies, we will assess risk of bias according to the following domains.

- Independance from other changes.
- Specification of the shape of effects before analysis.
- Independance from data collection.
- Knowledge of intervention allocation.
- Incomplete outcome data.
- Selective outcome reporting.
- Other bias.

We will rate each potential source of bias as high, low, or unclear and will provide a quote from the study report together with a justification for our judgement in the 'Risk of Bias' table, as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will summarise risk of bias judgements across different studies for each of the domains listed. We will consider blinding separately for different key outcomes when necessary (e.g. for unblinded outcome assessment, risk of bias for all-cause mortality may be different from that assigned for a patient-reported pain scale). When information on risk of bias is related to unpublished data or correspondence with a trialist, we will note this in the risk of bias table.
When considering treatment effects, we will take into account the risk of bias for studies that contribute to that outcome.

Assesment of bias in conducting the systematic review

We will conduct the review according to this published protocol and will report deviations from it in the 'Differences between protocol and review' section of the systematic review.

Measures of treatment effect

We will estimate the effect of the intervention using risk ratios for dichotomous data, and mean differences for continuous data. We will present all measures with associated 95% confidence intervals (CIs). We will ensure that an increase in scores for continuous outcomes can be interpreted in the same way for each outcome, will explain the direction to the reader, and will report when directions were reversed, if this was necessary.
We will define pre-intervention data points as all data collected before initiation of changes resulting from a Lean intervention. When possible, we will define postintervention data points as data collected following completion of changes resulting from a Lean intervention. However, we acknowledge that Lean dictates that improvement should be continuous, and therefore the implementation period may not be well defined. If this is the case, we will consider all data collected following initiation of changes resulting from a Lean intervention as postintervention data points; in such cases, we will note this and will consider it when drawing conclusions. In the case of interrupted time series studies, we will present the change in intercept for the postintervention phase as well as slope estimates for pre-intervention and postintervention phases.

Unit of analysis issues

We will include cluster-randomised trials and will combine them with randomised trials when clinical and statistical heterogeneity is low. We will deal with cluster-randomised trial results that do not include an intracluster correlation coefficient (ICC) as per the section below on dealing with missing data. However, we will not exclude studies from the review because of unit of analysis issues. We will retain these studies and will include them in a subsequent sensitivity analysis.

Dealing with missing data

We will contact investigators to verify key study characteristics and to obtain missing outcome data when possible (e.g. when a study is identified as abstract only). For trials of cluster-randomised design,

we will utilise an estimate of an ICC taken from an ICC database of the University of Aberdeen (ICC Database 2008).

If we find before-after comparisons that provide at least three pre-intervention and three postintervention measures, we will re-analyse them using segmented time series regression techniques (EPOC 2017d). We will extract data from graphic presentations using Engauge Digitizer (Mitchell 2016). For each analysis, we will report the pre-intervention intercept, the pre-intervention slope, the postintervention intercept, and the postintervention slope.

Assessment of heterogeneity

If we find a sufficient number of studies, we will conduct a meta-analysis. We will use the I^2 statistic to measure heterogeneity among the trials in each analysis. We will consider an I^2 value greater than 60% to serve as evidence of substantial heterogeneity of a magnitude at which statistical pooling is not appropriate. If we identify substantial heterogeneity, we will explore this by conducting prespecified subgroup analyses.

Assessment of reporting biases

We will attempt to contact study authors to ask them to provide missing outcome data. When this is not possible, and the missing data are thought to introduce serious bias, we will explore the impact of including such studies in the overall assessment of results by performing a sensitivity analysis**.** If we are able to pool more than 10 trials, we will create and examine a funnel plot to explore possible publication biases, while interpreting results with caution (Sterne 2011).

Data synthesis

We will undertake meta-analyses only when this is meaningful (i.e. when interventions, participants, and the underlying clinical question are similar enough for pooling to make sense). Trialists commonly indicate that data are skewed by reporting medians and interquartile ranges. When we encounter this, we will note that the data are skewed and will consider the implications of this. When a single trial reports inclusion of multiple trial arms, we will include only relevant arms. If two comparisons (e.g. Lean in Hospital A vs usual care and Lean in Hospital B vs usual care) must be entered into the same meta-analysis, we will halve the control group to avoid double counting.

'Summary of findings'

We will summarise the findings of the main intervention comparison for the most important outcomes (patient satisfaction, employee satisfaction, length of stay, wait times, error rates related to patient safety, costs, cycle time, errors rate related to resource use) in a 'Summary of findings' table to present conclusions about certainty of evidence included within the review text. Two review authors will independently assess certainty of evidence (high, moderate, low, and very low) using the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias). We will use methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions,* and in the worksheets, and will use GRADEpro software, if applicable (EPOC 2017e; GRADEproGDT 2015; Higgins 2011). We will resolve disagreement on certainty ratings through discussion and will provide justification for decisions to downgrade or upgrade these ratings by including footnotes in the table and making comments to aid readers' understanding of the review when necessary (Guyatt 2008). We will use plain language statements to describe effects of the intervention on review outcomes (EPOC 2017f).

Subgroup analysis and investigation of heterogeneity

We plan to group studies into the following categories.

- Subgroup of Lean methods (e.g. Lean, Lean Six Sigma) used.
- Setting (e.g. Emergency Department, Laboratory, Pharmacy) in which the intervention was implemented.

To conduct the subgroup analysis, we will use all outcomes that are common to at least three studies. We will perform a separate analysis for each outcome.

Sensitivity analysis

We will perform sensitivity analysis defined a priori to assess the robustness of our conclusions and to explore the impact of this analysis on effect size. This will involve:

- restricting the analysis to published studies;
- restricting the analysis to studies with low overall risk of bias; and
- imputing missing data.

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REFERENCES

Additional references

A3 Thinking 2015
A3 Thinking. A brief introduction to A3 thinking. http://a3thinking.com/whatis.html (accessed 27 May 2016).

Al-Balushi 2014
Al-Balushi S, Sohal AS, Singh PJ, Hajri AA, Farsi YMA, Abri RA. Readiness factors for lean implementation in healthcare settings - a literature review. *Journal of Health Organization and Management* 2014;**28**:135–53.

Andersen 2014
Andersen H, Rovik KA, Ingebrigtsen T. Lean thinking in hospitals: is there a cure for the absence of evidence? A systematic review of reviews. *BMJ Open* 2014;**4**:e003873.

ASQ 2009
American Society for Quality. Hospitals see benefits of Lean and Six Sigma. http://asq.org/qualitynews/qnt/execute/displaySetup?newsID=5843 (accessed 23 September 2014).

Baker 2001
Baker A. Crossing the quality chasm: a new health system for the 21st century. *BMJ* 2001;**323**:1192.

Black 2008
Black J, Miller D. *The Toyota Way to Healthcare Excellence: Increase Efficiency and Improve Quality With Lean*. Chicago, IL: Health Administration Press, 2008.

Burgess 2013
Burgess N, Radnor Z. Evaluating Lean in healthcare. *International Journal of Health Care Quality Assurance* 2013;**26**:220–35.

Casey 2009
Casey JT, Brinton TS, Gonzalez CM. Utilization of Lean management principles in the ambulatory clinic setting. *Nature Clinical Practice Urology* 2009;**6**:146–53.

Curatolo 2014
Curatolo N, Lamouri S, Huet JC, Rieutord A. A critical analysis of Lean approach structuring in hospitals. *Business Process Management Journal* 2014;**20**:433–54.

DelliFraine 2010
DelliFraine JL, Langabeer JR 2nd, Nembhard IM. Assessing the evidence of Six Sigma and Lean in the health care industry. *Quality Management in Health Care* 2010;**19**:211–25.

D'Andreamatteo 2015
D'Andreamatteo A, Ianni L, Lega F, Sargiacomo M. Lean in healthcare: a comprehensive review. *Health Policy* 2015;**119**:1197–209.

EndNote 2016 [Computer program]
Thomson Reuters. EndNote X7.5. New York, New York: Thomson Reuters, 2016.

EPOC 2017a
Effective Practice, Organisation of Care (EPOC). What study designs should be included in an EPOC review and what should they be called? EPOC Resources for Review Authors, 2017. Available at epoc.cochrane.org/epoc-resources-review-authors.

EPOC 2017b
Effective Practice, Organisation of Care (EPOC). What outcomes should be reported in Cochrane Effective Practice and Organisation of Care (EPOC) reviews? EPOC Resources for Review Authors, 2017. Available at epoc.cochrane.org/epoc-resources-review-authors.

EPOC 2017c
Effective Practice, Organisation of Care (EPOC). Suggested risk of bias criteria for EPOC reviews. EPOC Resources for Review Authors, 2017. Available at epoc.cochrane.org/epoc-resources-review-authors.

EPOC 2017d
Effective Practice, Organisation of Care (EPOC). Interrupted time series (ITS) analyses. EPOC Resources for Review Authors, 2017. Available at epoc.cochrane.org/epoc-resources-review-authors.

EPOC 2017e
Effective Practice, Organisation of Care (EPOC). EPOC worksheets for preparing a Summary of Findings (SoF) table using GRADE. EPOC Resources for Review Authors, 2017. Available at epoc.cochrane.org/epoc-resources-review-authors.

EPOC 2017f
Effective Practice, Organisation of Care (EPOC). Reporting the effects of an intervention in EPOC reviews. EPOC Resources for review authors, 2017. Available at epoc.cochrane.org/epoc-resources-review-authors.

Fine 2009
Fine BA, Golden B, Hannam R, Morra D. Leading Lean: a Canadian healthcare leader's guide. *Healthcare Quality* 2009;**12**:32–41.

GRADEproGDT 2015 [Computer program]
GRADEproGDT. GRADEpro Guideline Development Tool. Version accessed 10 May 2017. Hamilton (ON): McMaster University (developed by Evidence Prime, Inc.), www.gradepro.org, 2015.

Guyatt 2008
Guyatt GH, Oxman AD, Vist G, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al. for the GRADE Working Group. Rating quality of evidence and strength of recommendations. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ* 2008;**336**:924–6.

Hamilton 2014
Hamilton J, Verrall T, Maben J, Griffiths P, Avis K, Baker GR, et al. One size does not fit all: a qualitative content analysis of the importance of existing quality improvement capacity in the implementation of Releasing Time to Care: the Productive Ward in Saskatchewan, Canada. *BMC Health Services Research* 2014;**14**:642.

Higgins 2011
Higgins JPT, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions. Version 5.1.0 (updated March 2011)*. The Cochrane Collaboration. www.cochrane-handbook.org, 2011.

Holden 2011
Holden RJ. Lean thinking in emergency departments: a critical review. *Annals of Emergency Medicine* 2011;**57**: 265–78.

ICC Database 2008
University of Aberdeen Health Services Research Unit. Database of intra-correlation coefficients (ICCs). http://www.abdn.ac.uk/hsru/research/research-tools/study-design/ (accessed 21 June 2016).

JBA 2014
John Black, Associates. Lean Glossary: Module 25. http://blog.hqc.sk.ca/wp-content/uploads/2013/09/JBA-Lean-Glossary.pdf (accessed 25 October 2015).

Kaplan 2014
Kaplan GS, Patterson SH, Ching JM, Blackmore CC. Why Lean doesn't work for everyone. *BMJ Quality and Safety* 2014;**23**(12):1–4.

Kim 2006
Kim CS, Spahlinger DA, Kin JM, Billi JE. Lean health care: what can hospitals learn from a world-class automaker?. *Journal of Hospital Medicine* 2006;**1**:191–9.

Kohn 2000
Kohn LT, Corrigan J, Donaldson MS. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press, 2000.

Kruskal 2012
Kruskal JB, Reedy A, Pascal L, Rosen MP, Boiselle PM. Quality initiatives: Lean approach to improving performance and efficiency in a radiology department. *Radiographics* 2012;**32**:573–87.

Lefebvre 2011
Lefebvre C, Manheimer E, Glanville J. Chapter 6: Searching for studies. In: Higgins JP, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from handbook.cochrane.org.

Leggat 2015
Leggat S, Bartram T, Stanton P, Bamber GJ, Sohal AS. Have process redesign methods, such as Lean, been successful in changing care delivery in hospitals? A systematic review. *Public Money & Management* 2015;**35**(2):161–8.

Liberati 2009
Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *PLoS Medicine* 2009;**6**:e1000100.

Mann 2005
Mann D. *Creating a Lean Culture: Tools to Sustain Lean Conversions*. New York: Productivity Press, 2005.

Mann 2009
Mann D. The missing link: Lean leadership. *Frontiers of Health Service Management* 2009;**26**:15–26.

Mann 2010
Mann D. *Creating a Lean Culture: Tools to Sustain Lean Conversions, Second Edition*. New York: Productivity Press, 2010.

Mazzocato 2010
Mazzocato P, Savage C, Brommels M, Aronsson H, Thor J. Lean thinking in healthcare: a realist review of the literature. *Quality & Safety in Health Care* 2010;**19**:376–82.

Mazzocato 2012
Mazzocato P, Holden RJ, Brommels M, Aronsson H, Backman U, Elg M, et al. How does Lean work in emergency care? A case study of a Lean-inspired intervention at the Astrid Lindgren Children's hospital, Stockholm, Sweden. *BMC Health Services Research* 2012;**12**:28.

McIntosh 2014
McIntosh B, Sheppy B, Cohen I. Illusion or delusion - Lean management in the health sector. *International Journal of Health Care Quality Assurance* 2014;**27**:482–92.

Microsoft 2016 [Computer program]
Microsoft Corporation. Microsoft Access. Redmond, Washington: Microsoft Corporation, 2016.

Mitchell 2016 [Computer program]
Mitchell M, Muftakhidinov B, Winchen T, Trande A. Engauge Digitizer. Version 9.6. GitHub, 2016.

Poksinska 2010
Poksinska B. The current state of Lean implementation in health care: literature review. *Quality Management in Health Care* 2010;**19**:319–29.

Printezis 2007
Printezis A, Gopalakrishnan M. Current pulse: can a production system reduce medical errors in health care?. *Quality Management in Health Care* 2007;**16**:226.

Radnor 2012
Radnor ZJ, Holweg M, Waring J. Lean in healthcare: the unfilled promise?. *Social Science & Medicine* 2012;**74**: 364–71.

Reijula 2014
Reijula J, Nevala N, Lahtinen M, Ruohomaki V, Reijula K. Lean design improves both health-care facilities and processes: a literature review. *Intelligent Buildings International* 2014;**6**:170–85.

Rotter 2016
Rotter T, Kinsman L, Plishka C, Lawal A, Harrison L, Sari N, et al. Towards an operational definition of Lean in healthcare. What can we learn from the literature?. Unpublished work as supplied 11 October 2016.

RQHR 2015
Regina Qu' Appelle Health Region. Lean in action. http://www.rqhealth.ca/kaizen/files/25_glossary_v20130525.pdf (accessed 14 June 2016).

Shah 2007
Shah R, Ward PT. Defining and developing measures of lean production. *Journal of Operations Management* 2007; **25**:785–805.

SHR 2015
Saskatoon Health Region. Saskatchewan Healthcare Management System Resources: Glossary Terms. https://www.saskatoonhealthregion.ca/about/SHCMS/Pages/Resources.aspx (accessed 24 October 2015).

Spear 2005
Spear S. Fixing health care from the inside, today. *Harvard Business Review* 2005;**83**:78–91.

Sterne 2011
Sterne JA, Sutton AJ, Ioannidis JP, Terrin N, Jones DR, Lau J, et al. Recommendations for examining and interpreting funnel plot asymmetry in meta-analyses of randomised controlled trials. *BMJ* 2011;**343**:d4002. [DOI: 10.1136/bmj.d4002

Womack 1996
Womack JP. In: Jones Daniel T editor(s). *Lean Thinking: Banish Waste and Create Wealth in Your Corporation*. New York, NY: Simon & Schuster, 1996.

Young 2004
Young T, Brailsford S, Connell C, Davies R, Harper P, Klein JH. Using industrial processes to improve patient care. *British Medical Journal* 2004;**328**:162–4.

* *Indicates the major publication for the study*

ADDITIONAL TABLES

Table 1. Names and definitions of frequently used Lean activities

Lean activity	Description
Value stream mapping (VSM)	Visual tool plotting all processes required to deliver a healthcare service. VSM facilitates enhanced understanding of the flow of patients, supplies, or information through a healthcare process (RQHR 2015).
Rapid process improvement workshop (RPIW)	Generally a week-long event during which teams of patients and their families, staff, and clinicians focus on a single problem, identify the root cause, create solutions, and implement sustainable changes (SHR 2015)
5S events	Stands for 'Sort, Sweep, Simplify, Standardise, Sustain/Self-Discipline'; represents a set of concepts that ensure a clean and well-organised workplace (RQHR 2015)
A3 problem solving	Standardised method of addressing problems utilising an A3 report - a standardised form for planning and report writing. Content follows the plan-do-study-act (PDSA) cycle (A3 Thinking 2015).
Gemba walk	Japanese term that means 'the workplace'. This term simply refers to the 'work floor' or unit where necessary patient care is provided (SHR 2015). Refers to the action of a manager or CEO spending time on the hospital floor and speaking to front-line staff who understand problems and shortcomings of the organisation (Black 2008)

Table 1. Names and definitions of frequently used Lean activities (*Continued*)

'Stop the Line' techniques	Derived from manufacturing (specifically, the assembly line); term refers to the act of enabling all healthcare professionals to immediately stop the line (a process of care) when a defect or error is realised. This prevents errors from being passed on and makes causes of errors more salient (JBA 2014).
Levelled production	Refers to elimination of unnecessary variation (unevenness) in health care to avoid bottlenecks and backups, which can lead to patient wait times and wasted time for healthcare professionals (Black 2008). Requires rigorous study of organisational processes and scheduling of patients and clients according to actual or forecasted demand (Black 2008)
Daily visual management (DVM)	System aimed at improving communication and ensuring that information is available when needed. Achieved by displaying objectives, metrics, and progress transparently and using measures (e.g. staff injuries, patient falls) to manage change (RQHR 2015). Closely linked to the wider strategic management system or policy deployment system of an organisation (Black 2008)
Kanban	Just-In-Time inventory management system which utilizes visual indicators to limit excess inventory and trigger the acquisition or production of specified goods (Black 2008)
Standard work	Details the steps in a course of treatment or health care in a multi-disciplinary care plan. Prescribes a uniform way to achieve a desired service or patient outcome based on best available evidence. Serves as the basis for any kind of improvement (RQHR 2015)

DVM: daily visual management.
PDSA: plan-do-study-act cycle.
RPIW: rapid process improvement workshop.
VSM: value stream mapping.

APPENDICES

Appendix 1. MEDLINE search strategy

NOTE on strategy: The following search strategy will be edited and updated for our review, to ensure all lean concepts are included. We will also add methodological filters.
Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present> Run 2014
1 ((total quality or quality assurance or quality improvement) adj3 lean).ti,ab. (23)
2 (think lean or lean thinking).ti,ab. (83)
3 (lean adj3 (workflow? or efficienc$ or efficient$)).ti,ab. (92)
4 (lean and (approach or business model? or care or collaborat$ or design$ or enterpri?e or healthcare or health care or implementation? or industry or initiative? or intervention$ or leader$ or management or methodolog$ or method? or organi?ation$ or plan or planning or philosophy or practice or practices or principles or principle or process improvement? or production or program? or programme or

programmes or quality or redesign$ or reengineer$ or restructur$ or reorgani$ or safety or sigma or strategy or strategies or thinking or tool or tools or workshop$)).ti. (509)
5 (organi?ation$ adj5 lean).ab. (39)
6 (lean adj2 (approach or business model? or care or collaborat$ or design$ or enterpri?e or healthcare or health care or implementation? or industry or initiative? or intervention$ or leader$ or management or methodolog$ or plan or planning or philosophy or practice or practices or principles or principle or process improvement? or production or program? or programme or programmes or quality or redesign$ or reengineer$ or restructur$ or safety or sigma or strategy or strategies or thinking or tool or tools or workshop$)).ab. (568)
7 (lean and (admitting or clinic or clinics or emergency department? or emergency medicine or emergency room? or emergency service? or family practice? or general practice? or healthcare or health care or hospital? or hospitali?ed or inpatient? or intensive care or ICU or "length of stay or nursing" or oncology or outpatient? or patient care or pharmacist? or pharmacy or practitioner? or physician? or readmission? or surgeon? or surgery or surgical or trauma center? or trauma centre? or trauma service? or trauma care or ward or wards)).ti. (221)
8 (lean adj4 (admitting or clinic or clinics or emergency department? or emergency medicine or emergency room? or emergency service? or family practice? or general practice? or healthcare or health care or hospital? or hospitali?ed or inpatient? or intensive care or ICU or "length of stay or nursing" or oncology or outpatient? or patient care or pharmacist? or pharmacy or practitioner? or physician? or readmission? or surgeon? or surgery or surgical or trauma center? or trauma centre? or trauma service? or trauma care or ward or wards)).ab. (176)
9 (((PDSA or PDCA or TQIS) adj3 (cycle or process or processes or intervention or quality or lean or improv$)) or ("plan do study" or "plan do check")).ti,ab. (418)
10 (Lean and waste).ti. or (lean adj3 waste).ab. (18)
11 ((wait$ time? or reduc$ wait$) and lean).ti. or ((wait$ time? or reduc$ wait$) adj4 lean).ab. (6)
12 (lean and (overcrowd$ or patient$ flow? or wait time?)).ti,ab. (53)
13 (lean technique? or lean manufacturing).ti,ab. (55)
14 (lean basics or lean training).ti,ab. [added Feb 20] (3)
15 ((lean adj7 5s) or (5s adj3 (event? or method? or methodolog$ or model? or process or processes or safety or waste or quality))).ti,ab. (102)
16 ((a3 adj3 (healthcare or health care or problem solving or quality improv$ or workflow? or method? or methodology or process or processes)) or A3 thinking or (a3 adj3 lean)).ti,ab. (65)
17 toyota.ti,ab. (182)
18 (gemba or Kaizen or kanban).ti,ab. (64)
19 (innovation? adj2 collaborat$).ti,ab. (95)
20 (PROCESS MAP? or process mapping).ti,ab. (213)
21 (mistake proofing or value-stream map? or incident learning).ti,ab. (43)
22 Pareto diagram?.ti,ab. (18)
23 ((shewhart or shewart or deming) adj3 (cycle or method$)).ti,ab. (90)
24 process failure-mode-and-effects-analysis.ti,ab. (2)
25 (breakthrough adj3 (series or project or collaborative?)).ti,ab. (148)
26 rapid process improvement?.ti,ab. (8)
27 (rapid cycle adj3 (improvement or quality or process or processes)).ti,ab. (76)
28 quality improvement? tool?.ti,ab. (225)
29 (six sigma or 6 sigma).ti,ab. (398)
30 or/1-29 [Set 1] (2964)
31 (bibliography or biography or editorial or lectures or news or newspaper article).pt. (737304)
32 animals/ not (animals/ and humans/) (3909440)
33 30 not (or/31-32) [Set 1] (2687)
34 remove duplicates from 33 (2660)

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Co-ordinating the protocol: CP.

Designing search strategies: MF.

Writing the protocol: TR, CP.

Providing general advice on the protocol: LA, MF, EH, RF, JC, LK.

Securing funding for the protocol: TR, LK.

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NOTES

The methods section of this protocol is based on a standard template used by the Cochrane Effective Practice and Organisation of Care Group (EPOC).