

BMJ Open The use and application of Lean Management methods to research processes – a scoping review protocol

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ABSTRACT

Introduction Waste in medical research is a relatively well-known issue. However, only a few initiatives exist to address this issue. Lean Management methods (Lean) were developed in industrial manufacturing and later applied within healthcare improvement. Overall, the results from studies of the application of Lean to healthcare appear to be positive in terms of greater efficiency regarding treatment outcomes and patient care. Nevertheless, the application of Lean to improve research processes is not well studied and, given that research alongside clinical practice and experiential knowledge provides the foundation for the treatment and care of patients, it is paramount to identify approaches and review the degree to which they increase efficiency within research procedures. Therefore, this review will scope the landscape of studies that investigated Lean and how to implement Lean in research processes, particularly regarding healthcare research.

Methods and analysis Our approach follows the methodological framework of Arksey and O'Malley for conducting scoping reviews (PRISMA-ScR). The search strategy for this scoping review was developed using the PCC model. We will identify the relevant literature by searching four search databases: Scopus, Web of Science, Academic Search Premier and Business Source Complete. Next, we will use citation pearl growing to identify all relevant published literature. The data charting process will follow the PRISMA-ScR checklist and will be organised using NVivo. We will generate qualitative and quantitative assessments of the extracted data by using NVivo, RStudio and Excel. We will follow the PRISMA-ScR guideline when reporting the results.

Ethics and dissemination The review will comprise existing published studies and no primary data will be collected. Our findings will be shared through open access peer-reviewed journals, national and international conferences and emails to all relevant collaborative relationships. We plan to disseminate our findings via academic social media platforms, newspaper articles and blogposts.

INTRODUCTION

Waste in medical research encompasses the flawed collection, analysis and reporting of data, constituting a well-documented problem. Despite this, the challenge of waste

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A study motivated by the issue of waste in medical research and healthcare research.
- ⇒ The first scoping review to investigate the implementation of Lean Management to investigate and improve research processes.
- ⇒ A systematic approach following the methodological framework of Arksey and O'Malley and the Preferred Reporting Items of Systematic Reviews and Meta-Analysis extension for Scoping Reviews reporting guidelines (PRISMA-ScR).
- ⇒ This review is limited to articles published within the last 20 years.

in medical research remains unresolved, with few initiatives in place to address it.¹⁻⁴ Given the foundational role of research in shaping patient treatment, coupled with the complex nature of research and its numerous operational challenges (e.g., continuous regulatory and policy modifications, finding funding, approval of new studies and protocols, inclusion of patients, data gathering, data analysing, and publishing papers), it is paramount to identify approaches that promote efficiency and decrease unnecessary process components in this environment.^{1,5} Addressing this issue could entail the implementation of a continuous improvement model, as a Lean model, which emphasises on enhancing value for the end-user and for reducing production and transaction costs and, thus, 'provides a way to do more and more with less and less'.^{6,7} Lean Management is widely used within the hospital sector to create a better workflow for health professionals and to create efficiency of treatment and general patient care. This implementation of Lean Management in the hospital sector is a well-studied phenomenon.^{8,9}

When Lean Management found its way into the hospital sector, it was believed that its implementation would create the smoothest and quickest workflows with as few wasteful



activities as possible.¹⁰ This may be welcomed in the hospital sector, as this field is known to focus on practice and application, particularly effectiveness, safety and economic feasibility.¹¹ The first documented application of Lean Management in the hospital sector was seen in the 1990s at the Virginia Mason Medical Centre.¹² The original model was based on the Toyota car company's new strategy to create more efficiency within their production lines. The Virginia Mason Medical Centre succeeded in implementing a model that was originally created for the manufacturing industry, with the goal of creating efficiency in manufacturing productions.^{12 13} It is believed that healthcare and the manufacturing industry are quite similar, as they are both composed of a series of complex organisations and multiple interacting processes.^{1 9} However, the Lean Management model implemented at the Virginia Mason Medical Centre was not used as a manufacturing strategy but rather as a management strategy based on improving processes in a system.¹² In the academic literature, attention to Lean Management has developed from an initial 'shop-floor focus' on waste and cost reduction to an approach that consistently seeks to enhance benefit (or perceived benefit) for end-users by adding product or service features and/or removing 'wasteful' activities.¹⁴ Lean Management has been defined as a continuous improvement model to specify benefit, line up benefit-creating actions in the best sequence, conduct these activities and perform them more and more effectively.⁶ In practice, Lean Management is associated with a set of different tools to reduce errors and improve efficiencies in production processes.¹⁵ The implementation of Lean Management in the hospital sector is well studied, but little research has been done on the implementation of Lean Management models in healthcare research processes. Ideally, the foundation for treatments in healthcare begins with research, as the results from research provide valid argumentation for how and why specific treatments are the best treatments and lay the grounds for the best patient care practices. This argumentation is especially important within clinical healthcare research processes, as it affects both treatments and patient care.^{1 9 16 17}

Notwithstanding our interest in the implementation of Lean Management models in clinical healthcare research processes, we have expanded our scope to include all types of academic research settings (e.g., a research group, institution or department) to learn how these models can be applied and whether they are feasible in relation to research in general and healthcare research processes in particular. Nevertheless, we will employ more inclusive terminology, such as 'process improvement models' from the Lean family,¹⁸ to encompass a wider range of articles in our scoping review to include as many articles as possible in our scoping review. For the same reason, our search will include any academic research setting.

OBJECTIVE

The objective of the systematic scoping review is to investigate the use and consequences of the implementation of a process improvement model in process of conducting research (e.g., research processes). Therefore, the overall purpose of our scoping review is to answer the following question:

What do previous studies show regarding the use and consequences of the implementation of process improvement models (e.g., Lean) in the process of conducting research in an academic research settings?

1. To establish what kinds of process improvement models are implemented to research processes
2. To assess the effects of implementing a process improvement model implemented to research processes
3. To assess the feasibility (pros and cons) of implementing a process improvement model in implemented to research processes

METHODS AND ANALYSIS

A scoping review was considered as the best method for the broad aim of our study. Our scoping review and protocol follow the steps of Arskey and O'Malley's methodological framework for scoping reviews.¹⁹ Furthermore, we follow the Preferred Reporting Items of Systematic Reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR).²⁰

Stage 1: defining the research question

This scoping review aims to assess the implementation of process improvement models and to further assess the consequences of implementing these models as a part of the research processes in academic research environments. Therefore, the overall purpose of our scoping review is to answer the following question:

What do previous studies show regarding the use and consequences of the implementation of process improvement models (e.g., Lean) in the process of conducting research in academic research settings?

Stage 2: identifying relevant literature

Initial searches revealed a small number of a few relevant papers that could be used as inspiration for the search strategy. These initial searches were then followed by applying the citation pearl growing method to identify possible search terms in the relevant studies.²¹ The initial searches resulted in seven relevant studies, however, only four matched the problem statement completely. All seven studies were thoroughly read and analysed using the qualitative analysis tool NVivo to identify and code possible search terms. The coding of all the search terms was then analysed in RStudio, and a WordCloud was made to visualise which search terms are most mentioned and used in all the studies. The search strategy was based on the principles of the PCC framework²² and is represented in table 1.

Table 2 represents a search block and the letter C (concept) from the PCC model.²² This search block

Table 1 PCC framework for the scoping review: The use and application of Lean Management methods to research processes

AND/OR	OR		
AND	PCC	Definition	Description
	P	Population	A research group, a research centre, a research department, or a research faculty
	C	Concept	Implementation of a process improvement model (e.g., a model from the Lean family) to the processes of conducting research
	C	Context	Research

encompasses various search terms targeting synonyms related to process improvement models. Likewise, the search block related to the letter P (population) from the PCC model covers different search terms and synonyms related to an academic research centre (see the online supplemental table). A proximity operator was added to multiple search terms in each search block to allow for different wordings. For instance, ‘Model w/1 Improv*’ can result in ‘Model of Improvement’ or another relevant wording between Model and Improvement. The proximity operators (e.g., w/X or NEAR/X) in each search block, also presented in [table 2](#), therefore specify the maximum number (X) of words that separate the terms. The search strategy regarding the proximity operators was created in collaboration with two research librarians from the University Library of Southern Denmark. Finally, [table 2](#) describes the use of Boolean operators within and between each search block.

The search was conducted in multiple search databases: (A) Scopus, (B) Web of Science, (C) Academic Search Premier and (D) Business Source Complete, indexing Embase, Medline, and EBSCO. The databases cover different subject areas including, but not limited to, medicine, the social sciences, business, management, the humanities, psychology and engineering ([table 3](#)). These databases were chosen to optimise the results as well as to fulfil the purpose of the literature search in the best possible way. Further searches were conducted using the citation pearl growing method after identifying all relevant studies during the search strategy. Citation pearl growing includes two steps: the first step is to look at all studies cited in the original study, and the second step is to look through the reference lists of each of the original studies to identify all other relevant studies.²¹ The last step includes exporting all relevant articles to Covidence, a programme designed to manage references for systematic reviews and scoping reviews and to filter duplications.

Stage 3: article selection

During the article’s selection phase, all articles will be screened in a process of two phases. First, one screener will review each title and abstract based on the inclusion and exclusion criteria. Articles will be included if they: (A) are published peer-review journal articles, (B) investigate the implementation of any process improvement model in an academic research process, (C) assess

the usefulness of implementing a process improvement model to improve research processes (as a substudy we will also include studies that measure the effect of implementing a process improvement model in a research process), and (D) have been published within the last 20 years (2002–2022). The time frame was chosen to narrow the search and to exclude irrelevant literature (defined as irrelevant by the same exclusion criteria in the following paragraph), as the initial testing of the search strategy revealed a great deal of noise generated by multiple irrelevant articles. These inclusion criteria are intended to ensure the retrieval of articles with a diverse range of methodologies (e.g., quantitative, qualitative or mixed).

Articles will be excluded if they: (A) investigate the implementation of a process improvement model regarding the efficiency of a production line in a factory, (B) investigate the implementation of a process improvement model to create efficiency in the workflow in any workplace not related to an academic research environment, (C) investigate the implementation of a process improvement model in any hospital sector setting to improve the efficiency of treatments and workflow, (D) investigate management strategies or new public management using a process improvement model in any workplace and not specific to an academic research environment, or (E) investigate lean body and/or lean body mass index in humans or animals.

In the second phase, we will rely on intercoder reliability, as two team members will independently review the full text of all the articles included during the title and abstract screening step to further verify that they meet the inclusion criteria. After the full text screening, all included articles will be exported from Covidence to NVivo.

Stage 4: data charting

Data will be charted using NVivo to find the proposed variables and definitions described in [table 4](#). This methodology and selection of variables is inspired by the scoping review protocol from Lengnick-Hall²³ and Pollock.²² Clear procedures will be established for accessing, reading and charting data for each full-text article to create consistency across the data charting procedures. One of the protocol authors will be responsible for the data charting process. The other protocol authors will meet regularly and maintain continuous communication within the

Table 2 Representing search block 2 and the letter C (concept) from the PCC model (synonyms on process improvement models)

Term	Different variations	Search term
Model for Improvement	Model for improvement	'Model w/1 Improv**'
Lean	Lean, lean process, lean thinking, lean methods, lean model, lean tools, lean production, lean enterprise, lean process, lean leadership, lean quality improvement efforts, lean quality improvement research approach, lean quality improvement research toolkit	'Lean'
Six Sigma	Six Sigma, six sigma improvement, six sigma initiatives, six sigma methodology, six sigma techniques, six sigma approach, six sigma improvement model, six sigma quality improvement methodology	'Six sigma'
Lean and Six Sigma	Lean and six sigma, lean and six sigma approaches, lean and six sigma process improvement methods, lean and six sigma techniques	'Lean' 'Six Sigma'
Improvement	Improve process, improve process efficiency, improving the processes, improving process flow	'Improv* w/1 process**'
	Improvement approaches	'Improv* w/1 approach**'
	Improvement tools	'Improv* w/1 tool**'
	Improving of workflow	'Improv* W/1 workflow'
	Improve research practice, improve research processes	'Improv* w/1 research'
	Improving efficiency	'Improv* w/1 efficient* w/3 research'
	Improving quality	'Improv* w/1 quality w/3 research'
	Improvement methods	'Improv* w/1 method* w/3 research'
Process improvement	Improvement procedure	'Improvement w/1 procedure w/3 research'
	Process improvement, process improvement approaches, process improvement strategy, process improvement methods, process improvement principles, process improvement framework, process improvement efforts	'Process* W/1 improv**'
Other with processes	Approach to process improvement	'Approach w/1 process* w/1 improv**'
	Process centered	'Process* centered'
Quality improvement	Process assessment	'Process* assessment'
	Process quality improvement	'Process* w/1 quality w/1 improv**'
	Quality process improvement	'Quality w/1 process w/1 improv**'
	Quality improvement methods	'Quality w/1 improv* w/1 method**'
	Quality improvement interventions	'Quality w/1 improv* w/1 interventions**'
	Quality improvement training	'Quality w/1 improv* w/1 training**'
	Quality improvement activities	'Quality w/1 improv* w/1 activit**'
Research procedures	Quality improvement research, quality improvement research process, quality improvement research skills, quality improvement research methods, quality improvement research toolkit	'Quality w/1 improv* w/1 research**'
	Research processes	'Research w/1 process**'
	Research procedures	'Research w/1 procedure**'
	Research protocol	'Research w/1 protocol**'
Kaizen	Research process improvement programme	'Research w/1 process w/1 improvement w/1 programme'
	Kaizen	'Kaizen'
Quality management methodology	Quality management methodology	'Quality w/1 management w/1 methodology w/3 research'

Table 3 A description of the search databases and their subject areas

Database	Subject areas	Indexing
Scopus	Science, medicine, engineering, and the social sciences	Embase, Medline
Web of Science	Medicine, engineering, the social sciences and arts, and humanities	Medline
Academic Search Premier	Arts and entertainment, business, education, general interest, health and medicine, history, literature and writing, politics and government, psychology, science, social sciences and humanities, and technology	EBSCO
Business Source Complete	Business, marketing, economics, accounting, finance, management, management information system and production, and operations management	EBSCO

research team regarding questions throughout the data charting process.

Stage 5: collating, summarising and reporting the results

After the data charting process, we will collate and summarise the data by using NVivo, Excel, and RStudio as we expect the data charting process will generate quantitative and qualitative data. When reporting the results from the extracted data from the full-text articles, we will follow the PRISMA-ScR extension reporting guidelines for Scoping reviews.²⁰ Our anticipated 8 month timeline for completing this scoping review is presented in [table 5](#).

Patient and public involvement

Since the aim of this scoping review is to assess the implementation of process improvement models in research environments, patient and public involvement was not necessary for the design of our scoping review.

Probable limitations and strengths of review findings

By using Arksey and O'Malley's methodological framework for conducting scoping reviews¹⁹ and the PCC model²² for the development of our search strategy, charting the data with NVivo and reporting our results consistently with the PRISMA-ScR checklist,²⁰ the transparency and systematic approach in the methodology of our review and the trustworthiness of our future results are enhanced. Our future results will be organised and analysed using NVivo, Rstudio and Excel. We also anticipate that our review will be one of the first of its kind within the field of process improvement models implemented in research processes, as the field is not well studied.¹ Probable limitations to our review are that we will not report on the methodology of the included studies in this review. Moreover, we will not synthesise the results by calculating the effectiveness of the implementation, which is a

Table 4 Variables and definitions for data charting

Variable	Definitions
First author	The last name of the paper's first author
Year	Year the article was published
Title	Title of the article
Journal	Name of the journal
Setting	Primary setting in which the study was conducted: which research group, centre, department or institute
Country	The country in which the study is set
Population	The target group for the implementation of the process improvement model
Design	General type of study design
Type of data	Type of the data used to assess quantitative, qualitative or mixed method
Level	The level at which the outcome was analysed: individual researcher, researcher groups, researcher centres, departments or institutional
Objectives	Which questions or statements are being assessed with reference to their key elements (e.g., population, concepts and context) or other relevant elements used to conceptualise the review question and/or objective
Method	The type(s) of tools used to assess (outcome): survey, interview, administrative data, observation, focus group, checklist, self-report, case audit/chart reviews/electronic health record, validated questionnaire/instrument, vignette
Strategy name	What process improvement model(s) are being assessed
Results	The nature of the main results
Other notes	Additional observations, questions or information about the paper

**Table 5** Anticipated 8 month timeline for the scoping review: The use and application of Lean Management methods to research processes

Scoping review stage	Month							
	1	2	3	4	5	6	7	8
Stage 1: Defining the research question	X							
Stage 2: Identifying relevant literature	X	X	X	X				
Stage 3: Article selection				X				
Stage 4: Data extraction				X	X	X		
Stage 5: Collating, summarising and reporting the results						X	X	X

potential objective for future systematic reviews and meta-analyses. We are aware of some limitations to our search strategy, as we could have included searches of PubMed; however, we chose not to do so, as this database primarily covers subjects of life science and biomedicine. However, PubMed does index Medline, which is also represented in two of the search databases that we did include: Scopus and Web of Science. We added a time frame to our search strategy, and that time frame may exclude relevant studies that were published more than 20 years ago. We would also like to mention that our strategy includes search terms that are very broad and that could result in a very time-consuming process of screening all relevant articles. However, as we expect that very few studies on this topic exist, we chose to make the search as broad as possible to include as many studies as possible.

ETHICS AND DISSEMINATION

The review will comprise existing published studies and no primary data will be collected. It is not relevant for this review to obtain informed consent, protect anonymity or receive institutional review board approval, as there will be no human research participants. Our findings will be shared through open access peer-reviewed journals, national and international conferences and emails to all relevant collaborative relationships. Furthermore, we plan to disseminate our findings via academic social media platforms, newspaper articles, and blogposts.

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